

16.2.6 Individual Response Data

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
1001	VLN non-mentholated	-1	18.0	107	.
		1	18.1	.	.
		2	21.3	252	35
		3	17.3	.	.
		4	17.3	158	8
		5	16.7	.	.
		6	16.4	261	2
1002	VLN non-mentholated	-1	19.3	120	.
		1	12.0	.	.
		2	5.3	115	39
		3	1.4	.	.
		4	1.3	21	0
		5	2.0	.	.
		6	7.5	49	5
1003	VLN mentholated	-1	10.7	45	.
		1	10.7	.	.
		2	8.7	134	22
		3	10.1	.	.
		4	10.2	112	0
		5	10.0	.	.
		6	10.4	133	0
1007	VLN non-mentholated	-1	11.9	63	.
		1	14.7	.	.
		2	9.4	149	23
		3	4.1	.	.
		4	9.4	58	13

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
1007	VLN non-mentholated	5	6.4	.	.
		6	11.3	59	24
1008	VLN mentholated	-1	20.7	95	.
		1	22.3	.	.
		2	20.7	227	33
		3	20.7	.	.
		4	20.4	147	4
		5	21.0	.	.
		6	18.6	254	3
1010	UB mentholated	-1	21.4	127	.
		1	21.9	.	.
		2	22.3	321	.
		3	20.9	.	.
		4	23.4	258	.
		5	24.1	.	.
		6	21.6	322	.
1011	UB non-mentholated	-1	20.3	119	.
		1	20.0	.	.
		2	21.7	311	.
		3	18.6	.	.
		4	20.9	258	.
		5	18.9	.	.
		6	20.9	286	.
1013	VLN non-mentholated	-1	14.6	81	.
		1	9.7	.	.

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
1013	VLN non-mentholated	2	11.7	109	22
		3	8.9	.	.
		4	9.1	99	0
		5	13.4	.	.
		6	14.3	197	0
1014	VLN mentholated	-1	15.3	88	.
		1	16.0	.	.
		2	16.0	216	19
		3	15.1	.	.
		4	15.6	183	0
		5	15.7	.	.
1015	VLN mentholated	6	13.7	127	0
		-1	14.6	74	.
		1	9.0	.	.
		2	17.6	146	27
		3	13.1	.	.
		4	10.2	124	0
1016	UB non-mentholated	5	6.5	.	.
		6	10.3	101	1
		-1	20.9	118	.
		1	21.3	.	.
		2	20.4	288	.
		3	20.1	.	.
		4	20.4	240	.
		5	19.0	.	.
		6	19.3	253	.

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
1017	UB mentholated	-1	26.1	154	.
		1	24.7	.	.
		2	24.9	370	.
		3	25.1	.	.
		4	26.7	280	.
		5	26.4	.	.
		6	23.7	356	.
1018	VLN mentholated	-1	17.3	85	.
		1	15.9	.	.
		2	19.0	.	.
		3	4.0	.	.
1019	VLN non-mentholated	-1	19.1	111	.
		1	25.3	.	.
		2	24.4	344	47
		3	15.3	.	.
		4	17.0	174	0
		5	7.2	.	.
		6	10.7	127	0
1020	VLN non-mentholated	-1	23.2	141	.
		1	37.3	.	.
		2	27.7	462	23
		3	17.1	.	.
		4	18.0	218	0
		5	18.6	.	.
		6	15.3	210	0

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
1021	UB non-mentholated	-1	22.8	140	.
		1	25.0	.	.
		2	21.4	337	.
		3	21.3	.	.
		4	23.6	284	.
		5	21.4	.	.
		6	24.0	295	.
1023	VLN non-mentholated	-1	18.3	105	.
		1	20.4	.	.
		2	18.7	271	21
		3	19.0	.	.
		4	19.3	216	0
		5	20.4	.	.
		6	18.9	274	10
1029	VLN mentholated	-1	15.3	94	.
		1	12.1	.	.
		2	11.9	137	34
		3	12.0	.	.
		4	13.6	112	12
		5	13.9	.	.
		6	11.6	170	28
1032	VLN mentholated	-1	16.0	85	.
		1	17.7	.	.
		2	17.9	247	0
		3	20.0	.	.
		4	13.7	208	0

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
1032	VLN mentholated	5	10.7	.	.
		6	8.7	140	0
1034	VLN non-mentholated	-1	19.8	112	.
		1	25.0	.	.
		2	23.7	329	1
		3	33.7	.	.
		4	35.4	164	283
		5	28.0	.	.
		6	31.2	83	333
1035	VLN non-mentholated	-1	14.6	67	.
		1	17.3	.	.
		2	14.6	151	0
		3	10.9	.	.
		4	10.3	135	0
		5	10.9	.	.
		6	9.8	91	0
1036	UB mentholated	-1	33.3	76	.
		1	10.6	.	.
		2	10.9	168	.
		3	11.1	.	.
		4	10.9	158	.
		5	10.9	.	.
		6	10.6	218	.
1037	UB mentholated	-1	14.9	95	.
		1	14.3	.	.

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
1037	UB mentholated	2	11.6	169	.
		3	13.6	.	.
		4	13.3	176	.
		5	15.1	.	.
		6	14.4	206	.
1038	VLN non-mentholated	-1	18.0	103	.
		1	22.6	.	.
		2	19.1	294	0
		3	14.9	.	.
		4	13.6	162	0
		5	14.1	.	.
1042	VLN non-mentholated	6	12.7	189	0
		-1	22.8	125	.
		1	11.0	.	.
		2	9.4	149	0
		3	6.6	.	.
		4	5.1	75	0
1045	UB non-mentholated	5	5.1	.	.
		6	5.2	78	0
		-1	16.9	94	.
		1	15.7	.	.
		2	16.4	221	.
		3	14.9	.	.
		4	16.9	216	.
		5	17.6	.	.
		6	15.3	217	.

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
1046	UB mentholated	-1	19.0	108	.
		1	16.7	.	.
		2	17.3	238	.
		3	17.3	.	.
		4	16.7	213	.
		5	15.3	.	.
		6	17.4	235	.
1050	VLN non-mentholated	-1	20.1	119	.
		1	22.4	.	.
		2	18.3	277	1
		3	15.0	.	.
		4	15.9	158	8
		5	14.9	.	.
		6	11.6	153	5
1051	UB mentholated	-1	18.1	101	.
		1	17.1	.	.
		2	18.3	243	.
		3	17.9	.	.
		4	15.6	194	.
		5	13.0	.	.
		6	11.3	175	.
1052	VLN mentholated	-1	11.6	45	.
		1	12.4	.	.
		2	12.7	141	0
		3	10.0	.	.
		4	12.3	153	26

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
1052	VLN mentholated	5	8.3	.	.
		6	9.0	64	21
1053	VLN mentholated	-1	10.9	61	.
		1	13.7	.	.
		2	11.4	147	3
		3	12.3	.	.
		4	10.0	172	0
		5	7.3	.	.
		6	3.8	64	21
1054	UB non-mentholated	-1	14.4	107	.
		1	13.7	.	.
		2	13.1	235	.
		3	14.9	.	.
		4	18.3	220	.
		5	17.0	.	.
		6	16.7	234	.
1055	VLN mentholated	-1	15.7	89	.
		1	25.0	.	.
		2	21.7	312	0
		3	16.9	.	.
		4	17.0	180	23
		5	11.9	.	.
		6	6.5	71	73
1056	VLN non-mentholated	-1	15.3	85	.
		1	22.4	.	.

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
1056	VLN non-mentholated	2	13.3	295	1
		3	13.1	.	.
		4	10.0	137	0
		5	6.1	.	.
		6	7.3	67	0
1058	VLN non-mentholated	-1	17.7	100	.
		1	28.6	.	.
		2	26.0	370	0
		3	19.0	.	.
		4	14.4	159	0
		5	11.4	.	.
1059	UB non-mentholated	6	10.3	69	10
		-1	17.4	89	.
		1	16.3	.	.
		2	14.6	224	.
		3	14.3	.	.
		4	13.1	254	.
1060	VLN mentholated	5	14.7	.	.
		6	16.9	162	.
		-1	13.2	60	.
		1	10.7	.	.
		2	14.2	152	0
		3	10.0	.	.
		4	10.0	122	0
		5	10.0	.	.
		6	10.0	143	0

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
1063	VLN mentholated	-1	29.4	0	.
		1	28.2	.	.
		2	27.2	337	0
		3	17.8	.	.
		4	20.0	232	0
		5	10.6	.	.
		6	10.8	182	0
1064	UB non-mentholated	-1	24.7	99	.
		1	22.7	.	.
		2	16.2	136	.
1066	VLN non-mentholated	-1	16.0	89	.
		1	25.6	.	.
		2	18.1	316	0
		3	20.1	.	.
		4	17.4	231	0
		5	18.4	.	.
		6	18.0	15	0
1069	UB non-mentholated	-1	19.1	101	.
		1	18.6	.	.
		2	19.4	259	.
		3	19.4	.	.
		4	17.1	211	.
		5	17.3	.	.
		6	17.0	228	.
1070	VLN non-mentholated	-1	14.2	78	.

Subjects used their own usual brand cigarette at Week -1.

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UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
1070	VLN non-mentholated	1	14.4	.	.
		2	11.1	162	0
		3	15.6	.	.
		4	12.4	169	0
		5	15.6	.	.
		6	12.5	224	0
1071	VLN non-mentholated	-1	21.5	116	.
		1	21.9	.	.
		2	15.7	205	27
		3	17.1	.	.
		4	15.0	147	48
1072	VLN mentholated	-1	15.1	87	.
		1	14.3	.	.
		2	15.9	152	0
		3	15.6	.	.
		4	15.9	188	0
		5	14.0	.	.
1074	VLN non-mentholated	6	18.5	.	.
		-1	15.7	65	.
		1	11.7	.	.
		2	11.4	148	0
		3	10.9	.	.
		4	10.3	140	0
		5	10.0	.	.
		6	8.7	113	0

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

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UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

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(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
1075	UB non-mentholated	-1	17.4	98	.
		1	17.9	.	.
		2	18.7	271	.
		3	16.4	.	.
		4	18.6	203	.
		5	19.4	.	.
		6	18.1	276	.
1077	VLN non-mentholated	-1	21.0	113	.
		1	30.9	.	.
		2	28.3	435	0
		3	29.2	.	.
		4	29.0	340	0
		5	26.1	.	.
		6	23.3	361	0
1078	VLN non-mentholated	-1	18.7	74	.
		1	14.1	.	.
		2	15.4	161	10
		3	14.6	.	.
		4	12.3	111	0
		5	13.1	.	.
		6	12.3	171	1
1079	VLN mentholated	-1	13.8	65	.
		1	15.4	.	.
		2	12.6	175	0
		3	12.3	.	.
		4	13.3	139	0

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
1079	VLN mentholated	5	11.6	.	.
		6	9.8	148	0
1082	VLN non-mentholated	-1	14.8	80	.
		1	16.1	.	.
		2	12.4	202	0
		3	13.0	.	.
		4	11.7	152	0
		5	11.9	.	.
		6	9.0	146	0
1083	VLN non-mentholated	-1	24.6	158	.
		1	22.7	.	.
		2	25.5	282	41
		3	22.0	.	.
		4	20.2	24	0
		5	16.8	.	.
		6	15.8	178	0
1084	VLN non-mentholated	-1	14.1	82	.
		1	14.4	.	.
		2	11.9	176	50
		3	11.0	.	.
		4	12.8	140	5
1086	VLN non-mentholated	-1	25.9	181	.
		1	34.0	.	.
		2	26.4	393	70
		3	25.0	.	.

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
1086	VLN non-mentholated	4	19.3	265	7
		5	17.0	.	.
		6	14.8	235	9
1088	VLN mentholated	-1	10.0	50	.
		1	9.3	.	.
		2	12.8	132	17
		3	9.1	.	.
		4	7.7	104	0
		5	8.4	.	.
		6	8.0	108	0
1089	UB non-mentholated	-1	14.0	74	.
		1	11.7	.	.
		2	11.0	174	.
		3	9.6	.	.
		4	10.3	114	.
		5	10.7	.	.
		6	11.0	158	.
1092	VLN mentholated	-1	17.2	74	.
		1	21.6	.	.
		2	18.6	244	8
		3	18.0	.	.
		4	16.7	198	0
		5	16.1	.	.
		6	17.3	229	0
1094	VLN mentholated	-1	8.7	33	.

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
1094	VLN mentholated	1	9.1	.	.
		2	11.7	146	51
		3	8.6	.	.
		4	8.0	72	12
		5	8.1	.	.
		6	6.2	84	20
1095	VLN mentholated	-1	17.1	86	.
		1	13.4	.	.
		2	18.0	194	41
		3	14.6	.	.
		4	12.7	140	6
		5	12.9	.	.
1096	VLN non-mentholated	6	11.7	160	0
		6	.	234	0
		-1	13.8	88	.
		1	19.1	.	.
		2	18.7	132	27
		3	21.2	.	.
		4	20.6	131	0
		5	18.4	.	.
1097	VLN mentholated	-1	15.9	50	.
		1	3.5	.	.
		2	6.0	17	98
		3	12.7	.	.
		4	6.6	76	23
		6	2.5	54	11

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
1098	VLN non-mentholated	-1	19.6	111	.
		1	29.4	.	.
		2	30.3	391	1
		3	26.3	.	.
		4	20.4	338	1
		5	26.3	.	.
		6	24.0	378	4
1099	VLN non-mentholated	-1	14.9	81	.
		1	15.9	.	.
		2	15.9	199	10
		3	11.7	.	.
		4	13.1	147	3
		5	10.3	.	.
		6	12.7	153	3
1100	VLN non-mentholated	-1	15.2	86	.
		1	25.4	.	.
		2	15.4	277	14
		3	13.3	.	.
		4	13.3	152	0
		5	11.2	.	.
		6	13.9	151	36
1101	VLN non-mentholated	-1	18.3	102	.
		1	34.9	.	.
		2	24.4	291	5
		3	19.1	.	.
		4	18.7	249	0

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
1101	VLN non-mentholated	5	20.9	.	.
		6	25.9	203	4
1103	VLN non-mentholated	-1	20.4	113	.
		1	22.6	.	.
		2	24.4	303	0
		3	23.9	.	.
		4	24.1	288	0
		5	24.0	.	.
		6	24.3	345	0
1105	VLN non-mentholated	-1	19.6	92	.
		1	27.6	.	.
		2	23.7	273	32
		3	16.1	.	.
		4	14.0	179	30
		5	11.1	.	.
		6	10.6	111	33
1106	UB non-mentholated	-1	20.7	15	.
		1	22.7	.	.
		2	18.6	378	.
		3	27.1	.	.
		4	26.3	327	.
		5	21.6	.	.
		6	21.7	317	.
1107	VLN non-mentholated	-1	18.4	104	.
		1	28.1	.	.

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
1107	VLN non-mentholated	2	26.6	265	45
		3	17.7	.	.
		4	17.9	131	0
		5	19.4	.	.
		6	18.1	211	63
1108	UB non-mentholated	-1	18.6	101	.
		1	20.9	.	.
		2	18.0	270	.
		3	22.6	.	.
		4	17.4	228	.
		5	18.4	.	.
1109	UB non-mentholated	6	18.0	258	.
		-1	14.0	89	.
		1	14.7	.	.
		2	15.4	214	.
		3	19.6	.	.
		4	17.9	204	.
1112	VLN non-mentholated	5	16.3	.	.
		6	14.9	246	.
		-1	11.7	68	.
		1	17.7	.	.
		2	18.0	210	44
		3	16.0	.	.
		4	15.7	146	39
		5	12.0	.	.
		6	13.2	106	79

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
1114	UB non-mentholated	-1	14.0	75	.
		1	10.3	.	.
		2	8.9	140	.
		3	10.4	.	.
		4	7.3	78	.
		5	8.1	.	.
		6	8.4	85	.
1115	VLN non-mentholated	-1	17.1	14	.
		1	28.8	.	.
		2	23.9	348	10
		3	16.1	.	.
		4	23.0	93	29
		5	23.8	.	.
		6	26.6	.	.
2002	UB mentholated	-1	22.1	133	.
		1	24.4	.	.
		2	20.1	307	.
		3	23.9	.	.
		4	21.1	283	.
		5	22.7	.	.
		6	19.9	295	.
2003	VLN mentholated	-1	16.3	91	.
		1	17.6	.	.
		2	14.1	172	12
		3	14.1	.	.
		4	12.1	155	0

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
2003	VLN mentholated	5	12.3	.	.
		6	10.9	122	0
2007	VLN non-mentholated	-1	14.5	80	.
		1	20.1	.	.
		2	20.1	257	2
		3	20.3	.	.
		4	19.7	221	1
		5	16.6	.	.
		6	21.3	270	5
2008	VLN mentholated	-1	11.2	51	.
		1	13.1	.	.
		2	14.0	191	0
		3	13.0	.	.
		4	13.0	167	2
		5	13.0	.	.
		6	13.4	188	0
2009	VLN non-mentholated	-1	7.6	51	.
		1	6.0	.	.
		2	4.4	76	0
		3	4.1	.	.
		4	6.2	60	0
2010	UB mentholated	-1	11.1	86	.
		1	13.6	.	.
		2	15.7	192	.
		3	10.8	.	.

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
2010	UB mentholated	4	11.0	117	.
		5	11.4	.	.
		6	7.4	135	.
2011	VLN mentholated	-1	10.7	58	.
		1	11.6	.	.
		2	10.3	125	0
		3	10.4	.	.
		4	10.3	124	0
		5	10.3	.	.
2014	VLN mentholated	6	9.7	147	0
		-1	14.2	74	.
		1	24.7	.	.
		2	18.1	299	0
		3	13.9	.	.
		4	13.0	185	0
2015	UB mentholated	5	14.1	.	.
		6	14.3	201	0
		-1	14.0	43	.
		1	10.0	.	.
		2	10.9	140	.
		3	10.4	.	.
2016	VLN mentholated	4	10.9	136	.
		5	11.3	.	.
		6	12.9	170	.
		-1	8.0	54	.

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
2016	VLN mentholated	1	8.3	.	.
		2	6.3	75	4
2017	VLN mentholated	-1	18.3	104	.
		1	22.9	.	.
		2	22.9	300	0
		3	20.7	.	.
		4	15.7	230	0
		5	11.4	.	.
		6	15.0	180	0
2018	UB mentholated	-1	12.7	75	.
		1	16.3	.	.
		2	15.6	215	.
		3	15.3	.	.
		4	15.4	206	.
		5	16.3	.	.
		6	15.9	231	.
2020	VLN mentholated	-1	14.3	86	.
		1	15.9	.	.
		2	15.3	179	32
		3	11.0	.	.
		4	16.3	164	19
		5	12.7	.	.
		6	11.3	180	0
2021	VLN mentholated	-1	9.0	59	.
		1	9.9	.	.

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
2021	VLN mentholated	2	8.7	125	0
		3	10.4	.	.
		4	8.0	124	0
		5	9.4	.	.
		6	9.1	130	0
2023	VLN mentholated	-1	7.3	46	.
		1	11.3	.	.
		2	10.9	155	0
		3	10.3	.	.
		4	9.2	130	0
		5	8.7	.	.
2024	UB non-mentholated	6	6.9	104	0
		-1	14.1	53	.
		1	15.7	.	.
2025	UB non-mentholated	2	16.0	.	.
		-1	23.1	137	.
		1	25.7	.	.
		2	25.3	371	.
		3	23.1	.	.
		4	25.3	313	.
2028	VLN non-mentholated	5	24.1	.	.
		6	21.1	325	.
		-1	10.0	76	.
		1	16.1	.	.
		2	23.1	315	0

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
2028	VLN non-mentholated	3	22.7	.	.
		4	19.7	248	0
		5	16.6	.	.
		6	12.9	290	0
2029	UB mentholated	-1	16.1	128	.
		1	20.1	.	.
		2	20.0	425	.
		3	27.7	.	.
		4	25.9	367	.
		5	32.4	.	.
		6	24.3	366	.
2039	VLN mentholated	-1	13.7	88	.
		1	6.6	.	.
		2	5.1	65	0
		3	6.4	.	.
		4	6.9	72	1
		5	6.6	.	.
		6	5.3	86	0
2050	UB mentholated	-1	14.4	87	.
		1	19.0	.	.
		2	19.6	205	.
		3	17.1	.	.
		4	18.4	216	.
		5	16.0	.	.
		6	15.3	218	.

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
2052	VLN mentholated	-1	25.2	136	.
		1	34.0	.	.
		2	26.1	413	0
		3	30.4	.	.
		4	27.9	378	7
		5	19.7	.	.
		6	18.1	267	5
2057	VLN mentholated	-1	8.7	44	.
		1	10.0	.	.
		2	9.1	106	14
		3	5.9	.	.
		4	5.6	73	1
		5	6.6	.	.
		6	7.4	93	2
2058	VLN mentholated	-1	18.8	91	.
		1	7.9	.	.
		2	6.3	109	7
		3	11.1	.	.
		4	12.6	179	0
		5	10.7	.	.
		6	11.1	146	6
2059	UB mentholated	-1	17.1	53	.
		1	16.7	.	.
		2	14.7	188	.
		3	12.4	.	.
		4	13.3	132	.

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
2059	UB mentholated	5	13.1	.	.
		6	12.6	182	.
2060	VLN mentholated	-1	11.7	55	.
		1	7.5	.	.
		2	5.8	31	22
		3	5.4	.	.
		4	3.9	23	9
		5	3.6	.	.
		6	3.7	48	5
2064	VLN mentholated	-1	28.7	163	.
		1	21.0	.	.
		2	22.4	276	30
		3	20.4	.	.
		4	20.3	241	16
		5	19.1	.	.
		6	18.1	256	9
2066	VLN mentholated	-1	12.7	73	.
		1	10.7	.	.
		2	17.1	146	34
		3	8.7	.	.
		4	9.5	73	15
		5	7.3	.	.
		6	6.4	85	38
2067	VLN non-mentholated	-1	12.3	59	.
		1	15.4	.	.

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
2067	VLN non-mentholated	2	13.4	191	0
		3	12.3	.	.
		4	12.0	148	0
		5	10.0	.	.
		6	11.3	142	0
2075	VLN mentholated	-1	11.8	49	.
		1	12.1	.	.
		2	16.0	149	16
2076	VLN mentholated	-1	10.7	60	.
		1	14.7	.	.
		2	17.3	213	0
		3	10.3	.	.
		4	10.3	165	0
		5	10.0	.	.
2086	VLN non-mentholated	6	9.6	143	0
		-1	23.5	129	.
		1	24.1	.	.
		2	18.4	535	3
		3	24.9	.	.
2088	VLN mentholated	4	18.0	265	11
		-1	15.8	89	.
		1	12.6	.	.
		2	13.0	162	11
		3	9.0	.	.
		4	11.4	120	11

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
2088	VLN mentholated	5	10.1	.	.
		6	8.9	106	12
2092	VLN mentholated	-1	8.5	47	.
		1	11.1	.	.
		2	11.4	153	0
		3	9.4	.	.
		4	11.1	134	0
		5	8.4	.	.
		6	8.6	119	2
2099	VLN non-mentholated	-1	27.7	156	.
		1	30.3	.	.
		2	17.3	323	0
		3	20.3	.	.
		4	21.0	260	0
		5	20.0	.	.
		6	20.7	290	0
2100	UB mentholated	-1	12.6	68	.
		1	14.3	.	.
		2	14.4	194	.
		3	14.0	.	.
		4	14.6	183	.
		5	15.1	.	.
		6	15.0	223	.
2108	VLN non-mentholated	-1	39.2	206	.
		1	62.4	.	.

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-CIG.SAS 13JUN2019 4:24

Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
2108	VLN non-mentholated	2	53.9	719	72
		3	45.7	.	.
		4	44.6	538	33
		5	38.4	.	.
		6	34.9	460	70
2110	UB mentholated	-1	12.9	69	.
		1	11.9	.	.
		2	11.0	151	.
		3	9.6	.	.
		4	11.0	133	.
		5	9.9	.	.
2113	VLN mentholated	6	10.0	147	.
		-1	15.2	88	.
		1	12.7	.	.
		2	15.4	189	0
		3	10.4	.	.
2115	VLN mentholated	4	10.0	.	.
		-1	10.5	50	.
		1	11.4	.	.
2119	VLN mentholated	2	7.3	130	0
		-1	23.8	126	.
2119	VLN mentholated	1	24.0	.	.
		2	33.3	380	0
		3	28.6	.	.
		4	18.9	315	0

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-CIG.SAS 13JUN2019 4:24

Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
2119	VLN mentholated	5	18.3	.	.
		6	39.0	416	0
2120	VLN non-mentholated	-1	16.7	93	.
		1	14.7	.	.
		2	19.3	221	7
		3	17.3	.	.
		4	18.0	228	0
		5	18.7	.	.
		6	18.9	272	0
2122	UB non-mentholated	-1	18.4	113	.
		1	20.0	.	.
		2	19.6	280	.
		3	20.6	.	.
		4	20.3	257	.
		5	20.7	.	.
		6	17.0	264	.
2125	UB mentholated	-1	10.1	37	.
		1	10.3	.	.
		2	9.7	125	.
		3	9.1	.	.
		4	8.9	86	.
		5	9.0	.	.
		6	10.1	133	.
2126	VLN mentholated	-1	20.8	116	.
		1	24.7	.	.

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
2126	VLN mentholated	2	17.9	285	0
		3	11.6	.	.
		4	12.9	157	0
		5	8.0	.	.
		6	8.0	103	0
2136	VLN non-mentholated	-1	28.7	131	.
		1	21.0	.	.
		2	16.8	248	3
		3	16.2	.	.
		4	12.2	198	1
		5	12.3	.	.
2140	UB non-mentholated	6	10.7	154	5
		-1	11.1	54	.
		1	10.2	.	.
		2	14.9	163	.
		3	15.0	.	.
		4	12.0	179	.
2142	VLN non-mentholated	5	14.1	.	.
		6	17.0	225	.
		-1	26.2	166	.
2143	VLN non-mentholated	1	28.3	.	.
		2	24.8	394	7
2143	VLN non-mentholated	-1	26.0	156	.
		1	42.6	.	.
		2	38.4	556	0

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-CIG.SAS 13JUN2019 4:24

Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
2143	VLN non-mentholated	3	31.9	.	.
		4	34.9	426	0
		5	33.4	.	.
		6	33.4	466	0
2158	UB non-mentholated	-1	13.6	71	.
		1	10.6	.	.
		2	9.7	142	.
		3	10.6	.	.
		4	18.1	149	.
		5	59.4	.	.
		6	0.0	.	.
2159	VLN non-mentholated	-1	12.0	66	.
		1	26.1	.	.
		2	20.1	280	10
		3	20.0	.	.
		4	23.7	267	0
		5	20.0	.	.
		6	19.1	280	0
2164	VLN non-mentholated	-1	15.3	77	.
		1	29.0	.	.
		2	38.1	458	0
		3	40.9	.	.
		4	41.7	531	0
		5	36.6	.	.
		6	35.1	518	0

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
2168	VLN non-mentholated	-1	15.8	80	.
		1	12.9	.	.
		2	19.4	204	5
		3	16.3	.	.
		4	13.9	176	0
		5	12.7	.	.
		6	13.1	184	0
2170	UB non-mentholated	-1	10.0	44	.
		1	14.7	.	.
		2	9.7	162	.
		3	11.0	.	.
		4	11.4	105	.
		5	10.9	.	.
		6	10.0	162	.
2175	UB mentholated	-1	16.1	75	.
		1	16.9	.	.
		2	15.1	205	.
		3	16.3	.	.
		4	17.0	205	.
		5	15.9	.	.
		6	17.1	236	.
2189	VLN mentholated	-1	14.5	21	.
		1	13.0	.	.
		2	10.2	.	.
2211	VLN mentholated	-1	12.0	62	.

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
2211	VLN mentholated	1	15.4	.	.
		2	20.3	226	0
		3	13.3	.	.
		4	18.6	223	0
		5	17.7	.	.
		6	19.4	272	0
2212	UB mentholated	-1	15.6	87	.
		1	17.1	.	.
		2	16.6	231	.
		3	16.7	.	.
		4	17.0	220	.
		5	16.9	.	.
2213	VLN mentholated	6	15.3	236	.
		-1	32.8	187	.
		1	46.3	.	.
		2	30.9	515	3
		3	17.6	.	.
		4	46.9	408	1
2215	UB mentholated	5	57.1	.	.
		6	36.1	606	2
		-1	11.6	56	.
		1	11.0	.	.
		2	12.1	133	.
		3	12.9	.	.
		4	13.7	183	.
		5	12.7	.	.

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
2215	UB mentholated	6	11.7	153	.
2220	VLN non-mentholated	-1	11.2	66	.
		1	10.0	.	.
		2	10.1	128	0
		3	10.0	.	.
		4	10.4	134	2
		5	10.2	.	.
		6	10.7	139	5
2235	VLN mentholated	-1	11.3	60	.
		1	15.9	.	.
		2	19.3	240	0
		3	12.9	.	.
		4	14.3	175	0
		5	10.7	.	.
		6	9.6	156	0
2244	VLN non-mentholated	-1	13.3	68	.
		1	24.1	.	.
		2	16.1	245	0
		3	17.4	.	.
		4	15.9	218	0
		5	14.3	.	.
		6	12.4	200	0
2247	VLN mentholated	-1	9.8	41	.
		1	2.9	.	.
		2	5.8	75	0

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
2251	UB non-mentholated	-1	15.4	87	.
		1	16.0	.	.
		2	16.1	229	.
		3	16.1	.	.
		4	15.7	202	.
		5	15.6	.	.
		6	15.4	223	.
2257	UB non-mentholated	-1	14.9	76	.
		1	19.3	.	.
		2	18.4	252	.
		3	19.4	.	.
		4	16.9	238	.
		5	17.6	.	.
		6	16.0	236	.
2259	UB mentholated	-1	10.4	56	.
		1	9.4	.	.
		2	9.3	125	.
		3	8.7	.	.
		4	8.9	118	.
		5	8.6	.	.
		6	8.0	124	.
2269	VLN mentholated	-1	15.5	87	.
		1	10.0	.	.
		2	10.6	132	0
		3	10.7	.	.
		4	10.3	197	0

Subjects used their own usual brand cigarette at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.1 Number of Cigarettes Smoked and Number of Cigarette Butts Collected per Week
(Safety Population)

Subject Number	Product Group	Study Week	Average Number of Cigarettes Smoked Per Day	Number of Cigarettes Butts Collected	Number of Non-VLN Cigarettes Butts Collected
2269	VLN mentholated	5	10.1	.	.
		6	10.0	380	0
2272	VLN mentholated	-1	12.5	65	.
		1	13.7	.	.
		2	15.1	186	5
		3	7.7	.	.
		4	7.9	94	0
		5	8.0	.	.
		6	8.6	120	0

Subjects used their own usual brand cigarette at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.2 Puff Topography Parameters (Safety Population)

Subject Number	Product Group	Study Week	Number of Cigarettes	Average Number of Puffs	Average Puff Duration (sec)	Average Total Puff Duration (sec)	Average Puff Volume (mL)	Average Total Puff Volume (mL)	Average Inter-Puff Interval (sec)	Average Peak Flow (mL/sec)	Average Flow (mL/sec)	Intent- To- Treat Population	Per Protocol Population
1001	VLN non-mentholated	-1	2	10.50	1.77	18.65	54.81	575.91	31.40	51.94	33.71	Y	N
		2	2	10.00	1.62	16.20	47.80	478.02	26.77	48.37	31.59	Y	N
		6	2	11.00	1.56	16.98	46.40	510.23	20.12	48.78	32.48	Y	N
1002	VLN non-mentholated	-1	3	10.67	2.28	24.45	62.34	669.90	32.20	43.58	27.05	Y	N
		2	4	10.75	2.48	26.51	73.10	783.19	14.27	57.41	31.53	Y	N
		6	2	11.50	2.49	28.65	61.38	705.21	14.55	42.96	26.02	Y	N
1003	VLN mentholated	-1	2	19.00	1.32	24.80	38.49	718.58	20.93	45.41	30.54	Y	N
		2	1	20.00	1.70	33.95	33.51	670.24	16.94	31.73	20.52	Y	N
		6	2	15.00	1.32	19.85	33.83	507.49	21.59	41.23	26.78	Y	N
1007	VLN non-mentholated	-1	2	16.00	0.81	13.08	23.02	369.56	28.10	49.73	31.08	Y	Y
		2	1	19.00	0.94	17.90	23.39	444.44	12.15	43.72	26.37	Y	Y
		6	1	23.00	0.86	19.85	22.74	522.98	11.11	46.04	28.22	Y	Y
1008	VLN mentholated	-1	2	11.00	1.92	20.75	0.64	7.06	32.13	5.86	0.39	Y	N
		2	2	8.50	1.70	14.93	42.80	373.15	34.90	50.77	26.51	Y	N
		6	1	11.00	2.34	25.75	43.52	478.67	34.17	43.71	20.21	Y	N
1013	VLN non-mentholated	-1	1	15.00	2.01	30.10	47.58	713.66	19.29	41.46	24.30	Y	N
		2	1	9.00	2.00	18.00	51.47	463.22	21.30	46.06	27.19	Y	N
		6	1	9.00	1.71	15.35	54.67	491.99	19.51	59.39	35.33	Y	N
1014	VLN mentholated	-1	1	12.00	1.57	18.80	46.23	554.72	38.00	51.74	31.88	Y	N
		2	1	10.00	2.11	21.10	42.17	421.74	34.87	36.22	20.50	Y	N
		6	1	11.00	1.41	15.55	26.80	294.80	26.22	30.40	19.20	Y	N

Note: Y = Included, N = Not included
 Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.2 Puff Topography Parameters (Safety Population)

Subject Number	Product Group	Study Week	Number of Cigarettes	Average Number of Puffs	Average Puff Duration (sec)	Average Total Puff Duration (sec)	Average Puff Volume (mL)	Average Total Puff Volume (mL)	Average Inter-Puff Interval (sec)	Average Peak Flow (mL/sec)	Average Flow (mL/sec)	Intent-To-Treat Population	Per Protocol Population
1015	VLN mentholated	-1	1	15.00	2.13	31.95	46.52	697.85	31.85	34.00	22.42	Y	Y
		2	1	14.00	1.85	25.85	33.11	463.59	26.63	26.41	18.32	Y	Y
		6	1	16.00	1.91	30.55	31.89	510.16	21.63	26.16	16.52	Y	Y
1018	VLN mentholated	-1	1	12.00	1.62	19.40	66.66	799.97	34.85	79.05	44.20	Y	Y
1019	VLN non-mentholated	-1	2	7.00	2.18	15.28	52.61	365.64	52.30	43.68	27.64	Y	N
		2	2	6.00	1.95	11.70	54.87	329.21	43.63	41.70	30.38	Y	N
		6	1	7.00	2.20	15.40	61.97	433.80	27.28	41.63	30.03	Y	N
1020	VLN non-mentholated	-1	1	15.00	2.37	35.60	53.30	799.48	16.69	49.10	23.69	Y	N
		2	1	15.00	1.40	21.05	36.14	542.13	16.19	41.46	26.32	Y	N
		6	1	12.00	2.08	25.00	35.96	431.54	26.16	35.21	17.67	Y	N
1023	VLN non-mentholated	-1	2	9.50	2.95	28.13	54.96	521.40	40.29	32.70	19.30	Y	N
		2	1	10.00	2.66	26.55	49.40	493.99	33.16	30.66	19.44	Y	N
		6	1	11.00	2.42	26.65	44.41	488.53	28.58	29.31	18.32	Y	N
1029	VLN mentholated	-1	1	13.00	2.27	29.55	71.17	925.20	16.22	60.25	34.14	Y	N
		2	1	11.00	1.91	21.05	48.03	528.32	9.73	39.29	25.03	Y	N
1032	VLN mentholated	-1	2	12.00	2.12	25.58	123.47	1433.2	38.15	91.41	62.11	Y	Y
		2	1	12.00	1.95	23.40	42.70	512.42	20.33	34.72	22.44	Y	Y
		6	2	11.50	2.39	26.95	57.52	638.12	17.35	37.76	24.60	Y	Y
1034	VLN non-mentholated	-1	1	12.00	2.87	34.40	46.31	555.71	22.07	26.72	16.72	Y	N
		2	1	14.00	2.66	37.20	43.13	603.83	11.74	29.22	16.84	Y	N

Note: Y = Included, N = Not included
 Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.2 Puff Topography Parameters (Safety Population)

Subject Number	Product Group	Study Week	Number of Cigarettes	Average Number of Puffs	Average Puff Duration (sec)	Average Total Puff Duration (sec)	Average Puff Volume (mL)	Average Total Puff Volume (mL)	Average Inter-Puff Interval (sec)	Average Peak Flow (mL/sec)	Average Flow (mL/sec)	Intent-To-Treat Population	Per Protocol Population
1034	VLN non-mentholated	6	1	13.00	2.20	28.55	40.07	520.90	12.64	28.43	18.03	Y	N
1035	VLN non-mentholated	-1	2	14.00	2.13	29.83	50.86	712.08	20.91	36.09	24.97	Y	N
		2	2	11.00	2.20	24.30	46.99	509.96	33.70	31.73	22.54	Y	N
		6	1	11.00	2.48	27.25	46.14	507.53	22.22	28.21	19.93	Y	N
1038	VLN non-mentholated	-1	2	13.00	1.16	15.10	41.78	543.11	28.65	61.53	38.47	Y	N
		2	1	8.00	0.91	7.25	40.03	320.20	34.73	76.00	48.54	N	N
		6	1	7.00	1.04	7.25	46.32	324.21	23.22	81.16	47.83	Y	N
1042	VLN non-mentholated	-1	2	10.00	1.28	12.85	53.84	540.39	22.19	64.07	45.39	Y	N
		2	1	9.00	1.24	11.15	40.19	361.75	31.22	49.02	34.70	Y	N
		6	1	10.00	1.31	13.10	54.93	549.34	21.14	66.71	45.86	Y	N
1050	VLN non-mentholated	-1	2	12.00	2.24	26.85	44.32	531.89	23.72	39.32	20.82	Y	N
		2	2	8.00	2.81	22.48	54.60	436.81	28.22	39.49	20.29	Y	N
		6	1	11.00	2.35	25.85	45.29	498.15	16.57	39.00	20.51	Y	N
1052	VLN mentholated	-1	1	12.00	2.22	26.65	75.29	903.47	23.17	58.24	35.89	Y	N
		2	1	15.00	1.58	23.65	53.10	796.50	14.91	55.24	36.50	Y	N
		6	2	9.00	2.40	21.63	63.15	568.39	12.39	46.72	27.55	Y	N
1053	VLN mentholated	-1	2	11.50	2.76	31.80	49.68	570.70	29.94	30.50	18.16	Y	N
		2	1	11.00	2.17	23.90	55.99	615.89	20.74	52.67	29.48	Y	N
		6	2	8.00	1.84	14.93	44.54	350.08	46.08	44.87	27.37	Y	N
1055	VLN mentholated	-1	1	12.00	2.58	30.95	58.79	705.49	25.49	40.74	23.51	Y	N

Note: Y = Included, N = Not included
 Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.2 Puff Topography Parameters (Safety Population)

Subject Number	Product Group	Study Week	Number of Cigarettes	Average Number of Puffs	Average Puff Duration (sec)	Average Total Puff Duration (sec)	Average Puff Volume (mL)	Average Total Puff Volume (mL)	Average Inter-Puff Interval (sec)	Average Peak Flow (mL/sec)	Average Flow (mL/sec)	Intent-To-Treat Population	Per Protocol Population
1055	VLN mentholated	2	2	7.00	3.39	23.75	59.51	416.54	55.63	35.76	18.16	Y	N
		6	1	8.00	3.03	24.20	57.35	458.79	34.34	36.50	19.03	Y	N
1056	VLN non-mentholated	-1	2	13.50	1.82	24.53	21.48	279.65	31.15	22.98	12.20	Y	N
		2	2	13.00	1.87	24.43	20.69	249.11	24.20	22.23	11.80	Y	N
		6	1	14.00	1.80	25.15	39.37	551.20	18.17	36.76	22.71	Y	N
1058	VLN non-mentholated	-1	2	12.50	2.73	34.28	75.09	938.67	18.50	49.86	29.04	Y	N
		2	1	15.00	2.51	37.70	33.90	508.53	15.58	25.08	14.06	Y	N
		6	1	9.00	3.71	33.40	79.68	717.10	9.44	44.53	23.25	Y	N
1060	VLN mentholated	-1	2	13.00	2.14	27.83	61.92	805.00	22.69	47.71	30.78	Y	N
		2	2	18.00	1.50	27.03	42.88	771.87	14.75	44.89	30.51	Y	N
		6	2	15.00	1.70	25.43	42.11	632.76	18.20	39.49	25.89	Y	N
1063	VLN mentholated	-1	3	10.67	1.62	17.15	59.33	621.41	45.86	63.62	38.60	Y	Y
		2	2	9.00	1.89	16.98	45.36	408.23	49.88	53.60	32.06	Y	Y
		6	2	9.00	1.38	12.40	42.42	384.21	40.97	54.77	30.96	Y	Y
1066	VLN non-mentholated	-1	2	10.00	2.85	28.50	63.90	632.50	39.35	38.30	23.47	Y	Y
		2	2	7.00	4.83	33.40	32.81	262.13	29.01	16.47	7.97	Y	Y
		6	2	7.50	3.08	22.92	31.07	279.23	25.38	22.59	11.44	Y	Y
1070	VLN non-mentholated	-1	2	10.50	2.10	22.13	53.25	557.92	29.85	42.33	26.56	Y	Y
		2	2	12.00	2.30	27.50	60.57	720.71	17.10	70.81	29.20	Y	Y
		6	1	12.00	2.25	27.05	58.17	698.06	23.48	43.97	27.49	Y	Y

Note: Y = Included, N = Not included

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.2 Puff Topography Parameters (Safety Population)

Subject Number	Product Group	Study Week	Number of Cigarettes	Average Number of Puffs	Average Puff Duration (sec)	Average Total Puff Duration (sec)	Average Puff Volume (mL)	Average Total Puff Volume (mL)	Average Inter-Puff Interval (sec)	Average Peak Flow (mL/sec)	Average Flow (mL/sec)	Intent- To- Treat Population	Per Protocol Population
1071	VLN non-mentholated	-1	2	9.00	1.61	14.45	58.88	529.96	44.09	54.35	40.52	Y	N
		2	2	8.50	1.94	16.45	45.50	387.83	30.24	41.78	27.86	Y	N
1072	VLN mentholated	-1	2	12.50	2.88	35.95	60.59	756.79	35.28	28.81	21.16	Y	Y
		2	2	8.00	3.28	26.18	56.91	450.04	33.34	24.73	17.47	Y	Y
1078	VLN non-mentholated	-1	2	9.00	1.62	14.73	55.16	498.28	44.11	50.05	36.03	Y	N
		2	2	8.00	1.66	13.30	52.13	417.01	39.38	48.57	33.09	N	N
		6	2	9.00	1.68	15.03	46.98	421.75	38.21	43.59	29.06	Y	N
1079	VLN mentholated	-1	2	14.00	2.40	33.55	56.72	794.04	29.34	34.70	26.03	Y	Y
		2	2	13.00	2.31	30.00	71.52	929.78	23.40	41.78	30.29	Y	Y
		6	2	9.00	2.24	20.10	52.38	471.36	31.41	33.77	24.29	Y	Y
1088	VLN mentholated	-1	1	10.00	2.57	25.70	60.70	606.97	29.87	41.36	24.94	Y	N
		2	1	9.00	2.52	22.70	54.65	491.84	23.23	39.75	22.64	Y	N
		6	1	9.00	2.38	21.40	57.79	520.11	16.94	45.49	25.91	Y	N
1092	VLN mentholated	-1	2	11.00	1.51	16.92	46.88	514.63	35.85	52.54	33.41	Y	N
		2	1	13.00	1.15	14.90	33.38	433.89	27.12	48.80	30.69	Y	N
		6	1	9.00	1.34	12.10	42.76	384.83	42.15	49.38	33.12	Y	N
1094	VLN mentholated	-1	1	10.00	4.58	45.85	75.40	753.97	21.68	35.02	16.98	Y	N
		2	1	12.00	3.66	43.95	82.07	984.87	21.50	55.01	29.25	Y	N
		6	1	10.00	2.71	27.05	65.20	651.99	35.27	48.02	25.46	Y	N
1097	VLN mentholated	-1	2	15.50	2.38	36.93	43.60	675.62	14.70	26.39	18.64	Y	N

Note: Y = Included, N = Not included
 Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.2 Puff Topography Parameters (Safety Population)

Subject Number	Product Group	Study Week	Number of Cigarettes	Average Number of Puffs	Average Puff Duration (sec)	Average Total Puff Duration (sec)	Average Puff Volume (mL)	Average Total Puff Volume (mL)	Average Inter-Puff Interval (sec)	Average Peak Flow (mL/sec)	Average Flow (mL/sec)	Intent- To- Treat Population	Per Protocol Population
1097	VLN mentholated	2	1	11.00	2.20	24.20	47.83	526.16	24.71	33.12	22.35	Y	N
		6	1	13.00	2.61	33.95	40.02	520.20	9.53	22.04	15.00	Y	N

Note: Y = Included, N = Not included
 Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.3 Urinary NNAL (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1001	UB Non-mentholated	-1	203	2171.0	440.71	NA	NA	499	406.81	NA	NA	Y	N
	VLN Non-mentholated	2	137	1172.6	160.65	-280.07	-63.55	804	170.40	-236.42	-58.11	Y	N
		6	178	1249.1	222.34	-218.37	-49.55	843	211.15	-195.66	-48.10	Y	N
1002	UB Non-mentholated	-1	274	4356.5	1193.68	NA	NA	424	646.23	NA	NA	Y	N
	VLN Non-mentholated	2	146	4062.7	593.15	-600.53	-50.31	414	352.66	-293.57	-45.43	Y	N
		6	131	5759.6	754.51	-439.17	-36.79	333	393.39	-252.83	-39.12	Y	N
1003	UB Mentholated	-1	284	1385.0	393.34	NA	NA	1770	160.45	NA	NA	Y	N
	VLN Mentholated	2	268	410.0	109.88	-283.46	-72.06	2280	117.54	-42.91	-26.74	Y	N
		6	393	1017.7	399.96	6.62	1.68	2250	174.67	14.21	8.86	Y	N
1007	UB Non-mentholated	-1	158	1935.0	305.73	NA	NA	890	177.53	NA	NA	Y	Y
	VLN Non-mentholated	2	60.9	2199.9	133.97	-171.76	-56.18	947	64.31	-113.22	-63.78	Y	Y
		6	100	1700.3	170.03	-135.70	-44.39	1330	75.19	-102.34	-57.65	Y	Y
1008	UB Mentholated	-1	65.6	2014.0	132.12	NA	NA	1120	58.57	NA	NA	Y	N
	VLN Mentholated	2	191	1435.9	274.26	142.14	107.58	1550	123.23	64.65	110.39	Y	N
		6	101	1122.0	113.32	-18.80	-14.23	701	144.08	85.51	145.99	N	N
1010	UB Mentholated	-1	395	2030.0	801.85	NA	NA	941	419.77	NA	NA	Y	Y
		2	445	1539.6	685.12	-116.73	-14.56	1120	397.32	-22.44	-5.35	Y	Y
		6	300	1036.8	311.04	-490.81	-61.21	741	404.86	-14.91	-3.55	N	N

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

CFB = Change from Baseline, PCFB = Percent change from baseline, Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Values reported as below the limit of quantitation (BLQ) were set to one-half of the LLOQ for summarization and statistical analysis.

. = Value missing or not reportable.

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Appendix 16.2.6.3 Urinary NNAL (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1011	UB Non-mentholated	-1	653	1059.0	691.53	NA	NA	2360	276.69	NA	NA	Y	Y
		2	398	1364.0	542.87	-148.66	-21.50	1590	250.31	-26.38	-9.53	Y	Y
		6	378	628.7	237.65	-453.88	-65.63	1060	356.60	79.91	28.88	N	N
1013	UB Non-mentholated VLN Non-mentholated	-1	185	1664.0	307.84	NA	NA	1060	174.53	NA	NA	Y	N
		2	196	1043.8	.	.	.	1450	135.17	-39.36	-22.55	N	N
		6	300	874.0	262.20	-45.64	-14.83	1970	152.28	-22.24	-12.75	Y	N
1014	UB Mentholated VLN Mentholated	-1	351	2069.0	726.22	NA	NA	476	737.39	NA	NA	Y	N
		6	766	903.2	691.85	-34.37	-4.73	1330	575.94	-161.46	-21.90	Y	N
1015	UB Mentholated VLN Mentholated	-1	48.5	3550.0	172.18	NA	NA	371	130.73	NA	NA	Y	Y
		2	13.2	3406.2	44.96	-127.21	-73.89	373	35.39	-95.34	-72.93	Y	Y
		6	16.7	3477.7	58.08	-114.10	-66.27	392	42.60	-88.13	-67.41	Y	Y
1016	UB Non-mentholated	-1	488	1853.0	904.26	NA	NA	873	558.99	NA	NA	Y	Y
		2	384	2839.1	1090.21	185.95	20.56	528	727.27	168.28	30.10	Y	Y
		6	589	1899.3	1118.69	214.42	23.71	908	648.68	89.69	16.04	Y	Y
1017	UB Mentholated	-1	400	2490.0	996.00	NA	NA	507	788.95	NA	NA	Y	Y
		2	396	2593.9	1027.18	31.18	3.13	529	748.58	-40.37	-5.12	Y	Y
		6	578	1399.2	808.74	-187.26	-18.80	920	628.26	-160.69	-20.37	Y	Y
1018	UB Mentholated	-1	245	1721.0	421.65	NA	NA	672	364.58	NA	NA	Y	Y

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

CFB = Change from Baseline, PCFB = Percent change from baseline, Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Values reported as below the limit of quantitation (BLQ) were set to one-half of the LLOQ for summarization and statistical analysis.

. = Value missing or not reportable.

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Appendix 16.2.6.3 Urinary NNAL (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1019	UB Non-mentholated	-1	514	1431.0	735.53	NA	NA	1750	293.71	NA	NA	Y	N
	VLN Non-mentholated	2	121	3109.0	376.19	-359.35	-48.85	762	158.79	-134.92	-45.94	Y	N
		6	306	2290.1	700.77	-34.76	-4.73	1110	275.68	-18.04	-6.14	Y	N
1020	UB Non-mentholated	-1	759	1666.0	1264.49	NA	NA	773	981.89	NA	NA	Y	N
	VLN Non-mentholated	2	517	1240.9	641.55	-622.95	-49.26	1430	361.54	-620.35	-63.18	Y	N
		6	671	917.7	615.78	-648.72	-51.30	1280	524.22	-457.67	-46.61	Y	N
1021	UB Non-mentholated	-1	218	1808.0	394.14	NA	NA	681	320.12	NA	NA	N	N
		2	249	1842.4	458.76	.	.	710	350.70	.	.	Y	Y
		6	192	2136.5	410.21	.	.	637	301.41	.	.	Y	Y
1023	UB Non-mentholated	-1	152	2894.0	439.89	NA	NA	367	414.17	NA	NA	Y	N
	VLN Non-mentholated	2	46.1	3795.5	174.97	-264.92	-60.22	274	168.25	-245.92	-59.38	Y	N
		6	84.9	3600.0	305.64	-134.25	-30.52	334	254.19	-159.98	-38.63	Y	N
1029	UB Mentholated	-1	273	2525.2	689.38	NA	NA	554	492.78	NA	NA	Y	N
	VLN Mentholated	2	93.4	3098.0	289.35	-400.03	-58.03	505	184.95	-307.83	-62.47	Y	N
		6	164	2192.0	359.49	-329.89	-47.85	753	217.80	-274.98	-55.80	Y	N
1032	UB Mentholated	-1	120	3793.8	455.26	NA	NA	319	376.18	NA	NA	Y	Y
	VLN Mentholated	2	56.3	3479.0	195.87	-259.39	-56.98	411	136.98	-239.19	-63.59	Y	Y
		6	62.6	2345.0	146.80	-308.46	-67.76	602	103.99	-272.19	-72.36	Y	Y

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

CFB = Change from Baseline, PCFB = Percent change from baseline, Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Values reported as below the limit of quantitation (BLQ) were set to one-half of the LLOQ for summarization and statistical analysis.

. = Value missing or not reportable.

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Appendix 16.2.6.3 Urinary NNAL (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1034	UB Non-mentholated	-1	401	1275.1	511.32	NA	NA	1080	371.30	NA	NA	Y	N
	VLN Non-mentholated	2	442	969.0	428.30	-83.02	-16.24	1210	365.29	-6.01	-1.62	Y	N
		6	551	1037.0	571.39	60.07	11.75	1550	355.48	-15.81	-4.26	Y	N
1035	UB Non-mentholated	-1	508	2182.4	1108.66	NA	NA	1180	430.51	NA	NA	Y	N
	VLN Non-mentholated	2	308	2196.0	676.37	-432.29	-38.99	726	424.24	-6.27	-1.46	Y	N
		6	696	1204.0	837.98	-270.68	-24.41	1400	497.14	66.63	15.48	Y	N
1036	UB Mentholated	-1	79.6	1896.8	150.99	NA	NA	761	104.60	NA	NA	Y	Y
		2	89.6	1841.0	164.95	13.97	9.25	793	112.99	8.39	8.02	Y	Y
		6	126	1475.0	185.85	34.86	23.09	1110	113.51	8.91	8.52	Y	Y
1037	UB Mentholated	-1	121	5986.4	724.35	NA	NA	350	345.71	NA	NA	Y	Y
		2	239	2822.0	674.46	-49.90	-6.89	698	342.41	-3.31	-0.96	Y	Y
		6	225	2712.0	610.20	-114.15	-15.76	651	345.62	-0.09	-0.03	Y	Y
1038	UB Non-mentholated	-1	150	1610.1	241.52	NA	NA	802	187.03	NA	NA	Y	N
	VLN Non-mentholated	2	48.9	1705.0	83.37	-158.14	-65.48	830	58.92	-128.12	-68.50	Y	N
		6	67.0	1641.0	109.95	-131.57	-54.48	894	74.94	-112.09	-59.93	Y	N
1042	UB Non-mentholated	-1	105	5646.2	592.85	NA	NA	353	297.45	NA	NA	Y	N
	VLN Non-mentholated	2	43.1	3586.0	154.56	-438.29	-73.93	380	113.42	-184.03	-61.87	Y	N
		6	46.1	2769.0	127.65	-465.20	-78.47	429	107.46	-189.99	-63.87	Y	N

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

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Appendix 16.2.6.3 Urinary NNAL (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1045	UB Non-mentholated	-1	178	3025.5	538.54	NA	NA	613	290.38	NA	NA	Y	Y
		2	219	2443.0	535.02	-3.52	-0.65	654	334.86	44.49	15.32	Y	Y
		6	212	1894.0	401.53	-137.01	-25.44	921	230.18	-60.19	-20.73	Y	Y
1046	UB Mentholated	-1	143	3780.8	540.65	NA	NA	570	250.88	NA	NA	Y	Y
		2	150	2832.0	424.80	-115.85	-21.43	670	223.88	-27.00	-10.76	Y	Y
		6	147	2830.0	416.01	-124.64	-23.05	806	182.38	-68.50	-27.30	Y	Y
1050	UB Non-mentholated VLN Non-mentholated	-1	284	1520.3	431.77	NA	NA	781	363.64	NA	NA	Y	N
		2	52.0	3144.1	163.49	-268.27	-62.13	472	110.17	-253.47	-69.70	Y	N
		6	154	1578.0	243.01	-188.75	-43.72	825	186.67	-176.97	-48.67	Y	N
1051	UB Mentholated	-1	210	2216.8	465.53	NA	NA	762	275.59	NA	NA	Y	Y
		2	228	2040.0	465.12	-0.41	-0.09	789	288.97	13.38	4.86	Y	Y
		6	234	1784.0	417.46	-48.07	-10.33	1050	222.86	-52.73	-19.13	Y	Y
1052	UB Mentholated VLN Mentholated	-1	272	1539.8	418.83	NA	NA	1300	209.23	NA	NA	Y	N
		2	147	1602.0	235.49	-183.33	-43.77	1130	130.09	-79.14	-37.83	Y	N
		6	290	1065.0	308.85	-109.98	-26.26	1850	156.76	-52.47	-25.08	Y	N
1053	UB Mentholated VLN Mentholated	-1	205	2902.3	594.97	NA	NA	795	257.86	NA	NA	Y	N
		2	84.8	2790.0	236.59	-358.38	-60.23	933	90.89	-166.97	-64.75	Y	N
		6	81.9	2523.0	206.63	-388.34	-65.27	914	89.61	-168.26	-65.25	Y	N

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Appendix 16.2.6.3 Urinary NNAL (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1054	UB Non-mentholated	-1	1210	956.9	1157.85	NA	NA	2550	474.51	NA	NA	Y	Y
		2	559	1844.0	1030.80	-127.05	-10.97	1180	473.73	-0.78	-0.16	Y	Y
		6	870	1089.0	947.43	-210.42	-18.17	2130	408.45	-66.06	-13.92	Y	Y
1055	UB Mentholated VLN Mentholated	-1	165	3328.9	549.27	NA	NA	451	365.85	NA	NA	Y	N
		2	74.5	3391.6	252.67	-296.59	-54.00	495	150.51	-215.35	-58.86	Y	N
		6	172	1581.0	271.93	-277.34	-50.49	955	180.10	-185.75	-50.77	Y	N
1056	UB Non-mentholated VLN Non-mentholated	-1	214	3925.2	839.99	NA	NA	416	514.42	NA	NA	Y	N
		2	132	1334.0	176.09	-663.90	-79.04	799	165.21	-349.22	-67.89	Y	N
		6	300	1152.0	345.60	-494.39	-58.86	785	382.17	-132.26	-25.71	Y	N
1058	UB Non-mentholated VLN Non-mentholated	-1	123	3355.1	412.68	NA	NA	518	237.45	NA	NA	Y	N
		2	33.6	2869.0	96.40	-316.28	-76.64	520	64.62	-172.84	-72.79	Y	N
		6	127	1927.0	244.73	-167.95	-40.70	1190	106.72	-130.73	-55.05	Y	N
1059	UB Non-mentholated	-1	1740	956.0	1663.44	NA	NA	2300	756.52	NA	NA	Y	Y
		2	633	2124.7	1344.94	-318.50	-19.15	1040	608.65	-147.87	-19.55	Y	Y
		6	1140	1507.0	1717.98	54.54	3.28	1750	651.43	-105.09	-13.89	Y	Y
1060	UB Mentholated VLN Mentholated	-1	220	2414.0	531.08	NA	NA	751	292.94	NA	NA	Y	N
		2	113	2361.4	266.84	-264.24	-49.76	782	144.50	-148.44	-50.67	Y	N
		6	168	1742.0	292.66	-238.42	-44.89	950	176.84	-116.10	-39.63	Y	N

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Appendix 16.2.6.3 Urinary NNAL (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1063	UB Mentholated	-1	29.5	7095.2	209.31	NA	NA	306	96.41	NA	NA	Y	Y
	VLN Mentholated	2	14.6	3891.4	56.81	-152.49	-72.86	569	25.66	-70.75	-73.38	Y	Y
		6	10.9	3208.0	34.97	-174.34	-83.29	787	13.85	-82.56	-85.63	Y	Y
1064	UB Non-mentholated	-1	165	3268.0	539.22	NA	NA	749	220.29	NA	NA	Y	Y
		2	262	2273.1	595.55	56.33	10.45	1060	247.17	26.88	12.20	Y	Y
1066	UB Non-mentholated	-1	272	967.0	263.02	NA	NA	2190	124.20	NA	NA	Y	Y
	VLN Non-mentholated	2	97.7	1744.8	170.47	-92.56	-35.19	1050	93.05	-31.15	-25.08	Y	Y
		6	79.6	1725.0	137.31	-125.71	-47.80	1220	65.25	-58.96	-47.47	Y	Y
1069	UB Non-mentholated	-1	441	2554.0	1126.31	NA	NA	793	556.12	NA	NA	Y	Y
		2	404	2465.9	996.22	-130.09	-11.55	783	515.96	-40.15	-7.22	Y	Y
		6	534	2162.0	1154.51	28.19	2.50	973	548.82	-7.30	-1.31	Y	Y
1070	UB Non-mentholated	-1	349	3393.0	1184.16	NA	NA	633	551.34	NA	NA	Y	Y
	VLN Non-mentholated	2	99.6	2687.1	267.64	-916.52	-77.40	752	132.45	-418.90	-75.98	Y	Y
		6	145	1316.0	190.82	-993.34	-83.89	1800	80.56	-470.79	-85.39	Y	Y
1071	UB Non-mentholated	-1	162	2129.0	344.90	NA	NA	700	231.43	NA	NA	Y	N
	VLN Non-mentholated	2	77.4	2212.3	171.23	-173.67	-50.35	1230	62.93	-168.50	-72.81	Y	N
1072	UB Mentholated	-1	196	2181.0	427.48	NA	NA	806	243.18	NA	NA	Y	Y
	VLN Mentholated	2	139	1779.7	247.38	-180.10	-42.13	955	145.55	-97.63	-40.15	Y	Y

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Appendix 16.2.6.3 Urinary NNAL (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1074	UB Non-mentholated	-1	383	2211.0	846.81	NA	NA	876	437.21	NA	NA	Y	N
	VLN Non-mentholated	2	389	1464.3	569.61	-277.20	-32.73	1350	288.15	-149.07	-34.09	Y	N
		6	296	1677.0	496.39	-350.42	-41.38	1310	225.95	-211.26	-48.32	Y	N
1075	UB Non-mentholated	-1	186	2163.0	402.32	NA	NA	773	240.62	NA	NA	Y	Y
		2	185	1890.7	349.78	-52.54	-13.06	845	218.93	-21.69	-9.01	Y	Y
		6	310	1263.0	391.53	-10.79	-2.68	1340	231.34	-9.28	-3.86	Y	Y
1077	UB Non-mentholated	-1	60.7	3102.1	188.30	NA	NA	493	123.12	NA	NA	Y	Y
	VLN Non-mentholated	2	70.9	3008.3	213.29	24.99	13.27	596	118.96	-4.16	-3.38	Y	Y
		6	51.9	2743.0	142.36	-45.94	-24.40	693	74.89	-48.23	-39.17	Y	Y
1078	UB Non-mentholated	-1	300	1991.0	597.30	NA	NA	597	502.51	NA	NA	Y	N
	VLN Non-mentholated	2	102	3513.1	358.34	-238.96	-40.01	352	289.77	-212.74	-42.34	Y	N
		6	217	2384.0	517.33	-79.97	-13.39	654	331.80	-170.71	-33.97	Y	N
1079	UB Mentholated	-1	165	2154.0	355.41	NA	NA	1370	120.44	NA	NA	Y	Y
	VLN Mentholated	2	23.3	3647.6	84.99	-270.42	-76.09	802	29.05	-91.39	-75.88	Y	Y
		6	11.9	2605.0	31.00	-324.41	-91.28	1040	11.44	-109.00	-90.50	Y	Y
1082	UB Non-mentholated	-1	294	2790.0	820.26	NA	NA	843	348.75	NA	NA	Y	N
	VLN Non-mentholated	2	134	2629.9	352.41	-467.85	-57.04	926	144.71	-204.05	-58.51	Y	N
		6	216	2013.0	434.81	-385.45	-46.99	1200	180.00	-168.75	-48.39	Y	N

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Appendix 16.2.6.3 Urinary NNAL (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1083	UB Non-mentholated	-1	390	1708.0	666.12	NA	NA	762	511.81	NA	NA	Y	N
	VLN Non-mentholated	2	325	1788.0	581.10	-85.02	-12.76	892	364.35	-147.46	-28.81	Y	N
		6	330	2017.0	665.61	-0.51	-0.08	804	410.45	-101.36	-19.80	Y	N
1084	UB Non-mentholated	-1	390	1467.0	572.13	NA	NA	1380	282.61	NA	NA	Y	N
	VLN Non-mentholated	2	225	1158.4	260.64	-311.49	-54.44	1630	138.04	-144.57	-51.16	Y	N
1086	UB Non-mentholated	-1	331	1938.0	641.48	NA	NA	968	341.94	NA	NA	Y	N
	VLN Non-mentholated	2	232	1255.9	291.37	-350.11	-54.58	1410	164.54	-177.40	-51.88	Y	N
		6	240	1580.0	379.20	-262.28	-40.89	1040	230.77	-111.17	-32.51	Y	N
1088	UB Mentholated	-1	440	1662.0	731.28	NA	NA	1670	263.47	NA	NA	Y	N
	VLN Mentholated	2	384	1236.2	474.70	-256.58	-35.09	1820	210.99	-52.48	-19.92	Y	N
		6	297	1670.0	495.99	-235.29	-32.18	1520	195.39	-68.08	-25.84	Y	N
1089	UB Non-mentholated	-1	285	1795.0	511.58	NA	NA	669	426.01	NA	NA	Y	Y
		2	189	2415.3	456.49	-55.08	-10.77	544	347.43	-78.58	-18.45	Y	Y
		6	190	2062.0	391.78	-119.80	-23.42	559	339.89	-86.12	-20.21	Y	Y
1092	UB Mentholated	-1	267	2383.0	636.26	NA	NA	734	363.76	NA	NA	Y	N
	VLN Mentholated	2	251	1551.7	389.48	-246.78	-38.79	898	279.51	-84.25	-23.16	Y	N
		6	307	1587.0	487.21	-149.05	-23.43	1150	266.96	-96.80	-26.61	Y	N
1094	UB Mentholated	-1	168	1930.0	324.24	NA	NA	1230	136.59	NA	NA	Y	N

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Appendix 16.2.6.3 Urinary NNAL (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1094	VLN Mentholated	2	113	1307.6	147.76	-176.48	-54.43	1720	65.70	-70.89	-51.90	Y	N
		6	105	1040.0	109.20	-215.04	-66.32	1930	54.40	-82.18	-60.17	Y	N
1095	UB Mentholated	-1	116	2551.0	295.92	NA	NA	514	225.68	NA	NA	Y	N
	VLN Mentholated	2	161	430.3	69.28	-226.64	-76.59	982	163.95	-61.73	-27.35	N	N
		6	70.3	2131.0	149.81	-146.11	-49.37	390	180.26	-45.42	-20.13	Y	N
1096	UB Non-mentholated	-1	205	2532.0	519.06	NA	NA	634	323.34	NA	NA	Y	N
	VLN Non-mentholated	2	184	1934.5	355.95	-163.11	-31.42	679	270.99	-52.36	-16.19	Y	N
		6	156	2949.0	460.04	-59.02	-11.37	488	319.67	-3.67	-1.14	Y	N
1097	UB Mentholated	-1	272	1982.0	539.10	NA	NA	1250	217.60	NA	NA	Y	N
	VLN Mentholated	2	155	1598.3	247.74	-291.37	-54.05	1510	102.65	-114.95	-52.83	Y	N
		6	161	1814.0	292.05	-247.05	-45.83	1270	126.77	-90.83	-41.74	Y	N
1098	UB Non-mentholated	-1	594	1415.8	840.99	NA	NA	1060	560.38	NA	NA	Y	Y
	VLN Non-mentholated	2	155	1666.1	258.25	-582.74	-69.29	958	161.80	-398.58	-71.13	Y	Y
		6	130	1811.0	235.43	-605.56	-72.01	895	145.25	-415.13	-74.08	Y	Y
1099	UB Non-mentholated	-1	656	810.2	.	NA	NA	1420	461.97	NA	NA	N	N
	VLN Non-mentholated	2	238	1272.2	302.78	.	.	1060	224.53	.	.	Y	N
		6	394	1005.0	395.97	.	.	1250	315.20	.	.	Y	N
1100	UB Non-mentholated	-1	211	3350.7	707.00	NA	NA	550	383.64	NA	NA	Y	N

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Appendix 16.2.6.3 Urinary NNAL (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1100	VLN Non-mentholated	2	207	2653.5	549.27	-157.72	-22.31	684	302.63	-81.00	-21.11	Y	N
		6	194	2576.0	499.74	-207.25	-29.31	772	251.30	-132.34	-34.50	Y	N
1101	UB Non-mentholated	-1	449	1814.1	814.53	NA	NA	827	542.93	NA	NA	Y	N
	VLN Non-mentholated	2	323	2317.4	748.52	-66.01	-8.10	805	401.24	-141.68	-26.10	Y	N
		6	237	3707.0	878.56	64.03	7.86	258	918.60	375.68	69.20	Y	N
1103	UB Non-mentholated	-1	191	3479.4	664.57	NA	NA	297	643.10	NA	NA	Y	N
	VLN Non-mentholated	2	136	2449.2	333.09	-331.47	-49.88	762	178.48	-464.62	-72.25	Y	N
		6	205	2601.0	533.21	-131.36	-19.77	763	268.68	-374.42	-58.22	Y	N
1105	UB Non-mentholated	-1	634	527.3	334.31	NA	NA	1680	377.38	NA	NA	Y	N
	VLN Non-mentholated	2	304	825.2	250.86	-83.45	-24.96	1010	300.99	-76.39	-20.24	Y	N
		6	380	677.0	257.26	-77.05	-23.05	1420	267.61	-109.78	-29.09	Y	N
1106	UB Non-mentholated	-1	537	1380.1	741.11	NA	NA	1870	287.17	NA	NA	Y	Y
		2	566	1113.7	630.35	-110.76	-14.95	2330	242.92	-44.25	-15.41	Y	Y
		6	288	2435.0	701.28	-39.83	-5.37	968	297.52	10.35	3.61	Y	Y
1107	UB Non-mentholated	-1	186	2365.5	439.98	NA	NA	913	203.72	NA	NA	Y	N
	VLN Non-mentholated	2	121	2512.8	304.05	-135.93	-30.90	854	141.69	-62.04	-30.45	Y	N
		6	104	2599.0	270.30	-169.69	-38.57	806	129.03	-74.69	-36.66	Y	N
1108	UB Non-mentholated	-1	166	1782.0	295.81	NA	NA	1150	144.35	NA	NA	Y	Y

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Appendix 16.2.6.3 Urinary NNAL (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1108	UB Non-mentholated	2	120	2115.4	253.85	-41.96	-14.19	966	124.22	-20.12	-13.94	Y	Y
		6	130	1981.0	257.53	-38.28	-12.94	1030	126.21	-18.13	-12.56	Y	Y
1109	UB Non-mentholated	-1	320	1615.9	517.09	NA	NA	950	336.84	NA	NA	Y	Y
		2	277	1805.0	499.99	-17.10	-3.31	919	301.41	-35.43	-10.52	Y	Y
		6	427	1075.0	459.03	-58.06	-11.23	1490	286.58	-50.26	-14.92	Y	Y
1112	UB Non-mentholated VLN Non-mentholated	-1	221	2265.2	500.61	NA	NA	428	516.36	NA	NA	Y	N
		2	196	1829.3	358.54	-142.07	-28.38	613	319.74	-196.62	-38.08	Y	N
		6	173	2121.0	366.93	-133.68	-26.70	531	325.80	-190.55	-36.90	Y	N
1114	UB Non-mentholated	-1	107	1506.7	161.22	NA	NA	754	141.91	NA	NA	Y	Y
		2	39.5	2909.4	114.92	-46.30	-28.72	403	98.01	-43.89	-30.93	Y	Y
		6	62.8	1920.0	120.58	-40.64	-25.21	661	95.01	-46.90	-33.05	Y	Y
1115	UB Non-mentholated VLN Non-mentholated	-1	190	1785.7	339.28	NA	NA	1590	119.50	NA	NA	Y	Y
		2	60.7	1601.3	97.20	-242.08	-71.35	1770	34.29	-85.20	-71.30	Y	Y
2002	UB Mentholated	-1	204	2188.0	446.35	NA	NA	803	254.05	NA	NA	Y	Y
		2	195	1893.0	369.14	-77.22	-17.30	915	213.11	-40.93	-16.11	Y	Y
		6	145	3245.0	470.53	24.17	5.42	569	254.83	0.79	0.31	Y	Y
2003	UB Mentholated VLN Mentholated	-1	296	3036.0	898.66	NA	NA	342	865.50	NA	NA	Y	N
		2	157	4180.0	656.26	-242.40	-26.97	348	451.15	-414.35	-47.87	Y	N

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					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2003	VLN Mentholated	6	183	3245.0	593.84	-304.82	-33.92	373	490.62	-374.88	-43.31	Y	N
2007	UB Non-mentholated	-1	155	1535.0	237.93	NA	NA	696	222.70	NA	NA	Y	Y
	VLN Non-mentholated	2	106	1492.0	158.15	-79.77	-33.53	725	146.21	-76.49	-34.35	Y	Y
		6	100	1387.0	138.70	-99.23	-41.70	828	120.77	-101.93	-45.77	Y	Y
2008	UB Mentholated	-1	87.4	2663.0	232.75	NA	NA	900	97.11	NA	NA	Y	Y
	VLN Mentholated	2	50.9	3323.0	169.14	-63.61	-27.33	709	71.79	-25.32	-26.07	Y	Y
		6	88.7	1734.0	153.81	-78.94	-33.92	1300	68.23	-28.88	-29.74	Y	Y
2009	UB Non-mentholated	-1	27.8	2427.0	67.47	NA	NA	807	34.45	NA	NA	Y	N
	VLN Non-mentholated	2	55.9	1390.0	77.70	10.23	15.16	1420	39.37	4.92	14.28	Y	N
2010	UB Mentholated	-1	215	1673.0	359.70	NA	NA	1650	130.30	NA	NA	Y	Y
		2	190	1289.0	244.91	-114.79	-31.91	1390	136.69	6.39	4.90	Y	Y
		6	238	1158.0	275.60	-84.09	-23.38	2350	101.28	-29.03	-22.28	Y	Y
2011	UB Mentholated	-1	120	1639.0	196.68	NA	NA	1010	118.81	NA	NA	Y	N
	VLN Mentholated	2	78.0	1510.0	117.78	-78.90	-40.12	1110	70.27	-48.54	-40.86	Y	N
		6	120	1165.0	139.80	-56.88	-28.92	1510	79.47	-39.34	-33.11	Y	N
2014	UB Mentholated	-1	193	3009.0	580.74	NA	NA	738	261.52	NA	NA	Y	N
	VLN Mentholated	2	209	1438.0	300.54	-280.20	-48.25	1410	148.23	-113.29	-43.32	Y	N
		6	156	2776.0	433.06	-147.68	-25.43	718	217.27	-44.25	-16.92	Y	N

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Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2015	UB Mentholated	-1	178	1277.0	227.31	NA	NA	1080	164.81	NA	NA	Y	Y
		2	173	1774.0	306.90	79.60	35.02	800	216.25	51.44	31.21	Y	Y
		6	213	1070.0	227.91	0.60	0.27	1620	131.48	-33.33	-20.22	Y	Y
2016	UB Mentholated	-1	210	1787.0	375.27	NA	NA	642	327.10	NA	NA	Y	Y
2017	UB Mentholated VLN Mentholated	-1	317	1504.0	476.77	NA	NA	1290	245.74	NA	NA	Y	N
		2	104	1864.0	193.86	-282.91	-59.34	1110	93.69	-152.04	-61.87	Y	N
		6	162	1210.0	196.02	-280.75	-58.89	1530	105.88	-139.85	-56.91	Y	N
2018	UB Mentholated	-1	290	1191.0	345.39	NA	NA	1390	208.63	NA	NA	Y	Y
		2	298	1374.0	409.45	64.06	18.55	1120	266.07	57.44	27.53	Y	Y
		6	390	963.0	375.57	30.18	8.74	1620	240.74	32.11	15.39	Y	Y
2020	UB Mentholated VLN Mentholated	-1	227	1117.0	253.56	NA	NA	919	247.01	NA	NA	Y	N
		2	140	1155.0	161.70	-91.86	-36.23	1070	130.84	-116.17	-47.03	Y	N
		6	113	1300.0	146.90	-106.66	-42.06	929	121.64	-125.37	-50.76	Y	N
2021	UB Mentholated VLN Mentholated	-1	289	2086.0	602.85	NA	NA	1120	258.04	NA	NA	Y	Y
		2	117	2606.0	304.90	-297.95	-49.42	909	128.71	-129.32	-50.12	Y	Y
		6	115	2561.0	294.52	-308.34	-51.15	821	140.07	-117.96	-45.72	Y	Y
2023	UB Mentholated VLN Mentholated	-1	279	996.0	277.88	NA	NA	2220	125.68	NA	NA	Y	Y
		2	60.5	1252.0	75.75	-202.14	-72.74	1650	36.67	-89.01	-70.82	Y	Y

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Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2023	VLN Mentholated	6	48.2	999.0	48.15	-229.73	-82.67	2180	22.11	-103.57	-82.41	Y	Y
2024	UB Non-mentholated	-1	354	1112.0	393.65	NA	NA	1690	209.47	NA	NA	Y	Y
2025	UB Non-mentholated	-1	197	2766.0	544.90	NA	NA	674	292.28	NA	NA	Y	Y
		2	263	2484.0	653.29	108.39	19.89	844	311.61	19.33	6.61	Y	Y
		6	234	2746.0	642.56	97.66	17.92	866	270.21	-22.08	-7.55	Y	Y
2028	UB Non-mentholated VLN Non-mentholated	-1	457	1538.0	702.87	NA	NA	1270	359.84	NA	NA	Y	Y
		2	119	1876.0	223.24	-479.62	-68.24	834	142.69	-217.16	-60.35	Y	Y
		6	145	616.0	89.32	-613.55	-87.29	1780	81.46	-278.38	-77.36	Y	Y
2029	UB Mentholated	-1	189	1689.0	319.22	NA	NA	996	189.76	NA	NA	Y	Y
		2	199	1933.0	384.67	65.45	20.50	855	232.75	42.99	22.65	Y	Y
		6	124	2068.0	256.43	-62.79	-19.67	789	157.16	-32.60	-17.18	Y	Y
2039	UB Mentholated VLN Mentholated	-1	194	1765.0	342.41	NA	NA	762	254.59	NA	NA	Y	N
		2	154	1582.0	243.63	-98.78	-28.85	711	216.60	-38.00	-14.92	Y	N
		6	179	718.0	128.52	-213.89	-62.47	898	199.33	-55.26	-21.71	Y	N
2050	UB Mentholated	-1	292	1887.0	551.00	NA	NA	995	293.47	NA	NA	Y	Y
		2	249	1436.0	357.56	-193.44	-35.11	908	274.23	-19.24	-6.56	Y	Y
		6	293	1392.0	407.86	-143.15	-25.98	1300	225.38	-68.08	-23.20	Y	Y
2052	UB Mentholated	-1	201	2094.0	420.89	NA	NA	921	218.24	NA	NA	Y	Y

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Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2052	VLN Mentholated	2	96.9	1611.0	156.11	-264.79	-62.91	1190	81.43	-136.81	-62.69	Y	Y
		6	47.6	2735.0	130.19	-290.71	-69.07	664	71.69	-146.55	-67.15	Y	Y
2057	UB Mentholated	-1	89.9	3085.0	277.34	NA	NA	646	139.16	NA	NA	Y	N
	VLN Mentholated	2	31.6	3805.0	120.24	-157.10	-56.65	552	57.25	-81.92	-58.86	Y	N
		6	53.5	3820.0	204.37	-72.97	-26.31	592	90.37	-48.79	-35.06	Y	N
2058	UB Mentholated	-1	232	1240.0	287.68	NA	NA	1410	164.54	NA	NA	Y	N
	VLN Mentholated	2	78.1	1621.0	126.60	-161.08	-55.99	1000	78.10	-86.44	-52.53	Y	N
		6	46.9	2198.0	103.09	-184.59	-64.17	763	61.47	-103.07	-62.64	Y	N
2059	UB Mentholated	-1	229	1545.0	353.81	NA	NA	780	293.59	NA	NA	Y	Y
		2	231	1452.0	335.41	-18.39	-5.20	785	294.27	0.68	0.23	Y	Y
		6	268	1242.0	332.86	-20.95	-5.92	1100	243.64	-49.95	-17.01	Y	Y
2060	UB Mentholated	-1	545	773.0	421.29	NA	NA	1200	454.17	NA	NA	Y	N
	VLN Mentholated	2	308	684.0	210.67	-210.61	-49.99	1230	250.41	-203.76	-44.86	Y	N
		6	407	1465.0	596.26	174.97	41.53	971	419.16	-35.01	-7.71	Y	N
2064	UB Mentholated	-1	244	3404.0	830.58	NA	NA	450	542.22	NA	NA	Y	N
	VLN Mentholated	2	204	2844.0	580.18	-250.40	-30.15	649	314.33	-227.89	-42.03	Y	N
		6	189	2882.0	544.70	-285.88	-34.42	572	330.42	-211.80	-39.06	Y	N
2066	UB Mentholated	-1	589	1056.0	621.98	NA	NA	1810	325.41	NA	NA	Y	N

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					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2066	VLN Mentholated	2	285	912.0	259.92	-362.06	-58.21	1790	159.22	-166.20	-51.07	Y	N
		6	156	1617.0	252.25	-369.73	-59.44	1110	140.54	-184.87	-56.81	Y	N
2067	UB Non-mentholated	-1	321	2550.0	818.55	NA	NA	643	499.22	NA	NA	Y	N
	VLN Non-mentholated	2	320	1608.0	514.56	-303.99	-37.14	1070	299.07	-200.16	-40.09	Y	N
		6	212	2810.0	595.72	-222.83	-27.22	654	324.16	-175.06	-35.07	Y	N
2075	UB Mentholated	-1	120	3995.0	479.40	NA	NA	551	217.79	NA	NA	Y	Y
2076	UB Mentholated	-1	168	2036.0	342.05	NA	NA	943	178.15	NA	NA	Y	N
	VLN Mentholated	2	95.4	2229.0	212.65	-129.40	-37.83	928	102.80	-75.35	-42.30	Y	N
		6	111	2063.0	228.99	-113.06	-33.05	1030	107.77	-70.39	-39.51	Y	N
2086	UB Non-mentholated	-1	400	779.0	311.60	NA	NA	1640	243.90	NA	NA	Y	N
	VLN Non-mentholated	2	151	1692.0	255.49	-56.11	-18.01	1040	145.19	-98.71	-40.47	Y	N
2088	UB Mentholated	-1	224	3222.0	721.73	NA	NA	480	466.67	NA	NA	Y	N
	VLN Mentholated	2	114	2854.0	325.36	-396.37	-54.92	601	189.68	-276.98	-59.35	Y	N
		6	120	2370.0	284.40	-437.33	-60.59	680	176.47	-290.20	-62.18	Y	N
2092	UB Mentholated	-1	41.0	2002.0	82.08	NA	NA	445	92.13	NA	NA	Y	N
	VLN Mentholated	2	12.8	1940.0	24.83	-57.25	-69.75	457	28.01	-64.13	-69.60	Y	N
		6	BLQ<(5.00	2262.0	5.66	-76.43	-93.11	391	6.39	-85.74	-93.06	Y	N
2099	UB Non-mentholated	-1	349	1107.0	386.34	NA	NA	1350	258.52	NA	NA	Y	N

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Appendix 16.2.6.3 Urinary NNAL (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2099	VLN Non-mentholated	2	142	1523.0	216.27	-170.08	-44.02	968	146.69	-111.82	-43.26	Y	N
		6	247	1051.0	259.60	-126.75	-32.81	1430	172.73	-85.79	-33.19	Y	N
2100	UB Mentholated	-1	1190	577.0	686.63	NA	NA	2130	558.69	NA	NA	Y	Y
		2	749	1028.0	769.97	83.34	12.14	1200	624.17	65.48	11.72	Y	Y
		6	1310	550.0	720.50	33.87	4.93	2170	603.69	45.00	8.05	Y	Y
2108	UB Non-mentholated VLN Non-mentholated	-1	204	2860.0	583.44	NA	NA	286	713.29	NA	NA	Y	N
		2	110	3150.0	346.50	-236.94	-40.61	255	431.37	-281.91	-39.52	Y	N
		6	146	3399.0	496.25	-87.19	-14.94	252	579.37	-133.92	-18.78	Y	N
2110	UB Mentholated	-1	288	1034.0	297.79	NA	NA	818	352.08	NA	NA	Y	Y
		2	280	799.0	223.72	-74.07	-24.87	1050	266.67	-85.41	-24.26	Y	Y
		6	378	653.0	246.83	-50.96	-17.11	1190	317.65	-34.43	-9.78	Y	Y
2113	UB Mentholated VLN Mentholated	-1	258	843.0	217.49	NA	NA	1120	230.36	NA	NA	Y	Y
		2	88.5	878.0	77.70	-139.79	-64.27	910	97.25	-133.10	-57.78	Y	Y
2115	UB Mentholated	-1	301	1626.0	489.43	NA	NA	906	332.23	NA	NA	Y	Y
2119	UB Mentholated VLN Mentholated	-1	723	650.0	469.95	NA	NA	2390	302.51	NA	NA	Y	Y
		2	315	786.0	247.59	-222.36	-47.32	1910	164.92	-137.59	-45.48	Y	Y
		6	234	902.0	211.07	-258.88	-55.09	1590	147.17	-155.34	-51.35	Y	Y
2120	UB Non-mentholated	-1	308	1243.0	382.84	NA	NA	634	485.80	NA	NA	Y	Y

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VLN mentholated = Mentholated VLN cigarettes

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Appendix 16.2.6.3 Urinary NNAL (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2120	VLN Non-mentholated	2	101	1147.0	115.85	-267.00	-69.74	646	156.35	-329.46	-67.82	Y	Y
		6	60.5	1735.0	104.97	-277.88	-72.58	488	123.98	-361.83	-74.48	Y	Y
2122	UB Non-mentholated	-1	457	1396.0	637.97	NA	NA	1050	435.24	NA	NA	Y	Y
		2	417	1487.0	620.08	-17.89	-2.80	1010	412.87	-22.37	-5.14	Y	Y
		6	360	1643.0	591.48	-46.49	-7.29	954	377.36	-57.88	-13.30	Y	Y
2125	UB Mentholated	-1	251	1819.0	456.57	NA	NA	1600	156.88	NA	NA	Y	Y
		2	131	3746.0	490.73	34.16	7.48	755	173.51	16.63	10.60	Y	Y
		6	213	3110.0	662.43	205.86	45.09	960	221.88	65.00	41.43	Y	Y
2126	UB Mentholated VLN Mentholated	-1	330	1339.0	441.87	NA	NA	1200	275.00	NA	NA	Y	N
		2	184	1234.0	227.06	-214.81	-48.61	1110	165.77	-109.23	-39.72	Y	N
		6	234	1047.0	245.00	-196.87	-44.55	1510	154.97	-120.03	-43.65	Y	N
2136	UB Non-mentholated VLN Non-mentholated	-1	182	2199.0	400.22	NA	NA	803	226.65	NA	NA	Y	N
		2	226	1100.0	248.60	-151.62	-37.88	1490	151.68	-74.97	-33.08	Y	N
2140	UB Non-mentholated	-1	206	800.0	164.80	NA	NA	1470	140.14	NA	NA	Y	Y
		2	184	763.0	140.39	-24.41	-14.81	1610	114.29	-25.85	-18.45	Y	Y
		6	151	939.0	141.79	-23.01	-13.96	1250	120.80	-19.34	-13.80	Y	Y
2142	UB Non-mentholated	-1	252	2406.0	606.31	NA	NA	500	504.00	NA	NA	Y	Y
2143	UB Non-mentholated	-1	292	2510.0	732.92	NA	NA	595	490.76	NA	NA	Y	Y

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Appendix 16.2.6.3 Urinary NNAL (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2143	VLN Non-mentholated	2	137	2050.0	280.85	-452.07	-61.68	756	181.22	-309.54	-63.07	Y	Y
		6	94.6	2221.0	210.11	-522.81	-71.33	729	129.77	-360.99	-73.56	Y	Y
2158	UB Non-mentholated	-1	263	1684.0	442.89	NA	NA	843	311.98	NA	NA	Y	Y
		2	261	1211.0	316.07	-126.82	-28.63	1160	225.00	-86.98	-27.88	Y	Y
2159	UB Non-mentholated VLN Non-mentholated	-1	631	1506.0	950.29	NA	NA	795	793.71	NA	NA	Y	N
		2	668	1042.0	696.06	-254.23	-26.75	1100	607.27	-186.44	-23.49	Y	N
		6	586	1311.0	768.25	-182.04	-19.16	1050	558.10	-235.62	-29.69	Y	N
2164	UB Non-mentholated VLN Non-mentholated	-1	217	2448.0	531.22	NA	NA	520	417.31	NA	NA	Y	Y
		2	79.1	2822.0	223.22	-308.00	-57.98	464	170.47	-246.83	-59.15	Y	Y
		6	76.2	2302.0	175.41	-355.80	-66.98	568	134.15	-283.15	-67.85	Y	Y
2168	UB Non-mentholated VLN Non-mentholated	-1	793	1464.0	1160.95	NA	NA	459	1727.67	NA	NA	Y	N
		2	424	1163.0	493.11	-667.84	-57.53	528	803.03	-924.64	-53.52	Y	N
		6	454	216.0	.	.	.	427	1063.23	-664.44	-38.46	N	N
2170	UB Non-mentholated	-1	488	929.0	453.35	NA	NA	1190	410.08	NA	NA	Y	Y
		2	527	1105.0	582.34	128.98	28.45	1090	483.49	73.40	17.90	Y	Y
		6	725	1005.0	.	.	.	1550	467.74	57.66	14.06	N	N
2175	UB Mentholated	-1	342	1724.0	589.61	NA	NA	736	464.67	NA	NA	Y	Y
		2	325	1687.0	548.28	-41.33	-7.01	776	418.81	-45.86	-9.87	Y	Y

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Appendix 16.2.6.3 Urinary NNAL (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2175	UB Mentholated	6	388	1431.0	555.23	-34.38	-5.83	916	423.58	-41.09	-8.84	Y	Y
2189	UB Mentholated	-1	99.6	2385.0	237.55	NA	NA	806	123.57	NA	NA	Y	Y
2211	UB Mentholated VLN Mentholated	-1	112	2088.0	233.86	NA	NA	517	216.63	NA	NA	Y	N
		2	73.5	1946.0	143.03	-90.83	-38.84	591	124.37	-92.27	-42.59	Y	N
		6	112	297.0	33.26	-200.59	-85.78	685	163.50	-53.13	-24.53	Y	N
2212	UB Mentholated	-1	336	1397.0	469.39	NA	NA	1470	228.57	NA	NA	Y	Y
		2	263	1514.0	398.18	-71.21	-15.17	1400	187.86	-40.71	-17.81	Y	Y
		6	320	1016.0	325.12	-144.27	-30.74	2070	154.59	-73.98	-32.37	Y	Y
2213	UB Mentholated VLN Mentholated	-1	205	2513.0	515.17	NA	NA	930	220.43	NA	NA	Y	N
		2	88.1	2301.0	202.72	-312.45	-60.65	969	90.92	-129.51	-58.75	Y	N
		6	155	1689.0	261.80	-253.37	-49.18	1350	114.81	-105.62	-47.91	Y	N
2215	UB Mentholated	-1	270	1494.0	403.38	NA	NA	753	358.57	NA	NA	Y	Y
		2	287	1644.0	471.83	68.45	16.97	669	429.00	70.43	19.64	Y	Y
		6	349	1321.0	461.03	57.65	14.29	846	412.53	53.96	15.05	Y	Y
2220	UB Non-mentholated VLN Non-mentholated	-1	441	547.0	241.23	NA	NA	3260	135.28	NA	NA	Y	N
		2	212	1054.0	223.45	-17.78	-7.37	2100	100.95	-34.32	-25.37	Y	N
		6	314	900.0	282.60	41.37	17.15	2470	127.13	-8.15	-6.03	Y	N
2235	UB Mentholated	-1	296	1046.0	309.62	NA	NA	2100	140.95	NA	NA	Y	N

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Appendix 16.2.6.3 Urinary NNAL (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2235	VLN Mentholated	2	155	1129.0	175.00	-134.62	-43.48	2020	76.73	-64.22	-45.56	Y	N
		6	252	448.0	112.90	-196.72	-63.54	2030	124.14	-16.81	-11.93	Y	N
2244	UB Non-mentholated	-1	244	1370.0	334.28	NA	NA	1230	198.37	NA	NA	Y	N
	VLN Non-mentholated	2	337	1012.0	341.04	6.76	2.02	1940	173.71	-24.66	-12.43	Y	N
		6	370	926.0	342.62	8.34	2.49	1870	197.86	-0.51	-0.26	Y	N
2247	UB Mentholated	-1	259	1591.0	412.07	NA	NA	1430	181.12	NA	NA	Y	Y
	VLN Mentholated	2	120	1612.0	193.44	-218.63	-53.06	1270	94.49	-86.63	-47.83	Y	Y
2251	UB Non-mentholated	-1	325	1872.0	608.40	NA	NA	1050	309.52	NA	NA	Y	Y
		2	336	1851.0	621.94	13.54	2.22	1140	294.74	-14.79	-4.78	Y	Y
		6	569	1192.0	678.25	69.85	11.48	1870	304.28	-5.25	-1.69	Y	Y
2257	UB Non-mentholated	-1	140	2851.0	399.14	NA	NA	393	356.23	NA	NA	Y	Y
		2	185	1989.0	367.97	-31.18	-7.81	497	372.23	16.00	4.49	Y	Y
		6	163	1988.0	324.04	-75.10	-18.81	427	381.73	25.50	7.16	Y	Y
2259	UB Mentholated	-1	335	1236.0	414.06	NA	NA	2220	150.90	NA	NA	Y	Y
		2	393	1039.0	408.33	-5.73	-1.38	2440	161.07	10.16	6.74	Y	Y
		6	442	999.0	441.56	27.50	6.64	2520	175.40	24.50	16.23	Y	Y
2269	UB Mentholated	-1	225	1468.0	330.30	NA	NA	1540	146.10	NA	NA	Y	N
	VLN Mentholated	2	32.0	353.0	11.30	-319.00	-96.58	1120	28.57	-117.53	-80.44	Y	N

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Appendix 16.2.6.3 Urinary NNAL (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2269	VLN Mentholated	6	29.3	845.0	24.76	-305.54	-92.50	627	46.73	-99.37	-68.02	Y	N
2272	UB Mentholated	-1	230	889.0	204.47	NA	NA	2370	97.05	NA	NA	Y	N
	VLN Mentholated	2	74.4	1818.0	135.26	-69.21	-33.85	1070	69.53	-27.51	-28.35	Y	N
		6	107	1589.0	170.02	-34.45	-16.85	1290	82.95	-14.10	-14.53	Y	N

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1001	UB Non-mentholated	-1	8.25	2171.0	17.91	NA	NA	499	16.53	NA	NA	Y	N
	VLN Non-mentholated	2	4.43	1172.6	5.19	-12.72	-71.00	804	5.51	-11.02	-66.67	Y	N
		6	3.99	1249.1	4.98	-12.93	-72.17	843	4.73	-11.80	-71.37	Y	N
1002	UB Non-mentholated	-1	5.63	4356.5	24.53	NA	NA	424	13.28	NA	NA	Y	N
	VLN Non-mentholated	2	8.94	4062.7	36.32	11.79	48.08	414	21.59	8.32	62.63	Y	N
		6	5.52	5759.6	31.79	7.27	29.62	333	16.58	3.30	24.84	Y	N
1003	UB Mentholated	-1	7.43	1385.0	10.29	NA	NA	1770	4.20	NA	NA	Y	N
	VLN Mentholated	2	9.24	410.0	3.79	-6.50	-63.19	2280	4.05	-0.15	-3.46	Y	N
		6	8.29	1017.7	8.44	-1.85	-18.01	2250	3.68	-0.51	-12.23	Y	N
1007	UB Non-mentholated	-1	4.89	1935.0	9.46	NA	NA	890	5.49	NA	NA	Y	Y
	VLN Non-mentholated	2	3.78	2199.9	8.32	-1.15	-12.12	947	3.99	-1.50	-27.35	Y	Y
		6	6.56	1700.3	11.15	1.69	17.88	1330	4.93	-0.56	-10.23	Y	Y
1008	UB Mentholated	-1	2.97	2014.0	5.98	NA	NA	1120	2.65	NA	NA	Y	N
	VLN Mentholated	2	3.85	1435.9	5.53	-0.45	-7.58	1550	2.48	-0.17	-6.33	Y	N
		6	2.56	1122.0	2.87	-3.11	-51.98	701	3.65	1.00	37.72	N	N
1010	UB Mentholated	-1	11.7	2030.0	23.75	NA	NA	941	12.43	NA	NA	Y	Y
		2	10.9	1539.6	16.78	-6.97	-29.34	1120	9.73	-2.70	-21.73	Y	Y
		6	6.16	1036.8	6.39	-17.36	-73.11	741	8.31	-4.12	-33.14	N	N

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1011	UB Non-mentholated	-1	14.3	1059.0	15.14	NA	NA	2360	6.06	NA	NA	Y	Y
		2	12.0	1364.0	16.37	1.22	8.08	1590	7.55	1.49	24.55	Y	Y
		6	12.8	628.7	8.05	-7.10	-46.86	1060	12.08	6.02	99.29	N	N
1013	UB Non-mentholated VLN Non-mentholated	-1	9.67	1664.0	16.09	NA	NA	1060	9.12	NA	NA	Y	N
		2	7.39	1043.8	.	.	.	1450	5.10	-4.03	-44.13	N	N
		6	10.6	874.0	9.26	-6.83	-42.42	1970	5.38	-3.74	-41.02	Y	N
1014	UB Mentholated VLN Mentholated	-1	21.0	2069.0	43.45	NA	NA	476	44.12	NA	NA	Y	N
		6	18.1	903.2	16.35	-27.10	-62.37	1330	13.61	-30.51	-69.15	Y	N
1015	UB Mentholated VLN Mentholated	-1	2.29	3550.0	8.13	NA	NA	371	6.17	NA	NA	Y	Y
		2	1.59	3406.2	5.42	-2.71	-33.38	373	4.26	-1.91	-30.94	Y	Y
		6	1.18	3477.7	4.10	-4.03	-49.52	392	3.01	-3.16	-51.23	Y	Y
1016	UB Non-mentholated	-1	12.5	1853.0	23.16	NA	NA	873	14.32	NA	NA	Y	Y
		2	11.6	2839.1	32.93	9.77	42.18	528	21.97	7.65	53.44	Y	Y
		6	11.2	1899.3	21.27	-1.89	-8.16	908	12.33	-1.98	-13.85	Y	Y
1017	UB Mentholated	-1	15.4	2490.0	38.35	NA	NA	507	30.37	NA	NA	Y	Y
		2	14.2	2593.9	36.83	-1.51	-3.94	529	26.84	-3.53	-11.63	Y	Y
		6	13.8	1399.2	19.31	-19.04	-49.65	920	15.00	-15.37	-50.62	Y	Y
1018	UB Mentholated	-1	8.51	1721.0	14.65	NA	NA	672	12.66	NA	NA	Y	Y

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1019	UB Non-mentholated	-1	6.94	1431.0	9.93	NA	NA	1750	3.97	NA	NA	Y	N
	VLN Non-mentholated	2	3.55	3109.0	11.04	1.11	11.13	762	4.66	0.69	17.48	Y	N
		6	6.22	2290.1	14.24	4.31	43.43	1110	5.60	1.64	41.30	Y	N
1020	UB Non-mentholated	-1	14.2	1666.0	23.66	NA	NA	773	18.37	NA	NA	Y	N
	VLN Non-mentholated	2	13.3	1240.9	16.50	-7.15	-30.24	1430	9.30	-9.07	-49.37	Y	N
		6	6.43	917.7	5.90	-17.76	-75.06	1280	5.02	-13.35	-72.65	Y	N
1021	UB Non-mentholated	-1	4.12	1808.0	7.45	NA	NA	681	6.05	NA	NA	N	N
		2	5.64	1842.4	10.39	.	.	710	7.94	.	.	Y	Y
		6	5.58	2136.5	11.92	.	.	637	8.76	.	.	Y	Y
1023	UB Non-mentholated	-1	4.36	2894.0	12.62	NA	NA	367	11.88	NA	NA	Y	N
	VLN Non-mentholated	2	1.53	3795.5	5.81	-6.81	-53.98	274	5.58	-6.30	-53.00	Y	N
		6	2.84	3600.0	10.22	-2.39	-18.97	334	8.50	-3.38	-28.43	Y	N
1029	UB Mentholated	-1	5.00	2525.2	12.63	NA	NA	554	9.03	NA	NA	Y	N
	VLN Mentholated	2	1.28	3098.0	3.97	-8.66	-68.59	505	2.53	-6.49	-71.92	Y	N
		6	2.32	2192.0	5.09	-7.54	-59.72	753	3.08	-5.94	-65.86	Y	N
1032	UB Mentholated	-1	6.03	3793.8	22.88	NA	NA	319	18.90	NA	NA	Y	Y
	VLN Mentholated	2	5.13	3479.0	17.85	-5.03	-21.98	411	12.48	-6.42	-33.97	Y	Y
		6	4.24	2345.0	9.94	-12.93	-56.54	602	7.04	-11.86	-62.74	Y	Y

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1034	UB Non-mentholated	-1	16.9	1275.1	21.55	NA	NA	1080	15.65	NA	NA	Y	N
	VLN Non-mentholated	2	11.3	969.0	10.95	-10.60	-49.19	1210	9.34	-6.31	-40.32	Y	N
		6	15.5	1037.0	16.07	-5.48	-25.41	1550	10.00	-5.65	-36.09	Y	N
1035	UB Non-mentholated	-1	14.6	2182.4	31.86	NA	NA	1180	12.37	NA	NA	Y	N
	VLN Non-mentholated	2	13.5	2196.0	29.65	-2.22	-6.96	726	18.60	6.22	50.29	Y	N
		6	26.3	1204.0	31.67	-0.20	-0.62	1400	18.79	6.41	51.83	Y	N
1036	UB Mentholated	-1	3.40	1896.8	6.45	NA	NA	761	4.47	NA	NA	Y	Y
		2	3.04	1841.0	5.60	-0.85	-13.22	793	3.83	-0.63	-14.20	Y	Y
		6	3.37	1475.0	4.97	-1.48	-22.92	1110	3.04	-1.43	-32.05	Y	Y
1037	UB Mentholated	-1	5.15	5986.4	30.83	NA	NA	350	14.71	NA	NA	Y	Y
		2	6.39	2822.0	18.03	-12.80	-41.51	698	9.15	-5.56	-37.78	Y	Y
		6	6.54	2712.0	17.74	-13.09	-42.47	651	10.05	-4.67	-31.73	Y	Y
1038	UB Non-mentholated	-1	6.22	1610.1	10.01	NA	NA	802	7.76	NA	NA	Y	N
	VLN Non-mentholated	2	1.95	1705.0	3.32	-6.69	-66.80	830	2.35	-5.41	-69.71	Y	N
		6	3.16	1641.0	5.19	-4.83	-48.22	894	3.53	-4.22	-54.42	Y	N
1042	UB Non-mentholated	-1	4.80	5646.2	27.10	NA	NA	353	13.60	NA	NA	Y	N
	VLN Non-mentholated	2	2.24	3586.0	8.03	-19.07	-70.36	380	5.89	-7.70	-56.65	Y	N
		6	0.831	2769.0	2.30	-24.80	-91.51	429	1.94	-11.66	-85.75	Y	N

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1045	UB Non-mentholated	-1	36.2	3025.5	109.52	NA	NA	613	59.05	NA	NA	Y	Y
		2	39.7	2443.0	96.99	-12.54	-11.45	654	60.70	1.65	2.79	Y	Y
		6	49.2	1894.0	93.18	-16.34	-14.92	921	53.42	-5.63	-9.54	Y	Y
1046	UB Mentholated	-1	3.40	3780.8	12.85	NA	NA	570	5.96	NA	NA	Y	Y
		2	4.61	2832.0	13.06	0.20	1.56	670	6.88	0.92	15.35	Y	Y
		6	4.42	2830.0	12.51	-0.35	-2.69	806	5.48	-0.48	-8.06	Y	Y
1050	UB Non-mentholated VLN Non-mentholated	-1	7.93	1520.3	12.06	NA	NA	781	10.15	NA	NA	Y	N
		2	4.65	3144.1	14.62	2.56	21.27	472	9.85	-0.30	-2.97	Y	N
		6	3.91	1578.0	6.17	-5.89	-48.82	825	4.74	-5.41	-53.32	Y	N
1051	UB Mentholated	-1	7.23	2216.8	16.03	NA	NA	762	9.49	NA	NA	Y	Y
		2	7.20	2040.0	14.69	-1.34	-8.36	789	9.13	-0.36	-3.82	Y	Y
		6	5.85	1784.0	10.44	-5.59	-34.88	1050	5.57	-3.92	-41.28	Y	Y
1052	UB Mentholated VLN Mentholated	-1	3.39	1539.8	5.22	NA	NA	1300	2.61	NA	NA	Y	N
		2	2.67	1602.0	4.28	-0.94	-18.06	1130	2.36	-0.24	-9.39	Y	N
		6	3.65	1065.0	3.89	-1.33	-25.53	1850	1.97	-0.63	-24.34	Y	N
1053	UB Mentholated VLN Mentholated	-1	7.06	2902.3	20.49	NA	NA	795	8.88	NA	NA	Y	N
		2	3.38	2790.0	9.43	-11.06	-53.98	933	3.62	-5.26	-59.21	Y	N
		6	3.04	2523.0	7.67	-12.82	-62.57	914	3.33	-5.55	-62.55	Y	N

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1054	UB Non-mentholated	-1	23.6	956.9	22.58	NA	NA	2550	9.25	NA	NA	Y	Y
		2	16.1	1844.0	29.69	7.11	31.46	1180	13.64	4.39	47.43	Y	Y
		6	14.8	1089.0	16.12	-6.47	-28.63	2130	6.95	-2.31	-24.92	Y	Y
1055	UB Mentholated VLN Mentholated	-1	7.95	3328.9	26.46	NA	NA	451	17.63	NA	NA	Y	N
		2	5.98	3391.6	20.28	-6.18	-23.36	495	12.08	-5.55	-31.47	Y	N
		6	4.83	1581.0	7.64	-18.83	-71.15	955	5.06	-12.57	-71.31	Y	N
1056	UB Non-mentholated VLN Non-mentholated	-1	6.57	3925.2	25.79	NA	NA	416	15.79	NA	NA	Y	N
		2	5.94	1334.0	7.92	-17.86	-69.27	799	7.43	-8.36	-52.93	Y	N
		6	5.15	1152.0	5.93	-19.86	-76.99	785	6.56	-9.23	-58.46	Y	N
1058	UB Non-mentholated VLN Non-mentholated	-1	6.30	3355.1	21.14	NA	NA	518	12.16	NA	NA	Y	N
		2	2.42	2869.0	6.94	-14.19	-67.15	520	4.65	-7.51	-61.74	Y	N
		6	6.11	1927.0	11.77	-9.36	-44.30	1190	5.13	-7.03	-57.78	Y	N
1059	UB Non-mentholated	-1	76.2	956.0	72.85	NA	NA	2300	33.13	NA	NA	Y	Y
		2	27.3	2124.7	58.00	-14.84	-20.38	1040	26.25	-6.88	-20.77	Y	Y
		6	54.9	1507.0	82.73	9.89	13.57	1750	31.37	-1.76	-5.31	Y	Y
1060	UB Mentholated VLN Mentholated	-1	10.5	2414.0	25.35	NA	NA	751	13.98	NA	NA	Y	N
		2	5.32	2361.4	12.56	-12.78	-50.44	782	6.80	-7.18	-51.34	Y	N
		6	6.62	1742.0	11.53	-13.81	-54.50	950	6.97	-7.01	-50.16	Y	N

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1063	UB Mentholated	-1	2.59	7095.2	18.38	NA	NA	306	8.46	NA	NA	Y	Y
	VLN Mentholated	2	2.07	3891.4	8.06	-10.32	-56.17	569	3.64	-4.83	-57.02	Y	Y
		6	1.10	3208.0	3.53	-14.85	-80.80	787	1.40	-7.07	-83.49	Y	Y
1064	UB Non-mentholated	-1	4.50	3268.0	14.71	NA	NA	749	6.01	NA	NA	Y	Y
		2	6.64	2273.1	15.09	0.39	2.63	1060	6.26	0.26	4.26	Y	Y
1066	UB Non-mentholated	-1	45.0	967.0	43.52	NA	NA	2190	20.55	NA	NA	Y	Y
	VLN Non-mentholated	2	22.2	1744.8	38.73	-4.78	-10.99	1050	21.14	0.59	2.90	Y	Y
		6	12.7	1725.0	21.91	-21.61	-49.66	1220	10.41	-10.14	-49.34	Y	Y
1069	UB Non-mentholated	-1	11.3	2554.0	28.86	NA	NA	793	14.25	NA	NA	Y	Y
		2	10.9	2465.9	26.88	-1.98	-6.87	783	13.92	-0.33	-2.31	Y	Y
		6	14.2	2162.0	30.70	1.84	6.38	973	14.59	0.34	2.42	Y	Y
1070	UB Non-mentholated	-1	16.0	3393.0	54.29	NA	NA	633	25.28	NA	NA	Y	Y
	VLN Non-mentholated	2	6.42	2687.1	17.25	-37.04	-68.22	752	8.54	-16.74	-66.22	Y	Y
		6	9.09	1316.0	11.96	-42.33	-77.96	1800	5.05	-20.23	-80.02	Y	Y
1071	UB Non-mentholated	-1	3.01	2129.0	6.41	NA	NA	700	4.30	NA	NA	Y	N
	VLN Non-mentholated	2	2.05	2212.3	4.54	-1.87	-29.23	1230	1.67	-2.63	-61.24	Y	N
1072	UB Mentholated	-1	3.82	2181.0	8.33	NA	NA	806	4.74	NA	NA	Y	Y
	VLN Mentholated	2	4.66	1779.7	8.29	-0.04	-0.46	955	4.88	0.14	2.96	Y	Y

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1074	UB Non-mentholated	-1	3.40	2211.0	7.52	NA	NA	876	3.88	NA	NA	Y	N
	VLN Non-mentholated	2	2.76	1464.3	4.04	-3.48	-46.24	1350	2.04	-1.84	-47.33	Y	N
		6	1.56	1677.0	2.62	-4.90	-65.20	1310	1.19	-2.69	-69.32	Y	N
1075	UB Non-mentholated	-1	4.41	2163.0	9.54	NA	NA	773	5.71	NA	NA	Y	Y
		2	5.92	1890.7	11.19	1.65	17.34	845	7.01	1.30	22.80	Y	Y
		6	7.43	1263.0	9.38	-0.15	-1.62	1340	5.54	-0.16	-2.81	Y	Y
1077	UB Non-mentholated	-1	7.70	3102.1	23.89	NA	NA	493	15.62	NA	NA	Y	Y
	VLN Non-mentholated	2	10.0	3008.3	30.08	6.20	25.94	596	16.78	1.16	7.43	Y	Y
		6	7.55	2743.0	20.71	-3.18	-13.30	693	10.89	-4.72	-30.25	Y	Y
1078	UB Non-mentholated	-1	7.96	1991.0	15.85	NA	NA	597	13.33	NA	NA	Y	N
	VLN Non-mentholated	2	4.54	3513.1	15.95	0.10	0.64	352	12.90	-0.44	-3.27	Y	N
		6	3.94	2384.0	9.39	-6.46	-40.73	654	6.02	-7.31	-54.82	Y	N
1079	UB Mentholated	-1	6.39	2154.0	13.76	NA	NA	1370	4.66	NA	NA	Y	Y
	VLN Mentholated	2	1.45	3647.6	5.29	-8.48	-61.57	802	1.81	-2.86	-61.24	Y	Y
		6	0.859	2605.0	2.24	-11.53	-83.74	1040	0.83	-3.84	-82.29	Y	Y
1082	UB Non-mentholated	-1	12.9	2790.0	35.99	NA	NA	843	15.30	NA	NA	Y	N
	VLN Non-mentholated	2	7.35	2629.9	19.33	-16.66	-46.29	926	7.94	-7.37	-48.13	Y	N
		6	11.1	2013.0	22.34	-13.65	-37.92	1200	9.25	-6.05	-39.55	Y	N

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1083	UB Non-mentholated	-1	20.1	1708.0	34.33	NA	NA	762	26.38	NA	NA	Y	N
	VLN Non-mentholated	2	15.4	1788.0	27.54	-6.80	-19.79	892	17.26	-9.11	-34.55	Y	N
		6	15.2	2017.0	30.66	-3.67	-10.70	804	18.91	-7.47	-28.33	Y	N
1084	UB Non-mentholated	-1	7.24	1467.0	10.62	NA	NA	1380	5.25	NA	NA	Y	N
	VLN Non-mentholated	2	6.16	1158.4	7.14	-3.49	-32.82	1630	3.78	-1.47	-27.97	Y	N
1086	UB Non-mentholated	-1	12.1	1938.0	23.45	NA	NA	968	12.50	NA	NA	Y	N
	VLN Non-mentholated	2	13.5	1255.9	16.95	-6.50	-27.70	1410	9.57	-2.93	-23.40	Y	N
		6	10.2	1580.0	16.12	-7.33	-31.27	1040	9.81	-2.69	-21.54	Y	N
1088	UB Mentholated	-1	9.13	1662.0	15.17	NA	NA	1670	5.47	NA	NA	Y	N
	VLN Mentholated	2	3.92	1236.2	4.85	-10.33	-68.06	1820	2.15	-3.31	-60.60	Y	N
		6	5.82	1670.0	9.72	-5.45	-35.95	1520	3.83	-1.64	-29.96	Y	N
1089	UB Non-mentholated	-1	5.50	1795.0	9.87	NA	NA	669	8.22	NA	NA	Y	Y
		2	3.29	2415.3	7.95	-1.93	-19.51	544	6.05	-2.17	-26.44	Y	Y
		6	3.68	2062.0	7.59	-2.28	-23.14	559	6.58	-1.64	-19.92	Y	Y
1092	UB Mentholated	-1	4.32	2383.0	10.29	NA	NA	734	5.89	NA	NA	Y	N
	VLN Mentholated	2	5.25	1551.7	8.15	-2.15	-20.87	898	5.85	-0.04	-0.67	Y	N
		6	3.27	1587.0	5.19	-5.11	-49.59	1150	2.84	-3.04	-51.69	Y	N
1094	UB Mentholated	-1	11.6	1930.0	22.39	NA	NA	1230	9.43	NA	NA	Y	N

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

CFB = Change from Baseline, PCFB = Percent change from baseline, Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1094	VLN Mentholated	2	14.0	1307.6	18.31	-4.08	-18.23	1720	8.14	-1.29	-13.69	Y	N
		6	8.54	1040.0	8.88	-13.51	-60.33	1930	4.42	-5.01	-53.08	Y	N
1095	UB Mentholated	-1	3.53	2551.0	9.01	NA	NA	514	6.87	NA	NA	Y	N
	VLN Mentholated	2	14.4	430.3	6.20	-2.81	-31.19	982	14.66	7.80	113.52	N	N
		6	4.52	2131.0	9.63	0.63	6.96	390	11.59	4.72	68.76	Y	N
1096	UB Non-mentholated	-1	7.47	2532.0	18.91	NA	NA	634	11.78	NA	NA	Y	N
	VLN Non-mentholated	2	5.78	1934.5	11.18	-7.73	-40.88	679	8.51	-3.27	-27.75	Y	N
		6	6.12	2949.0	18.05	-0.87	-4.58	488	12.54	0.76	6.44	Y	N
1097	UB Mentholated	-1	2.87	1982.0	5.69	NA	NA	1250	2.30	NA	NA	Y	N
	VLN Mentholated	2	0.857	1598.3	1.37	-4.32	-75.92	1510	0.57	-1.73	-75.28	Y	N
		6	0.444	1814.0	0.81	-4.88	-85.84	1270	0.35	-1.95	-84.77	Y	N
1098	UB Non-mentholated	-1	53.8	1415.8	76.17	NA	NA	1060	50.75	NA	NA	Y	Y
	VLN Non-mentholated	2	17.3	1666.1	28.82	-47.35	-62.16	958	18.06	-32.70	-64.42	Y	Y
		6	13.2	1811.0	23.91	-52.26	-68.62	895	14.75	-36.01	-70.94	Y	Y
1099	UB Non-mentholated	-1	11.2	810.2	.	NA	NA	1420	7.89	NA	NA	N	N
	VLN Non-mentholated	2	5.63	1272.2	7.16	.	.	1060	5.31	.	.	Y	N
		6	6.92	1005.0	6.95	.	.	1250	5.54	.	.	Y	N
1100	UB Non-mentholated	-1	8.48	3350.7	28.41	NA	NA	550	15.42	NA	NA	Y	N

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1100	VLN Non-mentholated	2	7.35	2653.5	19.50	-8.91	-31.36	684	10.75	-4.67	-30.31	Y	N
		6	6.88	2576.0	17.72	-10.69	-37.63	772	8.91	-6.51	-42.20	Y	N
1101	UB Non-mentholated	-1	7.53	1814.1	13.66	NA	NA	827	9.11	NA	NA	Y	N
	VLN Non-mentholated	2	4.97	2317.4	11.52	-2.14	-15.69	805	6.17	-2.93	-32.19	Y	N
		6	6.25	3707.0	23.17	9.51	69.61	258	24.22	15.12	166.05	Y	N
1103	UB Non-mentholated	-1	5.92	3479.4	20.60	NA	NA	297	19.93	NA	NA	Y	N
	VLN Non-mentholated	2	6.55	2449.2	16.04	-4.56	-22.12	762	8.60	-11.34	-56.88	Y	N
		6	14.4	2601.0	37.45	16.86	81.83	763	18.87	-1.06	-5.32	Y	N
1105	UB Non-mentholated	-1	8.11	527.3	4.28	NA	NA	1680	4.83	NA	NA	Y	N
	VLN Non-mentholated	2	7.66	825.2	6.32	2.04	47.81	1010	7.58	2.76	57.11	Y	N
		6	8.24	677.0	5.58	1.30	30.45	1420	5.80	0.98	20.21	Y	N
1106	UB Non-mentholated	-1	6.37	1380.1	8.79	NA	NA	1870	3.41	NA	NA	Y	Y
		2	7.69	1113.7	8.56	-0.23	-2.58	2330	3.30	-0.11	-3.11	Y	Y
		6	5.10	2435.0	12.42	3.63	41.26	968	5.27	1.86	54.67	Y	Y
1107	UB Non-mentholated	-1	4.79	2365.5	11.33	NA	NA	913	5.25	NA	NA	Y	N
	VLN Non-mentholated	2	4.53	2512.8	11.38	0.05	0.46	854	5.30	0.06	1.11	Y	N
		6	3.02	2599.0	7.85	-3.48	-30.73	806	3.75	-1.50	-28.58	Y	N
1108	UB Non-mentholated	-1	6.95	1782.0	12.38	NA	NA	1150	6.04	NA	NA	Y	Y

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1108	UB Non-mentholated	2	8.40	2115.4	17.77	5.38	43.48	966	8.70	2.65	43.88	Y	Y
		6	7.94	1981.0	15.73	3.34	27.00	1030	7.71	1.67	27.55	Y	Y
1109	UB Non-mentholated	-1	13.5	1615.9	21.81	NA	NA	950	14.21	NA	NA	Y	Y
		2	9.94	1805.0	17.94	-3.87	-17.75	919	10.82	-3.39	-23.89	Y	Y
		6	13.8	1075.0	14.84	-6.98	-32.00	1490	9.26	-4.95	-34.82	Y	Y
1112	UB Non-mentholated VLN Non-mentholated	-1	6.54	2265.2	14.81	NA	NA	428	15.28	NA	NA	Y	N
		2	8.31	1829.3	15.20	0.39	2.61	613	13.56	-1.72	-11.28	Y	N
		6	5.65	2121.0	11.98	-2.83	-19.11	531	10.64	-4.64	-30.37	Y	N
1114	UB Non-mentholated	-1	3.33	1506.7	5.02	NA	NA	754	4.42	NA	NA	Y	Y
		2	1.36	2909.4	3.96	-1.06	-21.14	403	3.37	-1.04	-23.59	Y	Y
		6	1.77	1920.0	3.40	-1.62	-32.27	661	2.68	-1.74	-39.37	Y	Y
1115	UB Non-mentholated VLN Non-mentholated	-1	6.06	1785.7	10.82	NA	NA	1590	3.81	NA	NA	Y	Y
		2	3.61	1601.3	5.78	-5.04	-46.58	1770	2.04	-1.77	-46.49	Y	Y
2002	UB Mentholated	-1	4.86	2188.0	10.63	NA	NA	803	6.05	NA	NA	Y	Y
		2	6.27	1893.0	11.87	1.24	11.62	915	6.85	0.80	13.22	Y	Y
		6	4.47	3245.0	14.51	3.87	36.41	569	7.86	1.80	29.80	Y	Y
2003	UB Mentholated VLN Mentholated	-1	6.82	3036.0	20.71	NA	NA	342	19.94	NA	NA	Y	N
		2	3.75	4180.0	15.68	-5.03	-24.30	348	10.78	-9.17	-45.96	Y	N

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2003	VLN Mentholated	6	1.75	3245.0	5.68	-15.03	-72.57	373	4.69	-15.25	-76.47	Y	N
2007	UB Non-mentholated	-1	5.53	1535.0	8.49	NA	NA	696	7.95	NA	NA	Y	Y
	VLN Non-mentholated	2	5.73	1492.0	8.55	0.06	0.71	725	7.90	-0.04	-0.53	Y	Y
		6	3.48	1387.0	4.83	-3.66	-43.14	828	4.20	-3.74	-47.10	Y	Y
2008	UB Mentholated	-1	1.40	2663.0	3.73	NA	NA	900	1.56	NA	NA	Y	Y
	VLN Mentholated	2	1.12	3323.0	3.72	-0.01	-0.17	709	1.58	0.02	1.55	Y	Y
		6	1.53	1734.0	2.65	-1.08	-28.84	1300	1.18	-0.38	-24.34	Y	Y
2009	UB Non-mentholated	-1	0.589	2427.0	1.43	NA	NA	807	0.73	NA	NA	Y	N
	VLN Non-mentholated	2	1.44	1390.0	2.00	0.57	40.02	1420	1.01	0.28	38.94	Y	N
2010	UB Mentholated	-1	3.18	1673.0	5.32	NA	NA	1650	1.93	NA	NA	Y	Y
		2	3.99	1289.0	5.14	-0.18	-3.33	1390	2.87	0.94	48.94	Y	Y
		6	3.62	1158.0	4.19	-1.13	-21.21	2350	1.54	-0.39	-20.07	Y	Y
2011	UB Mentholated	-1	9.67	1639.0	15.85	NA	NA	1010	9.57	NA	NA	Y	N
	VLN Mentholated	2	6.11	1510.0	9.23	-6.62	-41.79	1110	5.50	-4.07	-42.51	Y	N
		6	4.71	1165.0	5.49	-10.36	-65.38	1510	3.12	-6.46	-67.42	Y	N
2014	UB Mentholated	-1	3.80	3009.0	11.43	NA	NA	738	5.15	NA	NA	Y	N
	VLN Mentholated	2	5.22	1438.0	7.51	-3.93	-34.35	1410	3.70	-1.45	-28.10	Y	N
		6	4.01	2776.0	11.13	-0.30	-2.65	718	5.58	0.44	8.47	Y	N

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2015	UB Mentholated	-1	2.92	1277.0	3.73	NA	NA	1080	2.70	NA	NA	Y	Y
		2	3.54	1774.0	6.28	2.55	68.42	800	4.43	1.72	63.66	Y	Y
		6	3.37	1070.0	3.61	-0.12	-3.30	1620	2.08	-0.62	-23.06	Y	Y
2016	UB Mentholated	-1	2.70	1787.0	4.82	NA	NA	642	4.21	NA	NA	Y	Y
2017	UB Mentholated VLN Mentholated	-1	8.52	1504.0	12.81	NA	NA	1290	6.60	NA	NA	Y	N
		2	5.71	1864.0	10.64	-2.17	-16.94	1110	5.14	-1.46	-22.11	Y	N
		6	4.01	1210.0	4.85	-7.96	-62.13	1530	2.62	-3.98	-60.32	Y	N
2018	UB Mentholated	-1	2.08	1191.0	2.48	NA	NA	1390	1.50	NA	NA	Y	Y
		2	2.51	1374.0	3.45	0.97	39.21	1120	2.24	0.74	49.76	Y	Y
		6	3.35	963.0	3.23	0.75	30.23	1620	2.07	0.57	38.19	Y	Y
2020	UB Mentholated VLN Mentholated	-1	3.30	1117.0	3.69	NA	NA	919	3.59	NA	NA	Y	N
		2	3.46	1155.0	4.00	0.31	8.42	1070	3.23	-0.36	-9.95	Y	N
		6	2.02	1300.0	2.63	-1.06	-28.76	929	2.17	-1.42	-39.45	Y	N
2021	UB Mentholated VLN Mentholated	-1	2.40	2086.0	5.01	NA	NA	1120	2.14	NA	NA	Y	Y
		2	1.57	2606.0	4.09	-0.91	-18.28	909	1.73	-0.42	-19.40	Y	Y
		6	0.916	2561.0	2.35	-2.66	-53.14	821	1.12	-1.03	-47.93	Y	Y
2023	UB Mentholated VLN Mentholated	-1	2.71	996.0	2.70	NA	NA	2220	1.22	NA	NA	Y	Y
		2	0.896	1252.0	1.12	-1.58	-58.44	1650	0.54	-0.68	-55.52	Y	Y

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2023	VLN Mentholated	6	0.671	999.0	0.67	-2.03	-75.17	2180	0.31	-0.91	-74.79	Y	Y
2024	UB Non-mentholated	-1	16.7	1112.0	18.57	NA	NA	1690	9.88	NA	NA	Y	Y
2025	UB Non-mentholated	-1	4.05	2766.0	11.20	NA	NA	674	6.01	NA	NA	Y	Y
		2	5.55	2484.0	13.79	2.58	23.07	844	6.58	0.57	9.43	Y	Y
		6	3.72	2746.0	10.22	-0.99	-8.81	866	4.30	-1.71	-28.51	Y	Y
2028	UB Non-mentholated VLN Non-mentholated	-1	8.32	1538.0	12.80	NA	NA	1270	6.55	NA	NA	Y	Y
		2	2.35	1876.0	4.41	-8.39	-65.55	834	2.82	-3.73	-56.99	Y	Y
		6	3.26	616.0	2.01	-10.79	-84.31	1780	1.83	-4.72	-72.04	Y	Y
2029	UB Mentholated	-1	3.94	1689.0	6.65	NA	NA	996	3.96	NA	NA	Y	Y
		2	3.35	1933.0	6.48	-0.18	-2.69	855	3.92	-0.04	-0.95	Y	Y
		6	2.50	2068.0	5.17	-1.48	-22.31	789	3.17	-0.79	-19.90	Y	Y
2039	UB Mentholated VLN Mentholated	-1	7.19	1765.0	12.69	NA	NA	762	9.44	NA	NA	Y	N
		2	5.21	1582.0	8.24	-4.45	-35.05	711	7.33	-2.11	-22.34	Y	N
		6	3.63	718.0	2.61	-10.08	-79.46	898	4.04	-5.39	-57.16	Y	N
2050	UB Mentholated	-1	5.85	1887.0	11.04	NA	NA	995	5.88	NA	NA	Y	Y
		2	4.92	1436.0	7.07	-3.97	-36.00	908	5.42	-0.46	-7.84	Y	Y
		6	2.85	1392.0	3.97	-7.07	-64.06	1300	2.19	-3.69	-62.71	Y	Y
2052	UB Mentholated	-1	6.11	2094.0	12.79	NA	NA	921	6.63	NA	NA	Y	Y

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2052	VLN Mentholated	2	5.01	1611.0	8.07	-4.72	-36.92	1190	4.21	-2.42	-36.54	Y	Y
		6	4.06	2735.0	11.10	-1.69	-13.21	664	6.11	-0.52	-7.83	Y	Y
2057	UB Mentholated	-1	4.43	3085.0	13.67	NA	NA	646	6.86	NA	NA	Y	N
	VLN Mentholated	2	2.24	3805.0	8.52	-5.14	-37.63	552	4.06	-2.80	-40.83	Y	N
		6	2.10	3820.0	8.02	-5.64	-41.30	592	3.55	-3.31	-48.27	Y	N
2058	UB Mentholated	-1	3.91	1240.0	4.85	NA	NA	1410	2.77	NA	NA	Y	N
	VLN Mentholated	2	1.46	1621.0	2.37	-2.48	-51.19	1000	1.46	-1.31	-47.35	Y	N
		6	1.48	2198.0	3.25	-1.60	-32.90	763	1.94	-0.83	-30.05	Y	N
2059	UB Mentholated	-1	6.85	1545.0	10.58	NA	NA	780	8.78	NA	NA	Y	Y
		2	6.44	1452.0	9.35	-1.23	-11.64	785	8.20	-0.58	-6.58	Y	Y
		6	7.42	1242.0	9.22	-1.37	-12.92	1100	6.75	-2.04	-23.19	Y	Y
2060	UB Mentholated	-1	21.5	773.0	16.62	NA	NA	1200	17.92	NA	NA	Y	N
	VLN Mentholated	2	5.97	684.0	4.08	-12.54	-75.43	1230	4.85	-13.06	-72.91	Y	N
		6	12.5	1465.0	18.31	1.69	10.19	971	12.87	-5.04	-28.15	Y	N
2064	UB Mentholated	-1	5.90	3404.0	20.08	NA	NA	450	13.11	NA	NA	Y	N
	VLN Mentholated	2	5.44	2844.0	15.47	-4.61	-22.97	649	8.38	-4.73	-36.07	Y	N
		6	3.47	2882.0	10.00	-10.08	-50.21	572	6.07	-7.04	-53.73	Y	N
2066	UB Mentholated	-1	21.8	1056.0	23.02	NA	NA	1810	12.04	NA	NA	Y	N

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2066	VLN Mentholated	2	13.7	912.0	12.49	-10.53	-45.73	1790	7.65	-4.39	-36.45	Y	N
		6	5.87	1617.0	9.49	-13.53	-58.77	1110	5.29	-6.76	-56.09	Y	N
2067	UB Non-mentholated	-1	4.42	2550.0	11.27	NA	NA	643	6.87	NA	NA	Y	N
	VLN Non-mentholated	2	4.66	1608.0	7.49	-3.78	-33.52	1070	4.36	-2.52	-36.64	Y	N
		6	4.18	2810.0	11.75	0.47	4.21	654	6.39	-0.48	-7.02	Y	N
2075	UB Mentholated	-1	2.72	3995.0	10.87	NA	NA	551	4.94	NA	NA	Y	Y
2076	UB Mentholated	-1	2.56	2036.0	5.21	NA	NA	943	2.71	NA	NA	Y	N
	VLN Mentholated	2	1.54	2229.0	3.43	-1.78	-34.14	928	1.66	-1.06	-38.87	Y	N
		6	0.825	2063.0	1.70	-3.51	-67.35	1030	0.80	-1.91	-70.50	Y	N
2086	UB Non-mentholated	-1	8.52	779.0	6.64	NA	NA	1640	5.20	NA	NA	Y	N
	VLN Non-mentholated	2	6.05	1692.0	10.24	3.60	54.23	1040	5.82	0.62	11.98	Y	N
2088	UB Mentholated	-1	7.06	3222.0	22.75	NA	NA	480	14.71	NA	NA	Y	N
	VLN Mentholated	2	2.87	2854.0	8.19	-14.56	-63.99	601	4.78	-9.93	-67.53	Y	N
		6	1.26	2370.0	2.99	-19.76	-86.87	680	1.85	-12.86	-87.40	Y	N
2092	UB Mentholated	-1	1.23	2002.0	2.46	NA	NA	445	2.76	NA	NA	Y	N
	VLN Mentholated	2	0.924	1940.0	1.79	-0.67	-27.20	457	2.02	-0.74	-26.85	Y	N
		6	0.416	2262.0	0.94	-1.52	-61.79	391	1.06	-1.70	-61.51	Y	N
2099	UB Non-mentholated	-1	7.87	1107.0	8.71	NA	NA	1350	5.83	NA	NA	Y	N

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2099	VLN Non-mentholated	2	4.21	1523.0	6.41	-2.30	-26.40	968	4.35	-1.48	-25.40	Y	N
		6	5.80	1051.0	6.10	-2.62	-30.03	1430	4.06	-1.77	-30.43	Y	N
2100	UB Mentholated	-1	21.2	577.0	12.23	NA	NA	2130	9.95	NA	NA	Y	Y
		2	11.6	1028.0	11.92	-0.31	-2.51	1200	9.67	-0.29	-2.88	Y	Y
		6	19.1	550.0	10.51	-1.73	-14.12	2170	8.80	-1.15	-11.57	Y	Y
2108	UB Non-mentholated VLN Non-mentholated	-1	2.91	2860.0	8.32	NA	NA	286	10.17	NA	NA	Y	N
		2	4.76	3150.0	14.99	6.67	80.16	255	18.67	8.49	83.46	Y	N
		6	3.92	3399.0	13.32	5.00	60.10	252	15.56	5.38	52.88	Y	N
2110	UB Mentholated	-1	5.26	1034.0	5.44	NA	NA	818	6.43	NA	NA	Y	Y
		2	6.87	799.0	5.49	0.05	0.92	1050	6.54	0.11	1.75	Y	Y
		6	7.17	653.0	4.68	-0.76	-13.92	1190	6.03	-0.41	-6.30	Y	Y
2113	UB Mentholated VLN Mentholated	-1	8.28	843.0	6.98	NA	NA	1120	7.39	NA	NA	Y	Y
		2	76.0	878.0	66.73	59.75	855.98	910	83.52	76.12	1029.69	Y	Y
2115	UB Mentholated	-1	3.10	1626.0	5.04	NA	NA	906	3.42	NA	NA	Y	Y
2119	UB Mentholated VLN Mentholated	-1	19.3	650.0	12.55	NA	NA	2390	8.08	NA	NA	Y	Y
		2	11.2	786.0	8.80	-3.74	-29.83	1910	5.86	-2.21	-27.39	Y	Y
		6	12.5	902.0	11.28	-1.27	-10.12	1590	7.86	-0.21	-2.65	Y	Y
2120	UB Non-mentholated	-1	6.24	1243.0	7.76	NA	NA	634	9.84	NA	NA	Y	Y

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2120	VLN Non-mentholated	2	2.70	1147.0	3.10	-4.66	-60.07	646	4.18	-5.66	-57.53	Y	Y
		6	4.17	1735.0	7.23	-0.52	-6.72	488	8.55	-1.30	-13.18	Y	Y
2122	UB Non-mentholated	-1	9.17	1396.0	12.80	NA	NA	1050	8.73	NA	NA	Y	Y
		2	8.96	1487.0	13.32	0.52	4.08	1010	8.87	0.14	1.58	Y	Y
		6	7.79	1643.0	12.80	0.00	-0.02	954	8.17	-0.57	-6.50	Y	Y
2125	UB Mentholated	-1	1.02	1819.0	1.86	NA	NA	1600	0.64	NA	NA	Y	Y
		2	0.888	3746.0	3.33	1.47	79.29	755	1.18	0.54	84.50	Y	Y
		6	1.83	3110.0	5.69	3.84	206.75	960	1.91	1.27	199.02	Y	Y
2126	UB Mentholated VLN Mentholated	-1	11.4	1339.0	15.26	NA	NA	1200	9.50	NA	NA	Y	N
		2	13.3	1234.0	16.41	1.15	7.52	1110	11.98	2.48	26.13	Y	N
		6	15.6	1047.0	16.33	1.07	7.00	1510	10.33	0.83	8.75	Y	N
2136	UB Non-mentholated VLN Non-mentholated	-1	7.04	2199.0	15.48	NA	NA	803	8.77	NA	NA	Y	N
		2	6.54	1100.0	7.19	-8.29	-53.53	1490	4.39	-4.38	-49.93	Y	N
2140	UB Non-mentholated	-1	5.42	800.0	4.34	NA	NA	1470	3.69	NA	NA	Y	Y
		2	3.18	763.0	2.43	-1.91	-44.04	1610	1.98	-1.71	-46.43	Y	Y
		6	3.12	939.0	2.93	-1.41	-32.43	1250	2.50	-1.19	-32.30	Y	Y
2142	UB Non-mentholated	-1	3.59	2406.0	8.64	NA	NA	500	7.18	NA	NA	Y	Y
2143	UB Non-mentholated	-1	8.62	2510.0	21.64	NA	NA	595	14.49	NA	NA	Y	Y

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2143	VLN Non-mentholated	2	5.00	2050.0	10.25	-11.39	-52.63	756	6.61	-7.87	-54.35	Y	Y
		6	5.54	2221.0	12.30	-9.33	-43.13	729	7.60	-6.89	-47.54	Y	Y
2158	UB Non-mentholated	-1	15.4	1684.0	25.93	NA	NA	843	18.27	NA	NA	Y	Y
		2	10.7	1211.0	12.96	-12.98	-50.04	1160	9.22	-9.04	-49.51	Y	Y
2159	UB Non-mentholated VLN Non-mentholated	-1	15.0	1506.0	22.59	NA	NA	795	18.87	NA	NA	Y	N
		2	23.2	1042.0	24.17	1.58	7.01	1100	21.09	2.22	11.78	Y	N
		6	20.7	1311.0	27.14	4.55	20.13	1050	19.71	0.85	4.49	Y	N
2164	UB Non-mentholated VLN Non-mentholated	-1	12.2	2448.0	29.87	NA	NA	520	23.46	NA	NA	Y	Y
		2	5.74	2822.0	16.20	-13.67	-45.76	464	12.37	-11.09	-47.27	Y	Y
		6	4.65	2302.0	10.70	-19.16	-64.16	568	8.19	-15.27	-65.11	Y	Y
2168	UB Non-mentholated VLN Non-mentholated	-1	18.5	1464.0	27.08	NA	NA	459	40.31	NA	NA	Y	N
		2	12.3	1163.0	14.30	-12.78	-47.18	528	23.30	-17.01	-42.20	Y	N
		6	10.8	216.0	.	.	.	427	25.29	-15.01	-37.25	N	N
2170	UB Non-mentholated	-1	12.4	929.0	11.52	NA	NA	1190	10.42	NA	NA	Y	Y
		2	11.5	1105.0	12.71	1.19	10.31	1090	10.55	0.13	1.25	Y	Y
		6	12.2	1005.0	.	.	.	1550	7.87	-2.55	-24.46	N	N
2175	UB Mentholated	-1	22.4	1724.0	38.62	NA	NA	736	30.43	NA	NA	Y	Y
		2	18.8	1687.0	31.72	-6.90	-17.87	776	24.23	-6.21	-20.40	Y	Y

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2175	UB Mentholated	6	16.7	1431.0	23.90	-14.72	-38.12	916	18.23	-12.20	-40.10	Y	Y
2189	UB Mentholated	-1	2.00	2385.0	4.77	NA	NA	806	2.48	NA	NA	Y	Y
2211	UB Mentholated VLN Mentholated	-1	5.73	2088.0	11.96	NA	NA	517	11.08	NA	NA	Y	N
		2	3.05	1946.0	5.94	-6.03	-50.39	591	5.16	-5.92	-53.44	Y	N
		6	1.31	297.0	0.39	-11.58	-96.75	685	1.91	-9.17	-82.74	Y	N
2212	UB Mentholated	-1	9.47	1397.0	13.23	NA	NA	1470	6.44	NA	NA	Y	Y
		2	7.64	1514.0	11.57	-1.66	-12.57	1400	5.46	-0.99	-15.29	Y	Y
		6	6.56	1016.0	6.66	-6.56	-49.62	2070	3.17	-3.27	-50.81	Y	Y
2213	UB Mentholated VLN Mentholated	-1	3.62	2513.0	9.10	NA	NA	930	3.89	NA	NA	Y	N
		2	2.91	2301.0	6.70	-2.40	-26.39	969	3.00	-0.89	-22.85	Y	N
		6	2.50	1689.0	4.22	-4.87	-53.58	1350	1.85	-2.04	-52.42	Y	N
2215	UB Mentholated	-1	11.5	1494.0	17.18	NA	NA	753	15.27	NA	NA	Y	Y
		2	10.8	1644.0	17.76	0.57	3.34	669	16.14	0.87	5.70	Y	Y
		6	9.81	1321.0	12.96	-4.22	-24.57	846	11.60	-3.68	-24.07	Y	Y
2220	UB Non-mentholated VLN Non-mentholated	-1	107	547.0	58.53	NA	NA	3260	32.82	NA	NA	Y	N
		2	62.8	1054.0	66.19	7.66	13.09	2100	29.90	-2.92	-8.89	Y	N
		6	67.4	900.0	60.66	2.13	3.64	2470	27.29	-5.53	-16.86	Y	N
2235	UB Mentholated	-1	8.28	1046.0	8.66	NA	NA	2100	3.94	NA	NA	Y	N

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2235	VLN Mentholated	2	3.66	1129.0	4.13	-4.53	-52.29	2020	1.81	-2.13	-54.05	Y	N
		6	6.80	448.0	3.05	-5.61	-64.83	2030	3.35	-0.59	-15.04	Y	N
2244	UB Non-mentholated VLN Non-mentholated	-1	11.4	1370.0	15.62	NA	NA	1230	9.27	NA	NA	Y	N
		2	9.11	1012.0	9.22	-6.40	-40.97	1940	4.70	-4.57	-49.33	Y	N
		6	11.5	926.0	10.65	-4.97	-31.82	1870	6.15	-3.12	-33.65	Y	N
2247	UB Mentholated VLN Mentholated	-1	2.87	1591.0	4.57	NA	NA	1430	2.01	NA	NA	Y	Y
		2	1.92	1612.0	3.10	-1.47	-32.22	1270	1.51	-0.50	-24.67	Y	Y
2251	UB Non-mentholated	-1	12.2	1872.0	22.84	NA	NA	1050	11.62	NA	NA	Y	Y
		2	9.76	1851.0	18.07	-4.77	-20.90	1140	8.56	-3.06	-26.32	Y	Y
		6	18.3	1192.0	21.81	-1.02	-4.49	1870	9.79	-1.83	-15.78	Y	Y
2257	UB Non-mentholated	-1	4.72	2851.0	13.46	NA	NA	393	12.01	NA	NA	Y	Y
		2	5.03	1989.0	10.00	-3.45	-25.65	497	10.12	-1.89	-15.73	Y	Y
		6	4.31	1988.0	8.57	-4.89	-36.33	427	10.09	-1.92	-15.96	Y	Y
2259	UB Mentholated	-1	4.50	1236.0	5.56	NA	NA	2220	2.03	NA	NA	Y	Y
		2	3.92	1039.0	4.07	-1.49	-26.77	2440	1.61	-0.42	-20.74	Y	Y
		6	4.59	999.0	4.59	-0.98	-17.56	2520	1.82	-0.21	-10.14	Y	Y
2269	UB Mentholated VLN Mentholated	-1	6.97	1468.0	10.23	NA	NA	1540	4.53	NA	NA	Y	N
		2	0.552	353.0	0.19	-10.04	-98.10	1120	0.49	-4.03	-89.11	Y	N

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

CFB = Change from Baseline, PCFB = Percent change from baseline, Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.4 Urinary NNN (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2269	VLN Mentholated	6	1.12	845.0	0.95	-9.29	-90.75	627	1.79	-2.74	-60.53	Y	N
2272	UB Mentholated	-1	5.72	889.0	5.09	NA	NA	2370	2.41	NA	NA	Y	N
	VLN Mentholated	2	6.15	1818.0	11.18	6.10	119.87	1070	5.75	3.33	138.15	Y	N
		6	4.37	1589.0	6.94	1.86	36.55	1290	3.39	0.97	40.36	Y	N

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

CFB = Change from Baseline, PCFB = Percent change from baseline, Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1001	UB Non-mentholated	-1	994	2171.0	2157.97	NA	NA	499	1991.98	NA	NA	Y	N
	VLN Non-mentholated	2	1640	1172.6	1923.06	-234.91	-10.89	804	2039.80	47.82	2.40	Y	N
		6	1220	1249.1	1523.90	-634.07	-29.38	843	1447.21	-544.77	-27.35	Y	N
1002	UB Non-mentholated	-1	1020	4356.5	4443.63	NA	NA	424	2405.66	NA	NA	Y	N
	VLN Non-mentholated	2	1460	4062.7	5931.54	1487.91	33.48	414	3526.57	1120.91	46.59	Y	N
		6	672	5759.6	3870.45	-573.18	-12.90	333	2018.02	-387.64	-16.11	Y	N
1003	UB Mentholated	-1	1480	1385.0	2049.80	NA	NA	1770	836.16	NA	NA	Y	N
	VLN Mentholated	2	2400	410.0	984.00	-1065.80	-52.00	2280	1052.63	216.47	25.89	Y	N
		6	1580	1017.7	1607.97	-441.83	-21.55	2250	702.22	-133.94	-16.02	Y	N
1007	UB Non-mentholated	-1	439	1935.0	849.47	NA	NA	890	493.26	NA	NA	Y	Y
	VLN Non-mentholated	2	352	2199.9	774.36	-75.10	-8.84	947	371.70	-121.56	-24.64	Y	Y
		6	512	1700.3	870.55	21.09	2.48	1330	384.96	-108.30	-21.96	Y	Y
1008	UB Mentholated	-1	1020	2014.0	2054.28	NA	NA	1120	910.71	NA	NA	Y	N
	VLN Mentholated	2	1210	1435.9	1737.44	-316.84	-15.42	1550	780.65	-130.07	-14.28	Y	N
		6	543	1122.0	609.25	-1445.03	-70.34	701	774.61	-136.11	-14.95	N	N
1010	UB Mentholated	-1	1230	2030.0	2496.90	NA	NA	941	1307.12	NA	NA	Y	Y
		2	1100	1539.6	1693.56	-803.34	-32.17	1120	982.14	-324.98	-24.86	Y	Y
		6	960	1036.8	995.33	-1501.57	-60.14	741	1295.55	-11.57	-0.89	N	N

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1011	UB Non-mentholated	-1	1310	1059.0	1387.29	NA	NA	2360	555.08	NA	NA	Y	Y
		2	1070	1364.0	1459.48	72.19	5.20	1590	672.96	117.87	21.23	Y	Y
		6	1560	628.7	980.77	-406.52	-29.30	1060	1471.70	916.61	165.13	N	N
1013	UB Non-mentholated VLN Non-mentholated	-1	821	1664.0	1366.14	NA	NA	1060	774.53	NA	NA	Y	N
		2	1150	1043.8	.	.	.	1450	793.10	18.58	2.40	N	N
		6	1690	874.0	1477.06	110.92	8.12	1970	857.87	83.34	10.76	Y	N
1014	UB Mentholated VLN Mentholated	-1	543	2069.0	1123.47	NA	NA	476	1140.76	NA	NA	Y	N
		6	1500	903.2	1354.80	231.33	20.59	1330	1127.82	-12.94	-1.13	Y	N
1015	UB Mentholated VLN Mentholated	-1	546	3550.0	1938.30	NA	NA	371	1471.70	NA	NA	Y	Y
		2	410	3406.2	1396.54	-541.76	-27.95	373	1099.20	-372.50	-25.31	Y	Y
		6	331	3477.7	1151.12	-787.18	-40.61	392	844.39	-627.31	-42.62	Y	Y
1016	UB Non-mentholated	-1	855	1853.0	1584.32	NA	NA	873	979.38	NA	NA	Y	Y
		2	664	2839.1	1885.16	300.85	18.99	528	1257.58	278.19	28.41	Y	Y
		6	1360	1899.3	2583.05	998.73	63.04	908	1497.80	518.42	52.93	Y	Y
1017	UB Mentholated	-1	572	2490.0	1424.28	NA	NA	507	1128.21	NA	NA	Y	Y
		2	625	2593.9	1621.19	196.91	13.83	529	1181.47	53.27	4.72	Y	Y
		6	884	1399.2	1236.89	-187.39	-13.16	920	960.87	-167.34	-14.83	Y	Y
1018	UB Mentholated	-1	1250	1721.0	2151.25	NA	NA	672	1860.12	NA	NA	Y	Y

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1019	UB Non-mentholated	-1	1710	1431.0	2447.01	NA	NA	1750	977.14	NA	NA	Y	N
	VLN Non-mentholated	2	700	3109.0	2176.30	-270.71	-11.06	762	918.64	-58.51	-5.99	Y	N
		6	1180	2290.1	2702.32	255.31	10.43	1110	1063.06	85.92	8.79	Y	N
1020	UB Non-mentholated	-1	795	1666.0	1324.47	NA	NA	773	1028.46	NA	NA	Y	N
	VLN Non-mentholated	2	1140	1240.9	1414.63	90.16	6.81	1430	797.20	-231.26	-22.49	Y	N
		6	762	917.7	699.29	-625.18	-47.20	1280	595.31	-433.15	-42.12	Y	N
1021	UB Non-mentholated	-1	438	1808.0	791.90	NA	NA	681	643.17	NA	NA	N	N
		2	519	1842.4	956.21	.	.	710	730.99	.	.	Y	Y
		6	425	2136.5	908.01	.	.	637	667.19	.	.	Y	Y
1023	UB Non-mentholated	-1	473	2894.0	1368.86	NA	NA	367	1288.83	NA	NA	Y	N
	VLN Non-mentholated	2	293	3795.5	1112.08	-256.78	-18.76	274	1069.34	-219.49	-17.03	Y	N
		6	325	3600.0	1170.00	-198.86	-14.53	334	973.05	-315.77	-24.50	Y	N
1029	UB Mentholated	-1	723	2525.2	1825.72	NA	NA	554	1305.05	NA	NA	Y	N
	VLN Mentholated	2	323	3098.0	1000.65	-825.07	-45.19	505	639.60	-665.45	-50.99	Y	N
		6	446	2192.0	977.63	-848.09	-46.45	753	592.30	-712.76	-54.62	Y	N
1032	UB Mentholated	-1	587	3793.8	2226.96	NA	NA	319	1840.13	NA	NA	Y	Y
	VLN Mentholated	2	641	3479.0	2230.04	3.08	0.14	411	1559.61	-280.51	-15.24	Y	Y
		6	658	2345.0	1543.01	-683.95	-30.71	602	1093.02	-747.10	-40.60	Y	Y

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1034	UB Non-mentholated	-1	1630	1275.1	2078.41	NA	NA	1080	1509.26	NA	NA	Y	N
	VLN Non-mentholated	2	1560	969.0	1511.64	-566.77	-27.27	1210	1289.26	-220.00	-14.58	Y	N
		6	1350	1037.0	1399.95	-678.46	-32.64	1550	870.97	-638.29	-42.29	Y	N
1035	UB Non-mentholated	-1	887	2182.4	1935.79	NA	NA	1180	751.69	NA	NA	Y	N
	VLN Non-mentholated	2	815	2196.0	1789.74	-146.05	-7.54	726	1122.59	370.89	49.34	Y	N
		6	799	1204.0	962.00	-973.79	-50.30	1400	570.71	-180.98	-24.08	Y	N
1036	UB Mentholated	-1	600	1896.8	1138.08	NA	NA	761	788.44	NA	NA	Y	Y
		2	509	1841.0	937.07	-201.01	-17.66	793	641.87	-146.57	-18.59	Y	Y
		6	778	1475.0	1147.55	9.47	0.83	1110	700.90	-87.54	-11.10	Y	Y
1037	UB Mentholated	-1	398	5986.4	2382.59	NA	NA	350	1137.14	NA	NA	Y	Y
		2	678	2822.0	1913.32	-469.27	-19.70	698	971.35	-165.80	-14.58	Y	Y
		6	806	2712.0	2185.87	-196.72	-8.26	651	1238.10	100.95	8.88	Y	Y
1038	UB Non-mentholated	-1	1250	1610.1	2012.63	NA	NA	802	1558.60	NA	NA	Y	N
	VLN Non-mentholated	2	485	1705.0	826.93	-1185.70	-58.91	830	584.34	-974.27	-62.51	Y	N
		6	478	1641.0	784.40	-1228.23	-61.03	894	534.68	-1023.93	-65.70	Y	N
1042	UB Non-mentholated	-1	438	5646.2	2473.04	NA	NA	353	1240.79	NA	NA	Y	N
	VLN Non-mentholated	2	296	3586.0	1061.46	-1411.58	-57.08	380	778.95	-461.85	-37.22	Y	N
		6	347	2769.0	960.84	-1512.19	-61.15	429	808.86	-431.94	-34.81	Y	N

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1045	UB Non-mentholated	-1	819	3025.5	2477.88	NA	NA	613	1336.05	NA	NA	Y	Y
		2	818	2443.0	1998.37	-479.51	-19.35	654	1250.76	-85.29	-6.38	Y	Y
		6	1190	1894.0	2253.86	-224.02	-9.04	921	1292.07	-43.98	-3.29	Y	Y
1046	UB Mentholated	-1	524	3780.8	1981.14	NA	NA	570	919.30	NA	NA	Y	Y
		2	602	2832.0	1704.86	-276.28	-13.95	670	898.51	-20.79	-2.26	Y	Y
		6	644	2830.0	1822.52	-158.62	-8.01	806	799.01	-120.29	-13.09	Y	Y
1050	UB Non-mentholated VLN Non-mentholated	-1	945	1520.3	1436.68	NA	NA	781	1209.99	NA	NA	Y	N
		2	509	3144.1	1600.35	163.66	11.39	472	1078.39	-131.60	-10.88	Y	N
		6	854	1578.0	1347.61	-89.07	-6.20	825	1035.15	-174.84	-14.45	Y	N
1051	UB Mentholated	-1	770	2216.8	1706.94	NA	NA	762	1010.50	NA	NA	Y	Y
		2	696	2040.0	1419.84	-287.10	-16.82	789	882.13	-128.37	-12.70	Y	Y
		6	851	1784.0	1518.18	-188.75	-11.06	1050	810.48	-200.02	-19.79	Y	Y
1052	UB Mentholated VLN Mentholated	-1	1200	1539.8	1847.76	NA	NA	1300	923.08	NA	NA	Y	N
		2	1320	1602.0	2114.64	266.88	14.44	1130	1168.14	245.06	26.55	Y	N
		6	1650	1065.0	1757.25	-90.51	-4.90	1850	891.89	-31.19	-3.38	Y	N
1053	UB Mentholated VLN Mentholated	-1	536	2902.3	1555.63	NA	NA	795	674.21	NA	NA	Y	N
		2	368	2790.0	1026.72	-528.91	-34.00	933	394.43	-279.79	-41.50	Y	N
		6	348	2523.0	878.00	-677.63	-43.56	914	380.74	-293.47	-43.53	Y	N

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1054	UB Non-mentholated	-1	3500	956.9	3349.15	NA	NA	2550	1372.55	NA	NA	Y	Y
		2	1410	1844.0	2600.04	-749.11	-22.37	1180	1194.92	-177.63	-12.94	Y	Y
		6	2070	1089.0	2254.23	-1094.92	-32.69	2130	971.83	-400.72	-29.20	Y	Y
1055	UB Mentholated VLN Mentholated	-1	695	3328.9	2313.59	NA	NA	451	1541.02	NA	NA	Y	N
		2	534	3391.6	1811.11	-502.47	-21.72	495	1078.79	-462.23	-30.00	Y	N
		6	591	1581.0	934.37	-1379.21	-59.61	955	618.85	-922.17	-59.84	Y	N
1056	UB Non-mentholated VLN Non-mentholated	-1	462	3925.2	1813.44	NA	NA	416	1110.58	NA	NA	Y	N
		2	940	1334.0	1253.96	-559.48	-30.85	799	1176.47	65.89	5.93	Y	N
		6	775	1152.0	892.80	-920.64	-50.77	785	987.26	-123.32	-11.10	Y	N
1058	UB Non-mentholated VLN Non-mentholated	-1	712	3355.1	2388.83	NA	NA	518	1374.52	NA	NA	Y	N
		2	425	2869.0	1219.33	-1169.51	-48.96	520	817.31	-557.21	-40.54	Y	N
		6	977	1927.0	1882.68	-506.15	-21.19	1190	821.01	-553.51	-40.27	Y	N
1059	UB Non-mentholated	-1	2520	956.0	2409.12	NA	NA	2300	1095.65	NA	NA	Y	Y
		2	887	2124.7	1884.61	-524.51	-21.77	1040	852.88	-242.77	-22.16	Y	Y
		6	1420	1507.0	2139.94	-269.18	-11.17	1750	811.43	-284.22	-25.94	Y	Y
1060	UB Mentholated VLN Mentholated	-1	897	2414.0	2165.36	NA	NA	751	1194.41	NA	NA	Y	N
		2	931	2361.4	2198.46	33.11	1.53	782	1190.54	-3.87	-0.32	Y	N
		6	990	1742.0	1724.58	-440.78	-20.36	950	1042.11	-152.30	-12.75	Y	N

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

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ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1063	UB Mentholated	-1	307	7095.2	2178.23	NA	NA	306	1003.27	NA	NA	Y	Y
	VLN Mentholated	2	423	3891.4	1646.06	-532.16	-24.43	569	743.41	-259.86	-25.90	Y	Y
		6	341	3208.0	1093.93	-1084.30	-49.78	787	433.29	-569.98	-56.81	Y	Y
1064	UB Non-mentholated	-1	752	3268.0	2457.54	NA	NA	749	1004.01	NA	NA	Y	Y
		2	1010	2273.1	2295.83	-161.71	-6.58	1060	952.83	-51.18	-5.10	Y	Y
1066	UB Non-mentholated	-1	1370	967.0	1324.79	NA	NA	2190	625.57	NA	NA	Y	Y
	VLN Non-mentholated	2	866	1744.8	1511.00	186.21	14.06	1050	824.76	199.19	31.84	Y	Y
		6	769	1725.0	1326.53	1.74	0.13	1220	630.33	4.76	0.76	Y	Y
1069	UB Non-mentholated	-1	841	2554.0	2147.91	NA	NA	793	1060.53	NA	NA	Y	Y
		2	797	2465.9	1965.32	-182.59	-8.50	783	1017.88	-42.65	-4.02	Y	Y
		6	1100	2162.0	2378.20	230.29	10.72	973	1130.52	69.99	6.60	Y	Y
1070	UB Non-mentholated	-1	750	3393.0	2544.75	NA	NA	633	1184.83	NA	NA	Y	Y
	VLN Non-mentholated	2	622	2687.1	1671.38	-873.37	-34.32	752	827.13	-357.71	-30.19	Y	Y
		6	897	1316.0	1180.45	-1364.30	-53.61	1800	498.33	-686.50	-57.94	Y	Y
1071	UB Non-mentholated	-1	1030	2129.0	2192.87	NA	NA	700	1471.43	NA	NA	Y	N
	VLN Non-mentholated	2	747	2212.3	1652.59	-540.28	-24.64	1230	607.32	-864.11	-58.73	Y	N
1072	UB Mentholated	-1	807	2181.0	1760.07	NA	NA	806	1001.24	NA	NA	Y	Y
	VLN Mentholated	2	821	1779.7	1461.13	-298.93	-16.98	955	859.69	-141.55	-14.14	Y	Y

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1074	UB Non-mentholated	-1	714	2211.0	1578.65	NA	NA	876	815.07	NA	NA	Y	N
	VLN Non-mentholated	2	1020	1464.3	1493.59	-85.07	-5.39	1350	755.56	-59.51	-7.30	Y	N
		6	499	1677.0	836.82	-741.83	-46.99	1310	380.92	-434.15	-53.27	Y	N
1075	UB Non-mentholated	-1	588	2163.0	1271.84	NA	NA	773	760.67	NA	NA	Y	Y
		2	618	1890.7	1168.45	-103.39	-8.13	845	731.36	-29.31	-3.85	Y	Y
		6	894	1263.0	1129.12	-142.72	-11.22	1340	667.16	-93.51	-12.29	Y	Y
1077	UB Non-mentholated	-1	541	3102.1	1678.24	NA	NA	493	1097.36	NA	NA	Y	Y
	VLN Non-mentholated	2	694	3008.3	2087.76	409.52	24.40	596	1164.43	67.07	6.11	Y	Y
		6	676	2743.0	1854.27	176.03	10.49	693	975.47	-121.89	-11.11	Y	Y
1078	UB Non-mentholated	-1	916	1991.0	1823.76	NA	NA	597	1534.34	NA	NA	Y	N
	VLN Non-mentholated	2	432	3513.1	1517.66	-306.10	-16.78	352	1227.27	-307.07	-20.01	Y	N
		6	593	2384.0	1413.71	-410.04	-22.48	654	906.73	-627.61	-40.90	Y	N
1079	UB Mentholated	-1	974	2154.0	2098.00	NA	NA	1370	710.95	NA	NA	Y	Y
	VLN Mentholated	2	410	3647.6	1495.52	-602.48	-28.72	802	511.22	-199.73	-28.09	Y	Y
		6	367	2605.0	956.04	-1141.96	-54.43	1040	352.88	-358.06	-50.36	Y	Y
1082	UB Non-mentholated	-1	803	2790.0	2240.37	NA	NA	843	952.55	NA	NA	Y	N
	VLN Non-mentholated	2	727	2629.9	1911.94	-328.43	-14.66	926	785.10	-167.45	-17.58	Y	N
		6	644	2013.0	1296.37	-944.00	-42.14	1200	536.67	-415.88	-43.66	Y	N

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1083	UB Non-mentholated	-1	1250	1708.0	2135.00	NA	NA	762	1640.42	NA	NA	Y	N
	VLN Non-mentholated	2	1820	1788.0	3254.16	1119.16	52.42	892	2040.36	399.94	24.38	Y	N
		6	1570	2017.0	3166.69	1031.69	48.32	804	1952.74	312.32	19.04	Y	N
1084	UB Non-mentholated	-1	955	1467.0	1400.99	NA	NA	1380	692.03	NA	NA	Y	N
	VLN Non-mentholated	2	978	1158.4	1132.92	-268.07	-19.13	1630	600.00	-92.03	-13.30	Y	N
1086	UB Non-mentholated	-1	1620	1938.0	3139.56	NA	NA	968	1673.55	NA	NA	Y	N
	VLN Non-mentholated	2	2600	1255.9	3265.34	125.78	4.01	1410	1843.97	170.42	10.18	Y	N
		6	1520	1580.0	2401.60	-737.96	-23.51	1040	1461.54	-212.02	-12.67	Y	N
1088	UB Mentholated	-1	1060	1662.0	1761.72	NA	NA	1670	634.73	NA	NA	Y	N
	VLN Mentholated	2	830	1236.2	1026.05	-735.67	-41.76	1820	456.04	-178.69	-28.15	Y	N
		6	829	1670.0	1384.43	-377.29	-21.42	1520	545.39	-89.34	-14.07	Y	N
1089	UB Non-mentholated	-1	851	1795.0	1527.55	NA	NA	669	1272.05	NA	NA	Y	Y
		2	547	2415.3	1321.17	-206.38	-13.51	544	1005.51	-266.53	-20.95	Y	Y
		6	552	2062.0	1138.22	-389.32	-25.49	559	987.48	-284.57	-22.37	Y	Y
1092	UB Mentholated	-1	873	2383.0	2080.36	NA	NA	734	1189.37	NA	NA	Y	N
	VLN Mentholated	2	867	1551.7	1345.32	-735.04	-35.33	898	965.48	-223.89	-18.82	Y	N
		6	786	1587.0	1247.38	-832.98	-40.04	1150	683.48	-505.90	-42.53	Y	N
1094	UB Mentholated	-1	752	1930.0	1451.36	NA	NA	1230	611.38	NA	NA	Y	N

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1094	VLN Mentholated	2	972	1307.6	1270.99	-180.37	-12.43	1720	565.12	-46.27	-7.57	Y	N
		6	930	1040.0	967.20	-484.16	-33.36	1930	481.87	-129.52	-21.18	Y	N
1095	UB Mentholated	-1	987	2551.0	2517.84	NA	NA	514	1920.23	NA	NA	Y	N
	VLN Mentholated	2	2200	430.3	946.66	-1571.18	-62.40	982	2240.33	320.09	16.67	N	N
		6	697	2131.0	1485.31	-1032.53	-41.01	390	1787.18	-133.05	-6.93	Y	N
1096	UB Non-mentholated	-1	647	2532.0	1638.20	NA	NA	634	1020.50	NA	NA	Y	N
	VLN Non-mentholated	2	723	1934.5	1398.64	-239.56	-14.62	679	1064.80	44.30	4.34	Y	N
		6	617	2949.0	1819.53	181.33	11.07	488	1264.34	243.84	23.89	Y	N
1097	UB Mentholated	-1	999	1982.0	1980.02	NA	NA	1250	799.20	NA	NA	Y	N
	VLN Mentholated	2	501	1598.3	800.75	-1179.27	-59.56	1510	331.79	-467.41	-58.48	Y	N
		6	439	1814.0	796.35	-1183.67	-59.78	1270	345.67	-453.53	-56.75	Y	N
1098	UB Non-mentholated	-1	1010	1415.8	1429.96	NA	NA	1060	952.83	NA	NA	Y	Y
	VLN Non-mentholated	2	1170	1666.1	1949.34	519.38	36.32	958	1221.29	268.46	28.18	Y	Y
		6	769	1811.0	1392.66	-37.30	-2.61	895	859.22	-93.61	-9.82	Y	Y
1099	UB Non-mentholated	-1	1790	810.2	.	NA	NA	1420	1260.56	NA	NA	N	N
	VLN Non-mentholated	2	1440	1272.2	1831.97	.	.	1060	1358.49	.	.	Y	N
		6	1130	1005.0	1135.65	.	.	1250	904.00	.	.	Y	N
1100	UB Non-mentholated	-1	502	3350.7	1682.05	NA	NA	550	912.73	NA	NA	Y	N

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1100	VLN Non-mentholated	2	603	2653.5	1600.06	-81.99	-4.87	684	881.58	-31.15	-3.41	Y	N
		6	537	2576.0	1383.31	-298.74	-17.76	772	695.60	-217.13	-23.79	Y	N
1101	UB Non-mentholated	-1	1710	1814.1	3102.11	NA	NA	827	2067.71	NA	NA	Y	N
	VLN Non-mentholated	2	1550	2317.4	3591.97	489.86	15.79	805	1925.47	-142.25	-6.88	Y	N
		6	697	3707.0	2583.78	-518.33	-16.71	258	2701.55	633.84	30.65	Y	N
1103	UB Non-mentholated	-1	545	3479.4	1896.27	NA	NA	297	1835.02	NA	NA	Y	N
	VLN Non-mentholated	2	854	2449.2	2091.62	195.34	10.30	762	1120.73	-714.28	-38.93	Y	N
		6	741	2601.0	1927.34	31.07	1.64	763	971.17	-863.85	-47.08	Y	N
1105	UB Non-mentholated	-1	2430	527.3	1281.34	NA	NA	1680	1446.43	NA	NA	Y	N
	VLN Non-mentholated	2	2210	825.2	1823.69	542.35	42.33	1010	2188.12	741.69	51.28	Y	N
		6	1370	677.0	927.49	-353.85	-27.62	1420	964.79	-481.64	-33.30	Y	N
1106	UB Non-mentholated	-1	2850	1380.1	3933.29	NA	NA	1870	1524.06	NA	NA	Y	Y
		2	3490	1113.7	3886.81	-46.47	-1.18	2330	1497.85	-26.21	-1.72	Y	Y
		6	1430	2435.0	3482.05	-451.24	-11.47	968	1477.27	-46.79	-3.07	Y	Y
1107	UB Non-mentholated	-1	594	2365.5	1405.11	NA	NA	913	650.60	NA	NA	Y	N
	VLN Non-mentholated	2	808	2512.8	2030.34	625.24	44.50	854	946.14	295.53	45.42	Y	N
		6	672	2599.0	1746.53	341.42	24.30	806	833.75	183.14	28.15	Y	N
1108	UB Non-mentholated	-1	1370	1782.0	2441.34	NA	NA	1150	1191.30	NA	NA	Y	Y

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1108	UB Non-mentholated	2	831	2115.4	1757.90	-683.44	-27.99	966	860.25	-331.06	-27.79	Y	Y
		6	773	1981.0	1531.31	-910.03	-37.28	1030	750.49	-440.82	-37.00	Y	Y
1109	UB Non-mentholated	-1	1330	1615.9	2149.15	NA	NA	950	1400.00	NA	NA	Y	Y
		2	959	1805.0	1731.00	-418.15	-19.46	919	1043.53	-356.47	-25.46	Y	Y
		6	1690	1075.0	1816.75	-332.40	-15.47	1490	1134.23	-265.77	-18.98	Y	Y
1112	UB Non-mentholated VLN Non-mentholated	-1	621	2265.2	1406.69	NA	NA	428	1450.93	NA	NA	Y	N
		2	1060	1829.3	1939.06	532.37	37.85	613	1729.20	278.27	19.18	Y	N
		6	578	2121.0	1225.94	-180.75	-12.85	531	1088.51	-362.42	-24.98	Y	N
1114	UB Non-mentholated	-1	569	1506.7	857.31	NA	NA	754	754.64	NA	NA	Y	Y
		2	211	2909.4	613.88	-243.43	-28.39	403	523.57	-231.07	-30.62	Y	Y
		6	347	1920.0	666.24	-191.07	-22.29	661	524.96	-229.68	-30.44	Y	Y
1115	UB Non-mentholated VLN Non-mentholated	-1	1500	1785.7	2678.55	NA	NA	1590	943.40	NA	NA	Y	Y
		2	1730	1601.3	2770.25	91.70	3.42	1770	977.40	34.00	3.60	Y	Y
2002	UB Mentholated	-1	788	2188.0	1724.14	NA	NA	803	981.32	NA	NA	Y	Y
		2	762	1893.0	1442.47	-281.68	-16.34	915	832.79	-148.53	-15.14	Y	Y
		6	624	3245.0	2024.88	300.74	17.44	569	1096.66	115.34	11.75	Y	Y
2003	UB Mentholated VLN Mentholated	-1	854	3036.0	2592.74	NA	NA	342	2497.08	NA	NA	Y	N
		2	449	4180.0	1876.82	-715.92	-27.61	348	1290.23	-1206.85	-48.33	Y	N

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2003	VLN Mentholated	6	283	3245.0	918.34	-1674.41	-64.58	373	758.71	-1738.36	-69.62	Y	N
2007	UB Non-mentholated	-1	463	1535.0	710.71	NA	NA	696	665.23	NA	NA	Y	Y
	VLN Non-mentholated	2	549	1492.0	819.11	108.40	15.25	725	757.24	92.01	13.83	Y	Y
		6	435	1387.0	603.35	-107.36	-15.11	828	525.36	-139.87	-21.03	Y	Y
2008	UB Mentholated	-1	486	2663.0	1294.22	NA	NA	900	540.00	NA	NA	Y	Y
	VLN Mentholated	2	214	3323.0	711.12	-583.10	-45.05	709	301.83	-238.17	-44.10	Y	Y
		6	436	1734.0	756.02	-538.19	-41.58	1300	335.38	-204.62	-37.89	Y	Y
2009	UB Non-mentholated	-1	235	2427.0	570.35	NA	NA	807	291.20	NA	NA	Y	N
	VLN Non-mentholated	2	547	1390.0	760.33	189.99	33.31	1420	385.21	94.01	32.28	Y	N
2010	UB Mentholated	-1	592	1673.0	990.42	NA	NA	1650	358.79	NA	NA	Y	Y
		2	602	1289.0	775.98	-214.44	-21.65	1390	433.09	74.31	20.71	Y	Y
		6	596	1158.0	690.17	-300.25	-30.32	2350	253.62	-105.17	-29.31	Y	Y
2011	UB Mentholated	-1	604	1639.0	989.96	NA	NA	1010	598.02	NA	NA	Y	N
	VLN Mentholated	2	489	1510.0	738.39	-251.57	-25.41	1110	440.54	-157.48	-26.33	Y	N
		6	571	1165.0	665.22	-324.74	-32.80	1510	378.15	-219.87	-36.77	Y	N
2014	UB Mentholated	-1	561	3009.0	1688.05	NA	NA	738	760.16	NA	NA	Y	N
	VLN Mentholated	2	1230	1438.0	1768.74	80.69	4.78	1410	872.34	112.18	14.76	Y	N
		6	591	2776.0	1640.62	-47.43	-2.81	718	823.12	62.96	8.28	Y	N

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

CFB = Change from Baseline, PCFB = Percent change from baseline, Subjects used their own usual brand cigarettes at Week -1.

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2015	UB Mentholated	-1	755	1277.0	964.14	NA	NA	1080	699.07	NA	NA	Y	Y
		2	669	1774.0	1186.81	222.67	23.10	800	836.25	137.18	19.62	Y	Y
		6	911	1070.0	974.77	10.64	1.10	1620	562.35	-136.73	-19.56	Y	Y
2016	UB Mentholated	-1	634	1787.0	1132.96	NA	NA	642	987.54	NA	NA	Y	Y
2017	UB Mentholated VLN Mentholated	-1	1530	1504.0	2301.12	NA	NA	1290	1186.05	NA	NA	Y	N
		2	848	1864.0	1580.67	-720.45	-31.31	1110	763.96	-422.08	-35.59	Y	N
		6	1090	1210.0	1318.90	-982.22	-42.68	1530	712.42	-473.63	-39.93	Y	N
2018	UB Mentholated	-1	845	1191.0	1006.40	NA	NA	1390	607.91	NA	NA	Y	Y
		2	738	1374.0	1014.01	7.62	0.76	1120	658.93	51.01	8.39	Y	Y
		6	1360	963.0	1309.68	303.29	30.14	1620	839.51	231.59	38.10	Y	Y
2020	UB Mentholated VLN Mentholated	-1	880	1117.0	982.96	NA	NA	919	957.56	NA	NA	Y	N
		2	736	1155.0	850.08	-132.88	-13.52	1070	687.85	-269.71	-28.17	Y	N
		6	405	1300.0	526.50	-456.46	-46.44	929	435.95	-521.61	-54.47	Y	N
2021	UB Mentholated VLN Mentholated	-1	375	2086.0	782.25	NA	NA	1120	334.82	NA	NA	Y	Y
		2	256	2606.0	667.14	-115.11	-14.72	909	281.63	-53.19	-15.89	Y	Y
		6	200	2561.0	512.20	-270.05	-34.52	821	243.61	-91.22	-27.24	Y	Y
2023	UB Mentholated VLN Mentholated	-1	1080	996.0	1075.68	NA	NA	2220	486.49	NA	NA	Y	Y
		2	466	1252.0	583.43	-492.25	-45.76	1650	282.42	-204.06	-41.95	Y	Y

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2023	VLN Mentholated	6	595	999.0	594.41	-481.28	-44.74	2180	272.94	-213.55	-43.90	Y	Y
2024	UB Non-mentholated	-1	1140	1112.0	1267.68	NA	NA	1690	674.56	NA	NA	Y	Y
2025	UB Non-mentholated	-1	805	2766.0	2226.63	NA	NA	674	1194.36	NA	NA	Y	Y
		2	895	2484.0	2223.18	-3.45	-0.15	844	1060.43	-133.94	-11.21	Y	Y
		6	1070	2746.0	2938.22	711.59	31.96	866	1235.57	41.20	3.45	Y	Y
2028	UB Non-mentholated VLN Non-mentholated	-1	763	1538.0	1173.49	NA	NA	1270	600.79	NA	NA	Y	Y
		2	431	1876.0	808.56	-364.94	-31.10	834	516.79	-84.00	-13.98	Y	Y
		6	901	616.0	555.02	-618.48	-52.70	1780	506.18	-94.61	-15.75	Y	Y
2029	UB Mentholated	-1	586	1689.0	989.75	NA	NA	996	588.35	NA	NA	Y	Y
		2	625	1933.0	1208.13	218.37	22.06	855	730.99	142.64	24.24	Y	Y
		6	459	2068.0	949.21	-40.54	-4.10	789	581.75	-6.60	-1.12	Y	Y
2039	UB Mentholated VLN Mentholated	-1	694	1765.0	1224.91	NA	NA	762	910.76	NA	NA	Y	N
		2	498	1582.0	787.84	-437.07	-35.68	711	700.42	-210.34	-23.09	Y	N
		6	358	718.0	257.04	-967.87	-79.02	898	398.66	-512.10	-56.23	Y	N
2050	UB Mentholated	-1	1620	1887.0	3056.94	NA	NA	995	1628.14	NA	NA	Y	Y
		2	1300	1436.0	1866.80	-1190.14	-38.93	908	1431.72	-196.42	-12.06	Y	Y
		6	1080	1392.0	1503.36	-1553.58	-50.82	1300	830.77	-797.37	-48.97	Y	Y
2052	UB Mentholated	-1	598	2094.0	1252.21	NA	NA	921	649.29	NA	NA	Y	Y

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2052	VLN Mentholated	2	870	1611.0	1401.57	149.36	11.93	1190	731.09	81.80	12.60	Y	Y
		6	346	2735.0	946.31	-305.90	-24.43	664	521.08	-128.21	-19.75	Y	Y
2057	UB Mentholated	-1	553	3085.0	1706.01	NA	NA	646	856.04	NA	NA	Y	N
	VLN Mentholated	2	289	3805.0	1099.65	-606.36	-35.54	552	523.55	-332.49	-38.84	Y	N
		6	308	3820.0	1176.56	-529.45	-31.03	592	520.27	-335.77	-39.22	Y	N
2058	UB Mentholated	-1	621	1240.0	770.04	NA	NA	1410	440.43	NA	NA	Y	N
	VLN Mentholated	2	332	1621.0	538.17	-231.87	-30.11	1000	332.00	-108.43	-24.62	Y	N
		6	224	2198.0	492.35	-277.69	-36.06	763	293.58	-146.85	-33.34	Y	N
2059	UB Mentholated	-1	706	1545.0	1090.77	NA	NA	780	905.13	NA	NA	Y	Y
		2	843	1452.0	1224.04	133.27	12.22	785	1073.89	168.76	18.64	Y	Y
		6	743	1242.0	922.81	-167.96	-15.40	1100	675.45	-229.67	-25.37	Y	Y
2060	UB Mentholated	-1	1740	773.0	1345.02	NA	NA	1200	1450.00	NA	NA	Y	N
	VLN Mentholated	2	801	684.0	547.88	-797.14	-59.27	1230	651.22	-798.78	-55.09	Y	N
		6	906	1465.0	1327.29	-17.73	-1.32	971	933.06	-516.94	-35.65	Y	N
2064	UB Mentholated	-1	723	3404.0	2461.09	NA	NA	450	1606.67	NA	NA	Y	N
	VLN Mentholated	2	752	2844.0	2138.69	-322.40	-13.10	649	1158.71	-447.96	-27.88	Y	N
		6	606	2882.0	1746.49	-714.60	-29.04	572	1059.44	-547.23	-34.06	Y	N
2066	UB Mentholated	-1	1390	1056.0	1467.84	NA	NA	1810	767.96	NA	NA	Y	N

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2066	VLN Mentholated	2	1110	912.0	1012.32	-455.52	-31.03	1790	620.11	-147.84	-19.25	Y	N
		6	385	1617.0	622.55	-845.30	-57.59	1110	346.85	-421.11	-54.84	Y	N
2067	UB Non-mentholated	-1	565	2550.0	1440.75	NA	NA	643	878.69	NA	NA	Y	N
	VLN Non-mentholated	2	779	1608.0	1252.63	-188.12	-13.06	1070	728.04	-150.66	-17.15	Y	N
		6	503	2810.0	1413.43	-27.32	-1.90	654	769.11	-109.58	-12.47	Y	N
2075	UB Mentholated	-1	517	3995.0	2065.42	NA	NA	551	938.29	NA	NA	Y	Y
2076	UB Mentholated	-1	659	2036.0	1341.72	NA	NA	943	698.83	NA	NA	Y	N
	VLN Mentholated	2	327	2229.0	728.88	-612.84	-45.68	928	352.37	-346.46	-49.58	Y	N
		6	429	2063.0	885.03	-456.70	-34.04	1030	416.50	-282.33	-40.40	Y	N
2086	UB Non-mentholated	-1	1600	779.0	1246.40	NA	NA	1640	975.61	NA	NA	Y	N
	VLN Non-mentholated	2	910	1692.0	1539.72	293.32	23.53	1040	875.00	-100.61	-10.31	Y	N
2088	UB Mentholated	-1	451	3222.0	1453.12	NA	NA	480	939.58	NA	NA	Y	N
	VLN Mentholated	2	297	2854.0	847.64	-605.48	-41.67	601	494.18	-445.41	-47.40	Y	N
		6	269	2370.0	637.53	-815.59	-56.13	680	395.59	-544.00	-57.90	Y	N
2092	UB Mentholated	-1	329	2002.0	658.66	NA	NA	445	739.33	NA	NA	Y	N
	VLN Mentholated	2	234	1940.0	453.96	-204.70	-31.08	457	512.04	-227.29	-30.74	Y	N
		6	136	2262.0	307.63	-351.03	-53.29	391	347.83	-391.50	-52.95	Y	N
2099	UB Non-mentholated	-1	822	1107.0	909.95	NA	NA	1350	608.89	NA	NA	Y	N

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2099	VLN Non-mentholated	2	602	1523.0	916.85	6.89	0.76	968	621.90	13.01	2.14	Y	N
		6	827	1051.0	869.18	-40.78	-4.48	1430	578.32	-30.57	-5.02	Y	N
2100	UB Mentholated	-1	2150	577.0	1240.55	NA	NA	2130	1009.39	NA	NA	Y	Y
		2	1400	1028.0	1439.20	198.65	16.01	1200	1166.67	157.28	15.58	Y	Y
		6	2260	550.0	1243.00	2.45	0.20	2170	1041.47	32.08	3.18	Y	Y
2108	UB Non-mentholated VLN Non-mentholated	-1	490	2860.0	1401.40	NA	NA	286	1713.29	NA	NA	Y	N
		2	526	3150.0	1656.90	255.50	18.23	255	2062.75	349.46	20.40	Y	N
		6	364	3399.0	1237.24	-164.16	-11.71	252	1444.44	-268.84	-15.69	Y	N
2110	UB Mentholated	-1	934	1034.0	965.76	NA	NA	818	1141.81	NA	NA	Y	Y
		2	1090	799.0	870.91	-94.85	-9.82	1050	1038.10	-103.71	-9.08	Y	Y
		6	1390	653.0	907.67	-58.09	-6.01	1190	1168.07	26.26	2.30	Y	Y
2113	UB Mentholated VLN Mentholated	-1	1450	843.0	1222.35	NA	NA	1120	1294.64	NA	NA	Y	Y
		2	655	878.0	575.09	-647.26	-52.95	910	719.78	-574.86	-44.40	Y	Y
2115	UB Mentholated	-1	978	1626.0	1590.23	NA	NA	906	1079.47	NA	NA	Y	Y
2119	UB Mentholated VLN Mentholated	-1	2960	650.0	1924.00	NA	NA	2390	1238.49	NA	NA	Y	Y
		2	2230	786.0	1752.78	-171.22	-8.90	1910	1167.54	-70.95	-5.73	Y	Y
		6	2210	902.0	1993.42	69.42	3.61	1590	1389.94	151.44	12.23	Y	Y
2120	UB Non-mentholated	-1	651	1243.0	809.19	NA	NA	634	1026.81	NA	NA	Y	Y

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2120	VLN Non-mentholated	2	402	1147.0	461.09	-348.10	-43.02	646	622.29	-404.52	-39.40	Y	Y
		6	522	1735.0	905.67	96.48	11.92	488	1069.67	42.86	4.17	Y	Y
2122	UB Non-mentholated	-1	920	1396.0	1284.32	NA	NA	1050	876.19	NA	NA	Y	Y
		2	934	1487.0	1388.86	104.54	8.14	1010	924.75	48.56	5.54	Y	Y
		6	943	1643.0	1549.35	265.03	20.64	954	988.47	112.28	12.81	Y	Y
2125	UB Mentholated	-1	468	1819.0	851.29	NA	NA	1600	292.50	NA	NA	Y	Y
		2	316	3746.0	1183.74	332.44	39.05	755	418.54	126.04	43.09	Y	Y
		6	487	3110.0	1514.57	663.28	77.91	960	507.29	214.79	73.43	Y	Y
2126	UB Mentholated VLN Mentholated	-1	868	1339.0	1162.25	NA	NA	1200	723.33	NA	NA	Y	N
		2	784	1234.0	967.46	-194.80	-16.76	1110	706.31	-17.03	-2.35	Y	N
		6	1230	1047.0	1287.81	125.56	10.80	1510	814.57	91.24	12.61	Y	N
2136	UB Non-mentholated VLN Non-mentholated	-1	600	2199.0	1319.40	NA	NA	803	747.20	NA	NA	Y	N
		2	789	1100.0	867.90	-451.50	-34.22	1490	529.53	-217.67	-29.13	Y	N
2140	UB Non-mentholated	-1	1180	800.0	944.00	NA	NA	1470	802.72	NA	NA	Y	Y
		2	509	763.0	388.37	-555.63	-58.86	1610	316.15	-486.57	-60.62	Y	Y
		6	592	939.0	555.89	-388.11	-41.11	1250	473.60	-329.12	-41.00	Y	Y
2142	UB Non-mentholated	-1	1080	2406.0	2598.48	NA	NA	500	2160.00	NA	NA	Y	Y
2143	UB Non-mentholated	-1	829	2510.0	2080.79	NA	NA	595	1393.28	NA	NA	Y	Y

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

CFB = Change from Baseline, PCFB = Percent change from baseline, Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2143	VLN Non-mentholated	2	1060	2050.0	2173.00	92.21	4.43	756	1402.12	8.84	0.63	Y	Y
		6	838	2221.0	1861.20	-219.59	-10.55	729	1149.52	-243.76	-17.50	Y	Y
2158	UB Non-mentholated	-1	985	1684.0	1658.74	NA	NA	843	1168.45	NA	NA	Y	Y
		2	1160	1211.0	1404.76	-253.98	-15.31	1160	1000.00	-168.45	-14.42	Y	Y
2159	UB Non-mentholated VLN Non-mentholated	-1	1490	1506.0	2243.94	NA	NA	795	1874.21	NA	NA	Y	N
		2	1840	1042.0	1917.28	-326.66	-14.56	1100	1672.73	-201.49	-10.75	Y	N
		6	1780	1311.0	2333.58	89.64	3.99	1050	1695.24	-178.98	-9.55	Y	N
2164	UB Non-mentholated VLN Non-mentholated	-1	732	2448.0	1791.94	NA	NA	520	1407.69	NA	NA	Y	Y
		2	600	2822.0	1693.20	-98.74	-5.51	464	1293.10	-114.59	-8.14	Y	Y
		6	607	2302.0	1397.31	-394.62	-22.02	568	1068.66	-339.03	-24.08	Y	Y
2168	UB Non-mentholated VLN Non-mentholated	-1	1310	1464.0	1917.84	NA	NA	459	2854.03	NA	NA	Y	N
		2	1230	1163.0	1430.49	-487.35	-25.41	528	2329.55	-524.49	-18.38	Y	N
		6	1330	216.0	.	.	.	427	3114.75	260.72	9.14	N	N
2170	UB Non-mentholated	-1	1720	929.0	1597.88	NA	NA	1190	1445.38	NA	NA	Y	Y
		2	1550	1105.0	1712.75	114.87	7.19	1090	1422.02	-23.36	-1.62	Y	Y
		6	1790	1005.0	.	.	.	1550	1154.84	-290.54	-20.10	N	N
2175	UB Mentholated	-1	1160	1724.0	1999.84	NA	NA	736	1576.09	NA	NA	Y	Y
		2	816	1687.0	1376.59	-623.25	-31.16	776	1051.55	-524.54	-33.28	Y	Y

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2175	UB Mentholated	6	1080	1431.0	1545.48	-454.36	-22.72	916	1179.04	-397.05	-25.19	Y	Y
2189	UB Mentholated	-1	554	2385.0	1321.29	NA	NA	806	687.34	NA	NA	Y	Y
2211	UB Mentholated VLN Mentholated	-1	583	2088.0	1217.30	NA	NA	517	1127.66	NA	NA	Y	N
		2	571	1946.0	1111.17	-106.14	-8.72	591	966.16	-161.50	-14.32	Y	N
		6	445	297.0	132.17	-1085.14	-89.14	685	649.64	-478.02	-42.39	Y	N
2212	UB Mentholated	-1	904	1397.0	1262.89	NA	NA	1470	614.97	NA	NA	Y	Y
		2	689	1514.0	1043.15	-219.74	-17.40	1400	492.14	-122.82	-19.97	Y	Y
		6	981	1016.0	996.70	-266.19	-21.08	2070	473.91	-141.05	-22.94	Y	Y
2213	UB Mentholated VLN Mentholated	-1	901	2513.0	2264.21	NA	NA	930	968.82	NA	NA	Y	N
		2	939	2301.0	2160.64	-103.57	-4.57	969	969.04	0.22	0.02	Y	N
		6	1070	1689.0	1807.23	-456.98	-20.18	1350	792.59	-176.22	-18.19	Y	N
2215	UB Mentholated	-1	1030	1494.0	1538.82	NA	NA	753	1367.86	NA	NA	Y	Y
		2	812	1644.0	1334.93	-203.89	-13.25	669	1213.75	-154.11	-11.27	Y	Y
		6	1010	1321.0	1334.21	-204.61	-13.30	846	1193.85	-174.01	-12.72	Y	Y
2220	UB Non-mentholated VLN Non-mentholated	-1	1710	547.0	935.37	NA	NA	3260	524.54	NA	NA	Y	N
		2	1010	1054.0	1064.54	129.17	13.81	2100	480.95	-43.59	-8.31	Y	N
		6	1290	900.0	1161.00	225.63	24.12	2470	522.27	-2.27	-0.43	Y	N
2235	UB Mentholated	-1	1860	1046.0	1945.56	NA	NA	2100	885.71	NA	NA	Y	N

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2235	VLN Mentholated	2	839	1129.0	947.23	-998.33	-51.31	2020	415.35	-470.37	-53.11	Y	N
		6	1740	448.0	779.52	-1166.04	-59.93	2030	857.14	-28.57	-3.23	Y	N
2244	UB Non-mentholated	-1	1580	1370.0	2164.60	NA	NA	1230	1284.55	NA	NA	Y	N
	VLN Non-mentholated	2	1430	1012.0	1447.16	-717.44	-33.14	1940	737.11	-547.44	-42.62	Y	N
		6	1870	926.0	1731.62	-432.98	-20.00	1870	1000.00	-284.55	-22.15	Y	N
2247	UB Mentholated	-1	900	1591.0	1431.90	NA	NA	1430	629.37	NA	NA	Y	Y
	VLN Mentholated	2	653	1612.0	1052.64	-379.26	-26.49	1270	514.17	-115.20	-18.30	Y	Y
2251	UB Non-mentholated	-1	1030	1872.0	1928.16	NA	NA	1050	980.95	NA	NA	Y	Y
		2	1040	1851.0	1925.04	-3.12	-0.16	1140	912.28	-68.67	-7.00	Y	Y
		6	1990	1192.0	2372.08	443.92	23.02	1870	1064.17	83.22	8.48	Y	Y
2257	UB Non-mentholated	-1	429	2851.0	1223.08	NA	NA	393	1091.60	NA	NA	Y	Y
		2	683	1989.0	1358.49	135.41	11.07	497	1374.25	282.64	25.89	Y	Y
		6	586	1988.0	1164.97	-58.11	-4.75	427	1372.37	280.76	25.72	Y	Y
2259	UB Mentholated	-1	1300	1236.0	1606.80	NA	NA	2220	585.59	NA	NA	Y	Y
		2	1290	1039.0	1340.31	-266.49	-16.59	2440	528.69	-56.90	-9.72	Y	Y
		6	1560	999.0	1558.44	-48.36	-3.01	2520	619.05	33.46	5.71	Y	Y
2269	UB Mentholated	-1	986	1468.0	1447.45	NA	NA	1540	640.26	NA	NA	Y	N
	VLN Mentholated	2	202	353.0	71.31	-1376.14	-95.07	1120	180.36	-459.90	-71.83	Y	N

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Appendix 16.2.6.5 Urinary 3-HPMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2269	VLN Mentholated	6	310	845.0	261.95	-1185.50	-81.90	627	494.42	-145.84	-22.78	Y	N
2272	UB Mentholated	-1	1140	889.0	1013.46	NA	NA	2370	481.01	NA	NA	Y	N
	VLN Mentholated	2	703	1818.0	1278.05	264.59	26.11	1070	657.01	176.00	36.59	Y	N
		6	620	1589.0	985.18	-28.28	-2.79	1290	480.62	-0.39	-0.08	Y	N

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1001	UB Non-mentholated	-1	2.66	2171.0	5.77	NA	NA	499	5.33	NA	NA	Y	N
	VLN Non-mentholated	2	5.24	1172.6	6.14	0.37	6.40	804	6.52	1.19	22.26	Y	N
		6	5.07	1249.1	6.33	0.56	9.66	843	6.01	0.68	12.82	Y	N
1002	UB Non-mentholated	-1	7.92	4356.5	34.50	NA	NA	424	18.68	NA	NA	Y	N
	VLN Non-mentholated	2	11.7	4062.7	47.53	13.03	37.76	414	28.26	9.58	51.30	Y	N
		6	6.70	5759.6	38.59	4.09	11.84	333	20.12	1.44	7.71	Y	N
1003	UB Mentholated	-1	5.03	1385.0	6.97	NA	NA	1770	2.84	NA	NA	Y	N
	VLN Mentholated	2	8.81	410.0	3.61	-3.35	-48.15	2280	3.86	1.02	35.97	Y	N
		6	7.82	1017.7	7.96	0.99	14.24	2250	3.48	0.63	22.30	Y	N
1007	UB Non-mentholated	-1	0.795	1935.0	1.54	NA	NA	890	0.89	NA	NA	Y	Y
	VLN Non-mentholated	2	0.960	2199.9	2.11	0.57	37.29	947	1.01	0.12	13.49	Y	Y
		6	1.16	1700.3	1.97	0.43	28.21	1330	0.87	-0.02	-2.36	Y	Y
1008	UB Mentholated	-1	4.44	2014.0	8.94	NA	NA	1120	3.96	NA	NA	Y	N
	VLN Mentholated	2	6.34	1435.9	9.10	0.16	1.81	1550	4.09	0.13	3.18	Y	N
		6	2.28	1122.0	2.56	-6.38	-71.39	701	3.25	-0.71	-17.96	N	N
1010	UB Mentholated	-1	15.0	2030.0	30.45	NA	NA	941	15.94	NA	NA	Y	Y
		2	13.8	1539.6	21.25	-9.20	-30.23	1120	12.32	-3.62	-22.70	Y	Y
		6	8.35	1036.8	8.66	-21.79	-71.57	741	11.27	-4.67	-29.31	N	N

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1011	UB Non-mentholated	-1	7.66	1059.0	8.11	NA	NA	2360	3.25	NA	NA	Y	Y
		2	5.40	1364.0	7.37	-0.75	-9.20	1590	3.40	0.15	4.64	Y	Y
		6	5.23	628.7	3.29	-4.82	-59.47	1060	4.93	1.69	52.01	N	N
1013	UB Non-mentholated VLN Non-mentholated	-1	4.40	1664.0	7.32	NA	NA	1060	4.15	NA	NA	Y	N
		2	6.98	1043.8	.	.	.	1450	4.81	0.66	15.97	N	N
		6	6.08	874.0	5.31	-2.01	-27.42	1970	3.09	-1.06	-25.65	Y	N
1014	UB Mentholated VLN Mentholated	-1	2.86	2069.0	5.92	NA	NA	476	6.01	NA	NA	Y	N
		6	6.97	903.2	6.30	0.38	6.39	1330	5.24	-0.77	-12.78	Y	N
1015	UB Mentholated VLN Mentholated	-1	2.51	3550.0	8.91	NA	NA	371	6.77	NA	NA	Y	Y
		2	2.61	3406.2	8.89	-0.02	-0.23	373	7.00	0.23	3.43	Y	Y
		6	1.99	3477.7	6.92	-1.99	-22.33	392	5.08	-1.69	-24.96	Y	Y
1016	UB Non-mentholated	-1	4.41	1853.0	8.17	NA	NA	873	5.05	NA	NA	Y	Y
		2	3.12	2839.1	8.86	0.69	8.40	528	5.91	0.86	16.98	Y	Y
		6	5.53	1899.3	10.50	2.33	28.53	908	6.09	1.04	20.56	Y	Y
1017	UB Mentholated	-1	5.75	2490.0	14.32	NA	NA	507	11.34	NA	NA	Y	Y
		2	6.45	2593.9	16.73	2.41	16.85	529	12.19	0.85	7.51	Y	Y
		6	9.03	1399.2	12.63	-1.68	-11.75	920	9.82	-1.53	-13.46	Y	Y
1018	UB Mentholated	-1	0.491	1721.0	0.85	NA	NA	672	0.73	NA	NA	Y	Y

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1019	UB Non-mentholated	-1	4.70	1431.0	6.73	NA	NA	1750	2.69	NA	NA	Y	N
	VLN Non-mentholated	2	2.72	3109.0	8.46	1.73	25.73	762	3.57	0.88	32.91	Y	N
		6	3.34	2290.1	7.65	0.92	13.73	1110	3.01	0.32	12.04	Y	N
1020	UB Non-mentholated	-1	5.65	1666.0	9.41	NA	NA	773	7.31	NA	NA	Y	N
	VLN Non-mentholated	2	9.00	1240.9	11.17	1.76	18.65	1430	6.29	-1.02	-13.89	Y	N
		6	5.89	917.7	5.41	-4.01	-42.58	1280	4.60	-2.71	-37.04	Y	N
1021	UB Non-mentholated	-1	3.77	1808.0	6.82	NA	NA	681	5.54	NA	NA	N	N
		2	3.98	1842.4	7.33	.	.	710	5.61	.	.	Y	Y
		6	2.99	2136.5	6.39	.	.	637	4.69	.	.	Y	Y
1023	UB Non-mentholated	-1	1.03	2894.0	2.98	NA	NA	367	2.81	NA	NA	Y	N
	VLN Non-mentholated	2	0.830	3795.5	3.15	0.17	5.68	274	3.03	0.22	7.93	Y	N
		6	0.892	3600.0	3.21	0.23	7.73	334	2.67	-0.14	-4.84	Y	N
1029	UB Mentholated	-1	4.26	2525.2	10.76	NA	NA	554	7.69	NA	NA	Y	N
	VLN Mentholated	2	2.59	3098.0	8.02	-2.73	-25.41	505	5.13	-2.56	-33.30	Y	N
		6	4.71	2192.0	10.32	-0.43	-4.03	753	6.25	-1.43	-18.66	Y	N
1032	UB Mentholated	-1	2.88	3793.8	10.93	NA	NA	319	9.03	NA	NA	Y	Y
	VLN Mentholated	2	4.52	3479.0	15.73	4.80	43.92	411	11.00	1.97	21.81	Y	Y
		6	4.78	2345.0	11.21	0.28	2.59	602	7.94	-1.09	-12.05	Y	Y

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1034	UB Non-mentholated	-1	11.6	1275.1	14.79	NA	NA	1080	10.74	NA	NA	Y	N
	VLN Non-mentholated	2	11.3	969.0	10.95	-3.84	-25.97	1210	9.34	-1.40	-13.05	Y	N
		6	10.1	1037.0	10.47	-4.32	-29.19	1550	6.52	-4.22	-39.33	Y	N
1035	UB Non-mentholated	-1	5.45	2182.4	11.89	NA	NA	1180	4.62	NA	NA	Y	N
	VLN Non-mentholated	2	6.05	2196.0	13.29	1.39	11.70	726	8.33	3.71	80.43	Y	N
		6	7.36	1204.0	8.86	-3.03	-25.50	1400	5.26	0.64	13.82	Y	N
1036	UB Mentholated	-1	0.769	1896.8	1.46	NA	NA	761	1.01	NA	NA	Y	Y
		2	0.932	1841.0	1.72	0.26	17.63	793	1.18	0.16	16.31	Y	Y
		6	1.24	1475.0	1.83	0.37	25.39	1110	1.12	0.11	10.55	Y	Y
1037	UB Mentholated	-1	3.51	5986.4	21.01	NA	NA	350	10.03	NA	NA	Y	Y
		2	6.55	2822.0	18.48	-2.53	-12.03	698	9.38	-0.64	-6.43	Y	Y
		6	8.23	2712.0	22.32	1.31	6.22	651	12.64	2.61	26.06	Y	Y
1038	UB Non-mentholated	-1	5.10	1610.1	8.21	NA	NA	802	6.36	NA	NA	Y	N
	VLN Non-mentholated	2	1.96	1705.0	3.34	-4.87	-59.30	830	2.36	-4.00	-62.87	Y	N
		6	4.20	1641.0	6.89	-1.32	-16.07	894	4.70	-1.66	-26.12	Y	N
1042	UB Non-mentholated	-1	1.51	5646.2	8.53	NA	NA	353	4.28	NA	NA	Y	N
	VLN Non-mentholated	2	1.29	3586.0	4.63	-3.90	-45.74	380	3.39	-0.88	-20.64	Y	N
		6	0.935	2769.0	2.59	-5.94	-69.63	429	2.18	-2.10	-49.05	Y	N

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

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VLN non-mentholated = Non-mentholated VLN cigarettes

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1045	UB Non-mentholated	-1	2.98	3025.5	9.02	NA	NA	613	4.86	NA	NA	Y	Y
		2	3.29	2443.0	8.04	-0.98	-10.85	654	5.03	0.17	3.48	Y	Y
		6	3.98	1894.0	7.54	-1.48	-16.39	921	4.32	-0.54	-11.11	Y	Y
1046	UB Mentholated	-1	2.37	3780.8	8.96	NA	NA	570	4.16	NA	NA	Y	Y
		2	3.13	2832.0	8.86	-0.10	-1.08	670	4.67	0.51	12.36	Y	Y
		6	2.88	2830.0	8.15	-0.81	-9.04	806	3.57	-0.58	-14.06	Y	Y
1050	UB Non-mentholated VLN Non-mentholated	-1	2.24	1520.3	3.41	NA	NA	781	2.87	NA	NA	Y	N
		2	1.29	3144.1	4.06	0.65	19.10	472	2.73	-0.14	-4.71	Y	N
		6	2.53	1578.0	3.99	0.59	17.23	825	3.07	0.20	6.92	Y	N
1051	UB Mentholated	-1	2.81	2216.8	6.23	NA	NA	762	3.69	NA	NA	Y	Y
		2	2.03	2040.0	4.14	-2.09	-33.52	789	2.57	-1.11	-30.23	Y	Y
		6	2.34	1784.0	4.17	-2.05	-32.98	1050	2.23	-1.46	-39.57	Y	Y
1052	UB Mentholated VLN Mentholated	-1	0.897	1539.8	1.38	NA	NA	1300	0.69	NA	NA	Y	N
		2	0.920	1602.0	1.47	0.09	6.71	1130	0.81	0.12	17.99	Y	N
		6	1.24	1065.0	1.32	-0.06	-4.39	1850	0.67	-0.02	-2.86	Y	N
1053	UB Mentholated VLN Mentholated	-1	0.448	2902.3	1.30	NA	NA	795	0.56	NA	NA	Y	N
		2	0.403	2790.0	1.12	-0.18	-13.53	933	0.43	-0.13	-23.35	Y	N
		6	0.238	2523.0	0.60	-0.70	-53.82	914	0.26	-0.30	-53.79	Y	N

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1054	UB Non-mentholated	-1	10.0	956.9	9.57	NA	NA	2550	3.92	NA	NA	Y	Y
		2	5.14	1844.0	9.48	-0.09	-0.95	1180	4.36	0.43	11.08	Y	Y
		6	6.15	1089.0	6.70	-2.87	-30.01	2130	2.89	-1.03	-26.37	Y	Y
1055	UB Mentholated VLN Mentholated	-1	4.89	3328.9	16.28	NA	NA	451	10.84	NA	NA	Y	N
		2	6.20	3391.6	21.03	4.75	29.18	495	12.53	1.68	15.52	Y	N
		6	7.53	1581.0	11.90	-4.37	-26.87	955	7.88	-2.96	-27.28	Y	N
1056	UB Non-mentholated VLN Non-mentholated	-1	0.187	3925.2	0.73	NA	NA	416	0.45	NA	NA	Y	N
		2	0.448	1334.0	0.60	-0.14	-18.58	799	0.56	0.11	24.73	Y	N
		6	0.401	1152.0	0.46	-0.27	-37.06	785	0.51	0.06	13.64	Y	N
1058	UB Non-mentholated VLN Non-mentholated	-1	1.05	3355.1	3.52	NA	NA	518	2.03	NA	NA	Y	N
		2	0.947	2869.0	2.72	-0.81	-22.88	520	1.82	-0.21	-10.16	Y	N
		6	1.45	1927.0	2.79	-0.73	-20.69	1190	1.22	-0.81	-39.89	Y	N
1059	UB Non-mentholated	-1	13.4	956.0	12.81	NA	NA	2300	5.83	NA	NA	Y	Y
		2	4.43	2124.7	9.41	-3.40	-26.53	1040	4.26	-1.57	-26.89	Y	Y
		6	7.17	1507.0	10.81	-2.01	-15.65	1750	4.10	-1.73	-29.68	Y	Y
1060	UB Mentholated VLN Mentholated	-1	3.62	2414.0	8.74	NA	NA	751	4.82	NA	NA	Y	N
		2	3.88	2361.4	9.16	0.42	4.85	782	4.96	0.14	2.93	Y	N
		6	3.44	1742.0	5.99	-2.75	-31.43	950	3.62	-1.20	-24.88	Y	N

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1063	UB Mentholated	-1	1.15	7095.2	8.16	NA	NA	306	3.76	NA	NA	Y	Y
	VLN Mentholated	2	1.53	3891.4	5.95	-2.21	-27.03	569	2.69	-1.07	-28.45	Y	Y
		6	1.18	3208.0	3.79	-4.37	-53.61	787	1.50	-2.26	-60.10	Y	Y
1064	UB Non-mentholated	-1	2.70	3268.0	8.82	NA	NA	749	3.60	NA	NA	Y	Y
		2	3.49	2273.1	7.93	-0.89	-10.09	1060	3.29	-0.31	-8.66	Y	Y
1066	UB Non-mentholated	-1	8.67	967.0	8.38	NA	NA	2190	3.96	NA	NA	Y	Y
	VLN Non-mentholated	2	8.27	1744.8	14.43	6.05	72.11	1050	7.88	3.92	98.95	Y	Y
		6	8.12	1725.0	14.01	5.62	67.07	1220	6.66	2.70	68.12	Y	Y
1069	UB Non-mentholated	-1	4.16	2554.0	10.62	NA	NA	793	5.25	NA	NA	Y	Y
		2	3.30	2465.9	8.14	-2.49	-23.41	783	4.21	-1.03	-19.66	Y	Y
		6	4.06	2162.0	8.78	-1.85	-17.38	973	4.17	-1.07	-20.46	Y	Y
1070	UB Non-mentholated	-1	5.35	3393.0	18.15	NA	NA	633	8.45	NA	NA	Y	Y
	VLN Non-mentholated	2	7.32	2687.1	19.67	1.52	8.36	752	9.73	1.28	15.17	Y	Y
		6	8.33	1316.0	10.96	-7.19	-39.61	1800	4.63	-3.82	-45.25	Y	Y
1071	UB Non-mentholated	-1	1.33	2129.0	2.83	NA	NA	700	1.90	NA	NA	Y	N
	VLN Non-mentholated	2	1.27	2212.3	2.81	-0.02	-0.78	1230	1.03	-0.87	-45.66	Y	N
1072	UB Mentholated	-1	2.47	2181.0	5.39	NA	NA	806	3.06	NA	NA	Y	Y
	VLN Mentholated	2	3.01	1779.7	5.36	-0.03	-0.56	955	3.15	0.09	2.85	Y	Y

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1074	UB Non-mentholated	-1	0.437	2211.0	0.97	NA	NA	876	0.50	NA	NA	Y	N
	VLN Non-mentholated	2	0.754	1464.3	1.10	0.14	14.27	1350	0.56	0.06	11.96	Y	N
		6	0.407	1677.0	0.68	-0.28	-29.36	1310	0.31	-0.19	-37.72	Y	N
1075	UB Non-mentholated	-1	5.79	2163.0	12.52	NA	NA	773	7.49	NA	NA	Y	Y
		2	6.59	1890.7	12.46	-0.06	-0.51	845	7.80	0.31	4.12	Y	Y
		6	8.99	1263.0	11.35	-1.17	-9.34	1340	6.71	-0.78	-10.43	Y	Y
1077	UB Non-mentholated	-1	4.07	3102.1	12.63	NA	NA	493	8.26	NA	NA	Y	Y
	VLN Non-mentholated	2	6.95	3008.3	20.91	8.28	65.60	596	11.66	3.41	41.25	Y	Y
		6	6.48	2743.0	17.77	5.15	40.78	693	9.35	1.10	13.26	Y	Y
1078	UB Non-mentholated	-1	5.00	1991.0	9.96	NA	NA	597	8.38	NA	NA	Y	N
	VLN Non-mentholated	2	2.97	3513.1	10.43	0.48	4.81	352	8.44	0.06	0.74	Y	N
		6	4.40	2384.0	10.49	0.53	5.37	654	6.73	-1.65	-19.67	Y	N
1079	UB Mentholated	-1	6.41	2154.0	13.81	NA	NA	1370	4.68	NA	NA	Y	Y
	VLN Mentholated	2	3.35	3647.6	12.22	-1.59	-11.50	802	4.18	-0.50	-10.72	Y	Y
		6	2.82	2605.0	7.35	-6.46	-46.79	1040	2.71	-1.97	-42.05	Y	Y
1082	UB Non-mentholated	-1	6.80	2790.0	18.97	NA	NA	843	8.07	NA	NA	Y	N
	VLN Non-mentholated	2	8.49	2629.9	22.33	3.36	17.69	926	9.17	1.10	13.66	Y	N
		6	6.35	2013.0	12.78	-6.19	-32.62	1200	5.29	-2.77	-34.40	Y	N

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1083	UB Non-mentholated	-1	1.66	1708.0	2.84	NA	NA	762	2.18	NA	NA	Y	N
	VLN Non-mentholated	2	2.20	1788.0	3.93	1.10	38.74	892	2.47	0.29	13.22	Y	N
		6	2.50	2017.0	5.04	2.21	77.85	804	3.11	0.93	42.74	Y	N
1084	UB Non-mentholated	-1	3.09	1467.0	4.53	NA	NA	1380	2.24	NA	NA	Y	N
	VLN Non-mentholated	2	2.96	1158.4	3.43	-1.10	-24.36	1630	1.82	-0.42	-18.90	Y	N
1086	UB Non-mentholated	-1	7.31	1938.0	14.17	NA	NA	968	7.55	NA	NA	Y	N
	VLN Non-mentholated	2	13.8	1255.9	17.33	3.16	22.34	1410	9.79	2.24	29.60	Y	N
		6	8.98	1580.0	14.19	0.02	0.15	1040	8.63	1.08	14.34	Y	N
1088	UB Mentholated	-1	4.07	1662.0	6.76	NA	NA	1670	2.44	NA	NA	Y	N
	VLN Mentholated	2	4.13	1236.2	5.11	-1.66	-24.52	1820	2.27	-0.17	-6.89	Y	N
		6	4.30	1670.0	7.18	0.42	6.16	1520	2.83	0.39	16.08	Y	N
1089	UB Non-mentholated	-1	3.49	1795.0	6.26	NA	NA	669	5.22	NA	NA	Y	Y
		2	2.25	2415.3	5.43	-0.83	-13.25	544	4.14	-1.08	-20.72	Y	Y
		6	2.33	2062.0	4.80	-1.46	-23.31	559	4.17	-1.05	-20.10	Y	Y
1092	UB Mentholated	-1	4.65	2383.0	11.08	NA	NA	734	6.34	NA	NA	Y	N
	VLN Mentholated	2	5.58	1551.7	8.66	-2.42	-21.86	898	6.21	-0.12	-1.92	Y	N
		6	5.28	1587.0	8.38	-2.70	-24.38	1150	4.59	-1.74	-27.53	Y	N
1094	UB Mentholated	-1	3.69	1930.0	7.12	NA	NA	1230	3.00	NA	NA	Y	N

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1094	VLN Mentholated	2	7.53	1307.6	9.85	2.72	38.26	1720	4.38	1.38	45.93	Y	N
		6	4.31	1040.0	4.48	-2.64	-37.06	1930	2.23	-0.77	-25.56	Y	N
1095	UB Mentholated	-1	1.12	2551.0	2.86	NA	NA	514	2.18	NA	NA	Y	N
	VLN Mentholated	2	2.29	430.3	0.99	-1.87	-65.51	982	2.33	0.15	7.02	N	N
		6	0.794	2131.0	1.69	-1.17	-40.78	390	2.04	-0.14	-6.57	Y	N
1096	UB Non-mentholated	-1	4.23	2532.0	10.71	NA	NA	634	6.67	NA	NA	Y	N
	VLN Non-mentholated	2	3.82	1934.5	7.39	-3.32	-31.00	679	5.63	-1.05	-15.68	Y	N
		6	2.93	2949.0	8.64	-2.07	-19.33	488	6.00	-0.67	-10.01	Y	N
1097	UB Mentholated	-1	8.69	1982.0	17.22	NA	NA	1250	6.95	NA	NA	Y	N
	VLN Mentholated	2	5.13	1598.3	8.20	-9.02	-52.40	1510	3.40	-3.55	-51.13	Y	N
		6	3.25	1814.0	5.90	-11.33	-65.77	1270	2.56	-4.39	-63.19	Y	N
1098	UB Non-mentholated	-1	3.18	1415.8	4.50	NA	NA	1060	3.00	NA	NA	Y	Y
	VLN Non-mentholated	2	4.17	1666.1	6.95	2.45	54.31	958	4.35	1.35	45.09	Y	Y
		6	3.18	1811.0	5.76	1.26	27.91	895	3.55	0.55	18.44	Y	Y
1099	UB Non-mentholated	-1	2.22	810.2	.	NA	NA	1420	1.56	NA	NA	N	N
	VLN Non-mentholated	2	2.15	1272.2	2.74	.	.	1060	2.03	.	.	Y	N
		6	2.91	1005.0	2.92	.	.	1250	2.33	.	.	Y	N
1100	UB Non-mentholated	-1	0.446	3350.7	1.49	NA	NA	550	0.81	NA	NA	Y	N

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

CFB = Change from Baseline, PCFB = Percent change from baseline, Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1100	VLN Non-mentholated	2	0.614	2653.5	1.63	0.13	9.02	684	0.90	0.09	10.70	Y	N
		6	0.546	2576.0	1.41	-0.09	-5.88	772	0.71	-0.10	-12.78	Y	N
1101	UB Non-mentholated	-1	5.50	1814.1	9.98	NA	NA	827	6.65	NA	NA	Y	N
	VLN Non-mentholated	2	4.83	2317.4	11.19	1.22	12.18	805	6.00	-0.65	-9.78	Y	N
		6	2.74	3707.0	10.16	0.18	1.80	258	10.62	3.97	59.69	Y	N
1103	UB Non-mentholated	-1	3.18	3479.4	11.06	NA	NA	297	10.71	NA	NA	Y	N
	VLN Non-mentholated	2	5.21	2449.2	12.76	1.70	15.33	762	6.84	-3.87	-36.14	Y	N
		6	4.67	2601.0	12.15	1.08	9.78	763	6.12	-4.59	-42.84	Y	N
1105	UB Non-mentholated	-1	8.32	527.3	4.39	NA	NA	1680	4.95	NA	NA	Y	N
	VLN Non-mentholated	2	9.03	825.2	7.45	3.06	69.85	1010	8.94	3.99	80.53	Y	N
		6	6.03	677.0	4.08	-0.30	-6.95	1420	4.25	-0.71	-14.25	Y	N
1106	UB Non-mentholated	-1	4.84	1380.1	6.68	NA	NA	1870	2.59	NA	NA	Y	Y
		2	5.44	1113.7	6.06	-0.62	-9.30	2330	2.33	-0.25	-9.79	Y	Y
		6	2.65	2435.0	6.45	-0.23	-3.40	968	2.74	0.15	5.77	Y	Y
1107	UB Non-mentholated	-1	1.46	2365.5	3.45	NA	NA	913	1.60	NA	NA	Y	N
	VLN Non-mentholated	2	3.21	2512.8	8.07	4.61	133.55	854	3.76	2.16	135.05	Y	N
		6	2.09	2599.0	5.43	1.98	57.28	806	2.59	0.99	62.15	Y	N
1108	UB Non-mentholated	-1	0.690	1782.0	1.23	NA	NA	1150	0.60	NA	NA	Y	Y

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

CFB = Change from Baseline, PCFB = Percent change from baseline, Subjects used their own usual brand cigarettes at Week -1.

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1108	UB Non-mentholated	2	0.593	2115.4	1.25	0.02	2.02	966	0.61	0.01	2.31	Y	Y
		6	0.558	1981.0	1.11	-0.12	-10.10	1030	0.54	-0.06	-9.71	Y	Y
1109	UB Non-mentholated	-1	3.38	1615.9	5.46	NA	NA	950	3.56	NA	NA	Y	Y
		2	3.37	1805.0	6.08	0.62	11.37	919	3.67	0.11	3.07	Y	Y
		6	4.92	1075.0	5.29	-0.17	-3.16	1490	3.30	-0.26	-7.19	Y	Y
1112	UB Non-mentholated VLN Non-mentholated	-1	0.420	2265.2	0.95	NA	NA	428	0.98	NA	NA	Y	N
		2	1.48	1829.3	2.71	1.76	184.57	613	2.41	1.43	146.03	Y	N
		6	0.953	2121.0	2.02	1.07	112.46	531	1.79	0.81	82.89	Y	N
1114	UB Non-mentholated	-1	2.52	1506.7	3.80	NA	NA	754	3.34	NA	NA	Y	Y
		2	1.12	2909.4	3.26	-0.54	-14.18	403	2.78	-0.56	-16.85	Y	Y
		6	1.64	1920.0	3.15	-0.65	-17.07	661	2.48	-0.86	-25.76	Y	Y
1115	UB Non-mentholated VLN Non-mentholated	-1	3.17	1785.7	5.66	NA	NA	1590	1.99	NA	NA	Y	Y
		2	4.68	1601.3	7.49	1.83	32.39	1770	2.64	0.65	32.62	Y	Y
2002	UB Mentholated	-1	3.51	2188.0	7.68	NA	NA	803	4.37	NA	NA	Y	Y
		2	3.58	1893.0	6.78	-0.90	-11.76	915	3.91	-0.46	-10.49	Y	Y
		6	3.60	3245.0	11.68	4.00	52.11	569	6.33	1.96	44.74	Y	Y
2003	UB Mentholated VLN Mentholated	-1	2.76	3036.0	8.38	NA	NA	342	8.07	NA	NA	Y	N
		2	2.52	4180.0	10.53	2.15	25.71	348	7.24	-0.83	-10.27	Y	N

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2003	VLN Mentholated	6	2.06	3245.0	6.68	-1.69	-20.22	373	5.52	-2.55	-31.57	Y	N
2007	UB Non-mentholated VLN Non-mentholated	-1	4.15	1535.0	6.37	NA	NA	696	5.96	NA	NA	Y	Y
		2	6.22	1492.0	9.28	2.91	45.68	725	8.58	2.62	43.88	Y	Y
		6	5.53	1387.0	7.67	1.30	20.41	828	6.68	0.72	12.01	Y	Y
2008	UB Mentholated VLN Mentholated	-1	1.20	2663.0	3.20	NA	NA	900	1.33	NA	NA	Y	Y
		2	0.522	3323.0	1.73	-1.46	-45.72	709	0.74	-0.60	-44.78	Y	Y
		6	0.791	1734.0	1.37	-1.82	-57.08	1300	0.61	-0.72	-54.37	Y	Y
2009	UB Non-mentholated VLN Non-mentholated	-1	1.42	2427.0	3.45	NA	NA	807	1.76	NA	NA	Y	N
		2	3.42	1390.0	4.75	1.31	37.94	1420	2.41	0.65	36.87	Y	N
2010	UB Mentholated	-1	0.997	1673.0	1.67	NA	NA	1650	0.60	NA	NA	Y	Y
		2	0.921	1289.0	1.19	-0.48	-28.83	1390	0.66	0.06	9.66	Y	Y
		6	1.05	1158.0	1.22	-0.45	-27.10	2350	0.45	-0.16	-26.05	Y	Y
2011	UB Mentholated VLN Mentholated	-1	2.56	1639.0	4.20	NA	NA	1010	2.53	NA	NA	Y	N
		2	2.57	1510.0	3.88	-0.32	-7.51	1110	2.32	-0.22	-8.65	Y	N
		6	3.22	1165.0	3.75	-0.44	-10.59	1510	2.13	-0.40	-15.87	Y	N
2014	UB Mentholated VLN Mentholated	-1	3.07	3009.0	9.24	NA	NA	738	4.16	NA	NA	Y	N
		2	10.3	1438.0	14.81	5.57	60.34	1410	7.30	3.15	75.60	Y	N
		6	4.48	2776.0	12.44	3.20	34.63	718	6.24	2.08	49.99	Y	N

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2015	UB Mentholated	-1	5.37	1277.0	6.86	NA	NA	1080	4.97	NA	NA	Y	Y
		2	5.77	1774.0	10.24	3.38	49.27	800	7.21	2.24	45.06	Y	Y
		6	6.70	1070.0	7.17	0.31	4.54	1620	4.14	-0.84	-16.82	Y	Y
2016	UB Mentholated	-1	2.81	1787.0	5.02	NA	NA	642	4.38	NA	NA	Y	Y
2017	UB Mentholated VLN Mentholated	-1	2.41	1504.0	3.62	NA	NA	1290	1.87	NA	NA	Y	N
		2	1.88	1864.0	3.50	-0.12	-3.32	1110	1.69	-0.17	-9.34	Y	N
		6	1.98	1210.0	2.40	-1.23	-33.90	1530	1.29	-0.57	-30.73	Y	N
2018	UB Mentholated	-1	2.88	1191.0	3.43	NA	NA	1390	2.07	NA	NA	Y	Y
		2	2.84	1374.0	3.90	0.47	13.76	1120	2.54	0.46	22.38	Y	Y
		6	5.01	963.0	4.82	1.39	40.66	1620	3.09	1.02	49.26	Y	Y
2020	UB Mentholated VLN Mentholated	-1	3.18	1117.0	3.55	NA	NA	919	3.46	NA	NA	Y	N
		2	3.08	1155.0	3.56	0.01	0.15	1070	2.88	-0.58	-16.81	Y	N
		6	2.28	1300.0	2.96	-0.59	-16.56	929	2.45	-1.01	-29.07	Y	N
2021	UB Mentholated VLN Mentholated	-1	3.51	2086.0	7.32	NA	NA	1120	3.13	NA	NA	Y	Y
		2	2.63	2606.0	6.85	-0.47	-6.39	909	2.89	-0.24	-7.68	Y	Y
		6	2.00	2561.0	5.12	-2.20	-30.05	821	2.44	-0.70	-22.27	Y	Y
2023	UB Mentholated VLN Mentholated	-1	2.14	996.0	2.13	NA	NA	2220	0.96	NA	NA	Y	Y
		2	1.17	1252.0	1.46	-0.67	-31.27	1650	0.71	-0.25	-26.44	Y	Y

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2023	VLN Mentholated	6	1.31	999.0	1.31	-0.82	-38.60	2180	0.60	-0.36	-37.66	Y	Y
2024	UB Non-mentholated	-1	6.69	1112.0	7.44	NA	NA	1690	3.96	NA	NA	Y	Y
2025	UB Non-mentholated	-1	5.64	2766.0	15.60	NA	NA	674	8.37	NA	NA	Y	Y
		2	5.94	2484.0	14.75	-0.85	-5.42	844	7.04	-1.33	-15.89	Y	Y
		6	6.68	2746.0	18.34	2.74	17.58	866	7.71	-0.65	-7.82	Y	Y
2028	UB Non-mentholated VLN Non-mentholated	-1	0.830	1538.0	1.28	NA	NA	1270	0.65	NA	NA	Y	Y
		2	0.450	1876.0	0.84	-0.43	-33.87	834	0.54	-0.11	-17.44	Y	Y
		6	0.751	616.0	0.46	-0.81	-63.76	1780	0.42	-0.23	-35.44	Y	Y
2029	UB Mentholated	-1	2.23	1689.0	3.77	NA	NA	996	2.24	NA	NA	Y	Y
		2	2.55	1933.0	4.93	1.16	30.87	855	2.98	0.74	33.21	Y	Y
		6	2.12	2068.0	4.38	0.62	16.40	789	2.69	0.45	20.01	Y	Y
2039	UB Mentholated VLN Mentholated	-1	1.05	1765.0	1.85	NA	NA	762	1.38	NA	NA	Y	N
		2	0.797	1582.0	1.26	-0.59	-31.97	711	1.12	-0.26	-18.65	Y	N
		6	0.838	718.0	0.60	-1.25	-67.53	898	0.93	-0.44	-32.28	Y	N
2050	UB Mentholated	-1	6.79	1887.0	12.81	NA	NA	995	6.82	NA	NA	Y	Y
		2	6.46	1436.0	9.28	-3.54	-27.60	908	7.11	0.29	4.26	Y	Y
		6	5.95	1392.0	8.28	-4.53	-35.36	1300	4.58	-2.25	-32.93	Y	Y
2052	UB Mentholated	-1	2.61	2094.0	5.47	NA	NA	921	2.83	NA	NA	Y	Y

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Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2052	VLN Mentholated	2	3.92	1611.0	6.32	0.85	15.55	1190	3.29	0.46	16.24	Y	Y
		6	2.34	2735.0	6.40	0.93	17.10	664	3.52	0.69	24.36	Y	Y
2057	UB Mentholated	-1	4.09	3085.0	12.62	NA	NA	646	6.33	NA	NA	Y	N
	VLN Mentholated	2	2.80	3805.0	10.65	-1.96	-15.56	552	5.07	-1.26	-19.88	Y	N
		6	3.03	3820.0	11.57	-1.04	-8.27	592	5.12	-1.21	-19.16	Y	N
2058	UB Mentholated	-1	8.67	1240.0	10.75	NA	NA	1410	6.15	NA	NA	Y	N
	VLN Mentholated	2	4.11	1621.0	6.66	-4.09	-38.03	1000	4.11	-2.04	-33.16	Y	N
		6	3.72	2198.0	8.18	-2.57	-23.94	763	4.88	-1.27	-20.71	Y	N
2059	UB Mentholated	-1	1.54	1545.0	2.38	NA	NA	780	1.97	NA	NA	Y	Y
		2	1.77	1452.0	2.57	0.19	8.02	785	2.25	0.28	14.20	Y	Y
		6	2.08	1242.0	2.58	0.20	8.58	1100	1.89	-0.08	-4.23	Y	Y
2060	UB Mentholated	-1	8.85	773.0	6.84	NA	NA	1200	7.38	NA	NA	Y	N
	VLN Mentholated	2	5.31	684.0	3.63	-3.21	-46.91	1230	4.32	-3.06	-41.46	Y	N
		6	6.32	1465.0	9.26	2.42	35.34	971	6.51	-0.87	-11.75	Y	N
2064	UB Mentholated	-1	3.26	3404.0	11.10	NA	NA	450	7.24	NA	NA	Y	N
	VLN Mentholated	2	4.46	2844.0	12.68	1.59	14.30	649	6.87	-0.37	-5.14	Y	N
		6	3.70	2882.0	10.66	-0.43	-3.91	572	6.47	-0.78	-10.71	Y	N
2066	UB Mentholated	-1	4.14	1056.0	4.37	NA	NA	1810	2.29	NA	NA	Y	N

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Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2066	VLN Mentholated	2	4.70	912.0	4.29	-0.09	-1.95	1790	2.63	0.34	14.80	Y	N
		6	2.40	1617.0	3.88	-0.49	-11.23	1110	2.16	-0.13	-5.47	Y	N
2067	UB Non-mentholated	-1	3.42	2550.0	8.72	NA	NA	643	5.32	NA	NA	Y	N
	VLN Non-mentholated	2	6.15	1608.0	9.89	1.17	13.40	1070	5.75	0.43	8.06	Y	N
		6	3.30	2810.0	9.27	0.55	6.33	654	5.05	-0.27	-5.13	Y	N
2075	UB Mentholated	-1	2.02	3995.0	8.07	NA	NA	551	3.67	NA	NA	Y	Y
2076	UB Mentholated	-1	1.06	2036.0	2.16	NA	NA	943	1.12	NA	NA	Y	N
	VLN Mentholated	2	0.678	2229.0	1.51	-0.65	-29.97	928	0.73	-0.39	-35.00	Y	N
		6	0.619	2063.0	1.28	-0.88	-40.83	1030	0.60	-0.52	-46.54	Y	N
2086	UB Non-mentholated	-1	5.02	779.0	3.91	NA	NA	1640	3.06	NA	NA	Y	N
	VLN Non-mentholated	2	4.19	1692.0	7.09	3.18	81.29	1040	4.03	0.97	31.62	Y	N
2088	UB Mentholated	-1	0.392	3222.0	1.26	NA	NA	480	0.82	NA	NA	Y	N
	VLN Mentholated	2	0.343	2854.0	0.98	-0.28	-22.49	601	0.57	-0.25	-30.12	Y	N
		6	0.419	2370.0	0.99	-0.27	-21.38	680	0.62	-0.20	-24.55	Y	N
2092	UB Mentholated	-1	2.70	2002.0	5.41	NA	NA	445	6.07	NA	NA	Y	N
	VLN Mentholated	2	2.73	1940.0	5.30	-0.11	-2.02	457	5.97	-0.09	-1.54	Y	N
		6	0.898	2262.0	2.03	-3.37	-62.42	391	2.30	-3.77	-62.15	Y	N
2099	UB Non-mentholated	-1	3.76	1107.0	4.16	NA	NA	1350	2.79	NA	NA	Y	N

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

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VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2099	VLN Non-mentholated	2	3.81	1523.0	5.80	1.64	39.41	968	3.94	1.15	41.32	Y	N
		6	4.72	1051.0	4.96	0.80	19.18	1430	3.30	0.52	18.51	Y	N
2100	UB Mentholated	-1	20.8	577.0	12.00	NA	NA	2130	9.77	NA	NA	Y	Y
		2	14.4	1028.0	14.80	2.80	23.34	1200	12.00	2.23	22.88	Y	Y
		6	25.4	550.0	13.97	1.97	16.40	2170	11.71	1.94	19.86	Y	Y
2108	UB Non-mentholated VLN Non-mentholated	-1	2.09	2860.0	5.98	NA	NA	286	7.31	NA	NA	Y	N
		2	2.67	3150.0	8.41	2.43	40.70	255	10.47	3.16	43.28	Y	N
		6	2.10	3399.0	7.14	1.16	19.41	252	8.33	1.03	14.04	Y	N
2110	UB Mentholated	-1	4.50	1034.0	4.65	NA	NA	818	5.50	NA	NA	Y	Y
		2	5.51	799.0	4.40	-0.25	-5.38	1050	5.25	-0.25	-4.61	Y	Y
		6	4.62	653.0	3.02	-1.64	-35.16	1190	3.88	-1.62	-29.43	Y	Y
2113	UB Mentholated VLN Mentholated	-1	4.53	843.0	3.82	NA	NA	1120	4.04	NA	NA	Y	Y
		2	2.12	878.0	1.86	-1.96	-51.26	910	2.33	-1.71	-42.40	Y	Y
2115	UB Mentholated	-1	2.76	1626.0	4.49	NA	NA	906	3.05	NA	NA	Y	Y
2119	UB Mentholated VLN Mentholated	-1	9.64	650.0	6.27	NA	NA	2390	4.03	NA	NA	Y	Y
		2	10.7	786.0	8.41	2.14	34.22	1910	5.60	1.57	38.89	Y	Y
		6	9.75	902.0	8.79	2.53	40.35	1590	6.13	2.10	52.03	Y	Y
2120	UB Non-mentholated	-1	1.35	1243.0	1.68	NA	NA	634	2.13	NA	NA	Y	Y

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2120	VLN Non-mentholated	2	1.37	1147.0	1.57	-0.11	-6.36	646	2.12	-0.01	-0.40	Y	Y
		6	1.38	1735.0	2.39	0.72	42.68	488	2.83	0.70	32.81	Y	Y
2122	UB Non-mentholated	-1	9.98	1396.0	13.93	NA	NA	1050	9.50	NA	NA	Y	Y
		2	10.4	1487.0	15.46	1.53	11.00	1010	10.30	0.79	8.34	Y	Y
		6	7.72	1643.0	12.68	-1.25	-8.96	954	8.09	-1.41	-14.86	Y	Y
2125	UB Mentholated	-1	1.20	1819.0	2.18	NA	NA	1600	0.75	NA	NA	Y	Y
		2	0.810	3746.0	3.03	0.85	39.01	755	1.07	0.32	43.05	Y	Y
		6	1.20	3110.0	3.73	1.55	70.97	960	1.25	0.50	66.67	Y	Y
2126	UB Mentholated VLN Mentholated	-1	3.97	1339.0	5.32	NA	NA	1200	3.31	NA	NA	Y	N
		2	4.68	1234.0	5.78	0.46	8.64	1110	4.22	0.91	27.44	Y	N
		6	5.60	1047.0	5.86	0.55	10.30	1510	3.71	0.40	12.10	Y	N
2136	UB Non-mentholated VLN Non-mentholated	-1	2.21	2199.0	4.86	NA	NA	803	2.75	NA	NA	Y	N
		2	3.41	1100.0	3.75	-1.11	-22.82	1490	2.29	-0.46	-16.84	Y	N
2140	UB Non-mentholated	-1	6.54	800.0	5.23	NA	NA	1470	4.45	NA	NA	Y	Y
		2	4.66	763.0	3.56	-1.68	-32.04	1610	2.89	-1.55	-34.94	Y	Y
		6	4.96	939.0	4.66	-0.57	-10.98	1250	3.97	-0.48	-10.81	Y	Y
2142	UB Non-mentholated	-1	4.51	2406.0	10.85	NA	NA	500	9.02	NA	NA	Y	Y
2143	UB Non-mentholated	-1	0.913	2510.0	2.29	NA	NA	595	1.53	NA	NA	Y	Y

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2143	VLN Non-mentholated	2	1.50	2050.0	3.08	0.78	34.18	756	1.98	0.45	29.31	Y	Y
		6	1.30	2221.0	2.89	0.60	25.99	729	1.78	0.25	16.21	Y	Y
2158	UB Non-mentholated	-1	4.70	1684.0	7.91	NA	NA	843	5.58	NA	NA	Y	Y
		2	6.82	1211.0	8.26	0.34	4.35	1160	5.88	0.30	5.45	Y	Y
2159	UB Non-mentholated VLN Non-mentholated	-1	4.17	1506.0	6.28	NA	NA	795	5.25	NA	NA	Y	N
		2	6.09	1042.0	6.35	0.07	1.05	1100	5.54	0.29	5.55	Y	N
		6	6.46	1311.0	8.47	2.19	34.86	1050	6.15	0.91	17.29	Y	N
2164	UB Non-mentholated VLN Non-mentholated	-1	3.23	2448.0	7.91	NA	NA	520	6.21	NA	NA	Y	Y
		2	3.58	2822.0	10.10	2.20	27.77	464	7.72	1.50	24.21	Y	Y
		6	3.83	2302.0	8.82	0.91	11.50	568	6.74	0.53	8.56	Y	Y
2168	UB Non-mentholated VLN Non-mentholated	-1	4.84	1464.0	7.09	NA	NA	459	10.54	NA	NA	Y	N
		2	6.68	1163.0	7.77	0.68	9.64	528	12.65	2.11	19.98	Y	N
		6	5.26	216.0	.	.	.	427	12.32	1.77	16.82	N	N
2170	UB Non-mentholated	-1	9.01	929.0	8.37	NA	NA	1190	7.57	NA	NA	Y	Y
		2	9.02	1105.0	9.97	1.60	19.08	1090	8.28	0.70	9.30	Y	Y
		6	10.7	1005.0	.	.	.	1550	6.90	-0.67	-8.83	N	N
2175	UB Mentholated	-1	6.23	1724.0	10.74	NA	NA	736	8.46	NA	NA	Y	Y
		2	4.68	1687.0	7.90	-2.85	-26.49	776	6.03	-2.43	-28.75	Y	Y

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2175	UB Mentholated	6	5.31	1431.0	7.60	-3.14	-29.25	916	5.80	-2.67	-31.52	Y	Y
2189	UB Mentholated	-1	1.49	2385.0	3.55	NA	NA	806	1.85	NA	NA	Y	Y
2211	UB Mentholated VLN Mentholated	-1	3.02	2088.0	6.31	NA	NA	517	5.84	NA	NA	Y	N
		2	4.74	1946.0	9.22	2.92	46.28	591	8.02	2.18	37.30	Y	N
		6	2.20	297.0	0.65	-5.65	-89.64	685	3.21	-2.63	-45.02	Y	N
2212	UB Mentholated	-1	6.04	1397.0	8.44	NA	NA	1470	4.11	NA	NA	Y	Y
		2	5.69	1514.0	8.61	0.18	2.10	1400	4.06	-0.04	-1.08	Y	Y
		6	6.35	1016.0	6.45	-1.99	-23.54	2070	3.07	-1.04	-25.34	Y	Y
2213	UB Mentholated VLN Mentholated	-1	2.91	2513.0	7.31	NA	NA	930	3.13	NA	NA	Y	N
		2	3.71	2301.0	8.54	1.22	16.74	969	3.83	0.70	22.36	Y	N
		6	4.06	1689.0	6.86	-0.46	-6.23	1350	3.01	-0.12	-3.89	Y	N
2215	UB Mentholated	-1	0.846	1494.0	1.26	NA	NA	753	1.12	NA	NA	Y	Y
		2	0.843	1644.0	1.39	0.12	9.65	669	1.26	0.14	12.16	Y	Y
		6	1.12	1321.0	1.48	0.22	17.06	846	1.32	0.20	17.83	Y	Y
2220	UB Non-mentholated VLN Non-mentholated	-1	6.21	547.0	3.40	NA	NA	3260	1.90	NA	NA	Y	N
		2	3.89	1054.0	4.10	0.70	20.70	2100	1.85	-0.05	-2.76	Y	N
		6	4.18	900.0	3.76	0.37	10.75	2470	1.69	-0.21	-11.16	Y	N
2235	UB Mentholated	-1	10.0	1046.0	10.46	NA	NA	2100	4.76	NA	NA	Y	N

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2235	VLN Mentholated	2	4.83	1129.0	5.45	-5.01	-47.87	2020	2.39	-2.37	-49.79	Y	N
		6	9.86	448.0	4.42	-6.04	-57.77	2030	4.86	0.10	2.00	Y	N
2244	UB Non-mentholated	-1	5.02	1370.0	6.88	NA	NA	1230	4.08	NA	NA	Y	N
	VLN Non-mentholated	2	5.93	1012.0	6.00	-0.88	-12.74	1940	3.06	-1.02	-25.10	Y	N
		6	7.54	926.0	6.98	0.10	1.52	1870	4.03	-0.05	-1.21	Y	N
2247	UB Mentholated	-1	0.445	1591.0	0.71	NA	NA	1430	0.31	NA	NA	Y	Y
	VLN Mentholated	2	0.486	1612.0	0.78	0.08	10.66	1270	0.38	0.07	22.97	Y	Y
2251	UB Non-mentholated	-1	1.08	1872.0	2.02	NA	NA	1050	1.03	NA	NA	Y	Y
		2	1.27	1851.0	2.35	0.33	16.27	1140	1.11	0.09	8.31	Y	Y
		6	1.70	1192.0	2.03	0.00	0.23	1870	0.91	-0.12	-11.62	Y	Y
2257	UB Non-mentholated	-1	1.07	2851.0	3.05	NA	NA	393	2.72	NA	NA	Y	Y
		2	1.67	1989.0	3.32	0.27	8.89	497	3.36	0.64	23.42	Y	Y
		6	1.44	1988.0	2.86	-0.19	-6.16	427	3.37	0.65	23.86	Y	Y
2259	UB Mentholated	-1	3.62	1236.0	4.47	NA	NA	2220	1.63	NA	NA	Y	Y
		2	4.25	1039.0	4.42	-0.06	-1.31	2440	1.74	0.11	6.82	Y	Y
		6	4.57	999.0	4.57	0.09	2.04	2520	1.81	0.18	11.21	Y	Y
2269	UB Mentholated	-1	3.25	1468.0	4.77	NA	NA	1540	2.11	NA	NA	Y	N
	VLN Mentholated	2	0.303	353.0	0.11	-4.66	-97.76	1120	0.27	-1.84	-87.18	Y	N

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Appendix 16.2.6.6 Urinary S-PMA (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (ng/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (µg/24hrs)	CFB (µg/24hrs)	PCFB (%)		Amount (µg/g Creat.)	CFB (µg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2269	VLN Mentholated	6	0.565	845.0	0.48	-4.29	-89.99	627	0.90	-1.21	-57.30	Y	N
2272	UB Mentholated	-1	5.80	889.0	5.16	NA	NA	2370	2.45	NA	NA	Y	N
	VLN Mentholated	2	8.97	1818.0	16.31	11.15	216.27	1070	8.38	5.94	242.55	Y	N
		6	6.23	1589.0	9.90	4.74	91.99	1290	4.83	2.38	97.34	Y	N

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1001	UB Non-mentholated	-1	176	2171.0	382.10	NA	NA	499	352.71	NA	NA	Y	N
	VLN Non-mentholated	2	245	1172.6	287.29	-94.81	-24.81	804	304.73	-47.98	-13.60	Y	N
		6	200	1249.1	249.82	-132.28	-34.62	843	237.25	-115.46	-32.73	Y	N
1002	UB Non-mentholated	-1	217	4356.5	945.36	NA	NA	424	511.79	NA	NA	Y	N
	VLN Non-mentholated	2	223	4062.7	905.98	-39.38	-4.17	414	538.65	26.85	5.25	Y	N
		6	187	5759.6	1077.05	131.68	13.93	333	561.56	49.77	9.72	Y	N
1003	UB Mentholated	-1	236	1385.0	326.86	NA	NA	1770	133.33	NA	NA	Y	N
	VLN Mentholated	2	287	410.0	117.67	-209.19	-64.00	2280	125.88	-7.46	-5.59	Y	N
		6	276	1017.7	280.89	-45.97	-14.07	2250	122.67	-10.67	-8.00	Y	N
1007	UB Non-mentholated	-1	123	1935.0	238.01	NA	NA	890	138.20	NA	NA	Y	Y
	VLN Non-mentholated	2	86.3	2199.9	189.85	-48.15	-20.23	947	91.13	-47.07	-34.06	Y	Y
		6	144	1700.3	244.84	6.84	2.87	1330	108.27	-29.93	-21.66	Y	Y
1008	UB Mentholated	-1	85.0	2014.0	171.19	NA	NA	1120	75.89	NA	NA	Y	N
	VLN Mentholated	2	75.1	1435.9	107.84	-63.35	-37.01	1550	48.45	-27.44	-36.16	Y	N
		6	70.0	1122.0	78.54	-92.65	-54.12	701	99.86	23.96	31.58	N	N
1010	UB Mentholated	-1	224	2030.0	454.72	NA	NA	941	238.04	NA	NA	Y	Y
		2	189	1539.6	290.98	-163.74	-36.01	1120	168.75	-69.29	-29.11	Y	Y
		6	147	1036.8	152.41	-302.31	-66.48	741	198.38	-39.66	-16.66	N	N

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1011	UB Non-mentholated	-1	348	1059.0	368.53	NA	NA	2360	147.46	NA	NA	Y	Y
		2	259	1364.0	353.28	-15.26	-4.14	1590	162.89	15.44	10.47	Y	Y
		6	198	628.7	124.48	-244.05	-66.22	1060	186.79	39.33	26.68	N	N
1013	UB Non-mentholated VLN Non-mentholated	-1	163	1664.0	271.23	NA	NA	1060	153.77	NA	NA	Y	N
		2	300	1043.8	.	.	.	1450	206.90	53.12	34.55	N	N
		6	264	874.0	230.74	-40.50	-14.93	1970	134.01	-19.76	-12.85	Y	N
1014	UB Mentholated VLN Mentholated	-1	200	2069.0	413.80	NA	NA	476	420.17	NA	NA	Y	N
		6	657	903.2	593.40	179.60	43.40	1330	493.98	73.82	17.57	Y	N
1015	UB Mentholated VLN Mentholated	-1	72.0	3550.0	255.60	NA	NA	371	194.07	NA	NA	Y	Y
		2	49.4	3406.2	168.27	-87.33	-34.17	373	132.44	-61.63	-31.76	Y	Y
		6	45.0	3477.7	156.50	-99.10	-38.77	392	114.80	-79.27	-40.85	Y	Y
1016	UB Non-mentholated	-1	208	1853.0	385.42	NA	NA	873	238.26	NA	NA	Y	Y
		2	138	2839.1	391.80	6.37	1.65	528	261.36	23.10	9.70	Y	Y
		6	251	1899.3	476.72	91.30	23.69	908	276.43	38.17	16.02	Y	Y
1017	UB Mentholated	-1	131	2490.0	326.19	NA	NA	507	258.38	NA	NA	Y	Y
		2	137	2593.9	355.36	29.17	8.94	529	258.98	0.60	0.23	Y	Y
		6	203	1399.2	284.04	-42.15	-12.92	920	220.65	-37.73	-14.60	Y	Y
1018	UB Mentholated	-1	282	1721.0	485.32	NA	NA	672	419.64	NA	NA	Y	Y

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1019	UB Non-mentholated	-1	405	1431.0	579.56	NA	NA	1750	231.43	NA	NA	Y	N
	VLN Non-mentholated	2	133	3109.0	413.50	-166.06	-28.65	762	174.54	-56.89	-24.58	Y	N
		6	272	2290.1	622.91	43.35	7.48	1110	245.05	13.62	5.88	Y	N
1020	UB Non-mentholated	-1	308	1666.0	513.13	NA	NA	773	398.45	NA	NA	Y	N
	VLN Non-mentholated	2	464	1240.9	575.78	62.65	12.21	1430	324.48	-73.97	-18.57	Y	N
		6	315	917.7	289.08	-224.05	-43.66	1280	246.09	-152.35	-38.24	Y	N
1021	UB Non-mentholated	-1	129	1808.0	233.23	NA	NA	681	189.43	NA	NA	N	N
		2	123	1842.4	226.62	.	.	710	173.24	.	.	Y	Y
		6	97.4	2136.5	208.10	.	.	637	152.90	.	.	Y	Y
1023	UB Non-mentholated	-1	67.9	2894.0	196.50	NA	NA	367	185.01	NA	NA	Y	N
	VLN Non-mentholated	2	49.7	3795.5	188.64	-7.87	-4.00	274	181.39	-3.63	-1.96	Y	N
		6	42.4	3600.0	152.64	-43.86	-22.32	334	126.95	-58.07	-31.39	Y	N
1029	UB Mentholated	-1	80.6	2525.2	203.53	NA	NA	554	145.49	NA	NA	Y	N
	VLN Mentholated	2	42.8	3098.0	132.59	-70.94	-34.85	505	84.75	-60.73	-41.75	Y	N
		6	70.3	2192.0	154.10	-49.43	-24.29	753	93.36	-52.13	-35.83	Y	N
1032	UB Mentholated	-1	111	3793.8	421.11	NA	NA	319	347.96	NA	NA	Y	Y
	VLN Mentholated	2	162	3479.0	563.60	142.49	33.84	411	394.16	46.20	13.28	Y	Y
		6	107	2345.0	250.92	-170.20	-40.42	602	177.74	-170.22	-48.92	Y	Y

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1034	UB Non-mentholated	-1	257	1275.1	327.70	NA	NA	1080	237.96	NA	NA	Y	N
	VLN Non-mentholated	2	201	969.0	194.77	-132.93	-40.56	1210	166.12	-71.85	-30.19	Y	N
		6	307	1037.0	318.36	-9.34	-2.85	1550	198.06	-39.90	-16.77	Y	N
1035	UB Non-mentholated	-1	128	2182.4	279.35	NA	NA	1180	108.47	NA	NA	Y	N
	VLN Non-mentholated	2	92.4	2196.0	202.91	-76.44	-27.36	726	127.27	18.80	17.33	Y	N
		6	165	1204.0	198.66	-80.69	-28.88	1400	117.86	9.38	8.65	Y	N
1036	UB Mentholated	-1	347	1896.8	658.19	NA	NA	761	455.98	NA	NA	Y	Y
		2	150	1841.0	276.15	-382.04	-58.04	793	189.16	-266.82	-58.52	Y	Y
		6	220	1475.0	324.50	-333.69	-50.70	1110	198.20	-257.78	-56.53	Y	Y
1037	UB Mentholated	-1	74.1	5986.4	443.59	NA	NA	350	211.71	NA	NA	Y	Y
		2	129	2822.0	364.04	-79.55	-17.93	698	184.81	-26.90	-12.71	Y	Y
		6	179	2712.0	485.45	41.86	9.44	651	274.96	63.25	29.87	Y	Y
1038	UB Non-mentholated	-1	430	1610.1	692.34	NA	NA	802	536.16	NA	NA	Y	N
	VLN Non-mentholated	2	316	1705.0	538.78	-153.56	-22.18	830	380.72	-155.44	-28.99	Y	N
		6	285	1641.0	467.69	-224.66	-32.45	894	318.79	-217.37	-40.54	Y	N
1042	UB Non-mentholated	-1	62.5	5646.2	352.89	NA	NA	353	177.05	NA	NA	Y	N
	VLN Non-mentholated	2	32.0	3586.0	114.75	-238.14	-67.48	380	84.21	-92.84	-52.44	Y	N
		6	29.4	2769.0	81.41	-271.48	-76.93	429	68.53	-108.52	-61.29	Y	N

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1045	UB Non-mentholated	-1	153	3025.5	462.90	NA	NA	613	249.59	NA	NA	Y	Y
		2	149	2443.0	364.01	-98.89	-21.36	654	227.83	-21.76	-8.72	Y	Y
		6	191	1894.0	361.75	-101.15	-21.85	921	207.38	-42.21	-16.91	Y	Y
1046	UB Mentholated	-1	63.1	3780.8	238.57	NA	NA	570	110.70	NA	NA	Y	Y
		2	60.3	2832.0	170.77	-67.80	-28.42	670	90.00	-20.70	-18.70	Y	Y
		6	70.6	2830.0	199.80	-38.77	-16.25	806	87.59	-23.11	-20.87	Y	Y
1050	UB Non-mentholated VLN Non-mentholated	-1	289	1520.3	439.37	NA	NA	781	370.04	NA	NA	Y	N
		2	91.9	3144.1	288.94	-150.42	-34.24	472	194.70	-175.34	-47.38	Y	N
		6	204	1578.0	321.91	-117.45	-26.73	825	247.27	-122.77	-33.18	Y	N
1051	UB Mentholated	-1	246	2216.8	545.33	NA	NA	762	322.83	NA	NA	Y	Y
		2	224	2040.0	456.96	-88.37	-16.21	789	283.90	-38.93	-12.06	Y	Y
		6	263	1784.0	469.19	-76.14	-13.96	1050	250.48	-72.36	-22.41	Y	Y
1052	UB Mentholated VLN Mentholated	-1	79.7	1539.8	122.72	NA	NA	1300	61.31	NA	NA	Y	N
		2	114	1602.0	182.63	59.91	48.81	1130	100.88	39.58	64.56	Y	N
		6	126	1065.0	134.19	11.47	9.34	1850	68.11	6.80	11.09	Y	N
1053	UB Mentholated VLN Mentholated	-1	121	2902.3	351.18	NA	NA	795	152.20	NA	NA	Y	N
		2	90.1	2790.0	251.38	-99.80	-28.42	933	96.57	-55.63	-36.55	Y	N
		6	81.1	2523.0	204.62	-146.56	-41.73	914	88.73	-63.47	-41.70	Y	N

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Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1054	UB Non-mentholated	-1	460	956.9	440.17	NA	NA	2550	180.39	NA	NA	Y	Y
		2	174	1844.0	320.86	-119.32	-27.11	1180	147.46	-32.93	-18.26	Y	Y
		6	290	1089.0	315.81	-124.36	-28.25	2130	136.15	-44.24	-24.53	Y	Y
1055	UB Mentholated VLN Mentholated	-1	152	3328.9	505.99	NA	NA	451	337.03	NA	NA	Y	N
		2	110	3391.6	373.08	-132.92	-26.27	495	222.22	-114.81	-34.06	Y	N
		6	168	1581.0	265.61	-240.38	-47.51	955	175.92	-161.11	-47.80	Y	N
1056	UB Non-mentholated VLN Non-mentholated	-1	50.9	3925.2	199.79	NA	NA	416	122.36	NA	NA	Y	N
		2	64.9	1334.0	86.58	-113.22	-56.67	799	81.23	-41.13	-33.61	Y	N
		6	87.6	1152.0	100.92	-98.88	-49.49	785	111.59	-10.76	-8.80	Y	N
1058	UB Non-mentholated VLN Non-mentholated	-1	54.9	3355.1	184.19	NA	NA	518	105.98	NA	NA	Y	N
		2	36.1	2869.0	103.57	-80.62	-43.77	520	69.42	-36.56	-34.50	Y	N
		6	76.5	1927.0	147.42	-36.78	-19.97	1190	64.29	-41.70	-39.34	Y	N
1059	UB Non-mentholated	-1	448	956.0	428.29	NA	NA	2300	194.78	NA	NA	Y	Y
		2	197	2124.7	418.57	-9.72	-2.27	1040	189.42	-5.36	-2.75	Y	Y
		6	361	1507.0	544.03	115.74	27.02	1750	206.29	11.50	5.91	Y	Y
1060	UB Mentholated VLN Mentholated	-1	144	2414.0	347.62	NA	NA	751	191.74	NA	NA	Y	N
		2	130	2361.4	306.98	-40.63	-11.69	782	166.24	-25.50	-13.30	Y	N
		6	146	1742.0	254.33	-93.28	-26.84	950	153.68	-38.06	-19.85	Y	N

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Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1063	UB Mentholated	-1	21.6	7095.2	153.26	NA	NA	306	70.59	NA	NA	Y	Y
	VLN Mentholated	2	36.6	3891.4	142.43	-10.83	-7.07	569	64.32	-6.26	-8.88	Y	Y
		6	28.6	3208.0	91.75	-61.51	-40.13	787	36.34	-34.25	-48.52	Y	Y
1064	UB Non-mentholated	-1	115	3268.0	375.82	NA	NA	749	153.54	NA	NA	Y	Y
		2	179	2273.1	406.88	31.06	8.27	1060	168.87	15.33	9.98	Y	Y
1066	UB Non-mentholated	-1	491	967.0	474.80	NA	NA	2190	224.20	NA	NA	Y	Y
	VLN Non-mentholated	2	176	1744.8	307.08	-167.71	-35.32	1050	167.62	-56.58	-25.24	Y	Y
		6	170	1725.0	293.25	-181.55	-38.24	1220	139.34	-84.86	-37.85	Y	Y
1069	UB Non-mentholated	-1	90.6	2554.0	231.39	NA	NA	793	114.25	NA	NA	Y	Y
		2	85.5	2465.9	210.83	-20.56	-8.88	783	109.20	-5.05	-4.42	Y	Y
		6	131	2162.0	283.22	51.83	22.40	973	134.64	20.39	17.84	Y	Y
1070	UB Non-mentholated	-1	93.7	3393.0	317.92	NA	NA	633	148.03	NA	NA	Y	Y
	VLN Non-mentholated	2	72.6	2687.1	195.08	-122.84	-38.64	752	96.54	-51.48	-34.78	Y	Y
		6	161	1316.0	211.88	-106.05	-33.36	1800	89.44	-58.58	-39.57	Y	Y
1071	UB Non-mentholated	-1	160	2129.0	340.64	NA	NA	700	228.57	NA	NA	Y	N
	VLN Non-mentholated	2	91.8	2212.3	203.09	-137.55	-40.38	1230	74.63	-153.94	-67.35	Y	N
1072	UB Mentholated	-1	207	2181.0	451.47	NA	NA	806	256.82	NA	NA	Y	Y
	VLN Mentholated	2	203	1779.7	361.28	-90.19	-19.98	955	212.57	-44.26	-17.23	Y	Y

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1074	UB Non-mentholated	-1	84.9	2211.0	187.71	NA	NA	876	96.92	NA	NA	Y	N
	VLN Non-mentholated	2	98.2	1464.3	143.79	-43.92	-23.40	1350	72.74	-24.18	-24.95	Y	N
		6	70.9	1677.0	118.90	-68.81	-36.66	1310	54.12	-42.80	-44.16	Y	N
1075	UB Non-mentholated	-1	117	2163.0	253.07	NA	NA	773	151.36	NA	NA	Y	Y
		2	173	1890.7	327.09	74.02	29.25	845	204.73	53.38	35.26	Y	Y
		6	295	1263.0	372.59	119.51	47.23	1340	220.15	68.79	45.45	Y	Y
1077	UB Non-mentholated	-1	95.4	3102.1	295.94	NA	NA	493	193.51	NA	NA	Y	Y
	VLN Non-mentholated	2	70.6	3008.3	212.39	-83.55	-28.23	596	118.46	-75.05	-38.79	Y	Y
		6	66.4	2743.0	182.14	-113.81	-38.46	693	95.82	-97.69	-50.49	Y	Y
1078	UB Non-mentholated	-1	134	1991.0	266.79	NA	NA	597	224.46	NA	NA	Y	N
	VLN Non-mentholated	2	48.4	3513.1	170.03	-96.76	-36.27	352	137.50	-86.96	-38.74	Y	N
		6	112	2384.0	267.01	0.21	0.08	654	171.25	-53.20	-23.70	Y	N
1079	UB Mentholated	-1	187	2154.0	402.80	NA	NA	1370	136.50	NA	NA	Y	Y
	VLN Mentholated	2	60.8	3647.6	221.77	-181.02	-44.94	802	75.81	-60.69	-44.46	Y	Y
		6	67.6	2605.0	176.10	-226.70	-56.28	1040	65.00	-71.50	-52.38	Y	Y
1082	UB Non-mentholated	-1	131	2790.0	365.49	NA	NA	843	155.40	NA	NA	Y	N
	VLN Non-mentholated	2	134	2629.9	352.41	-13.08	-3.58	926	144.71	-10.69	-6.88	Y	N
		6	188	2013.0	378.44	12.95	3.54	1200	156.67	1.27	0.82	Y	N

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1083	UB Non-mentholated	-1	306	1708.0	522.65	NA	NA	762	401.57	NA	NA	Y	N
	VLN Non-mentholated	2	263	1788.0	470.24	-52.40	-10.03	892	294.84	-106.73	-26.58	Y	N
		6	283	2017.0	570.81	48.16	9.22	804	351.99	-49.58	-12.35	Y	N
1084	UB Non-mentholated	-1	204	1467.0	299.27	NA	NA	1380	147.83	NA	NA	Y	N
	VLN Non-mentholated	2	187	1158.4	216.62	-82.65	-27.62	1630	114.72	-33.10	-22.39	Y	N
1086	UB Non-mentholated	-1	182	1938.0	352.72	NA	NA	968	188.02	NA	NA	Y	N
	VLN Non-mentholated	2	162	1255.9	203.46	-149.26	-42.32	1410	114.89	-73.12	-38.89	Y	N
		6	140	1580.0	221.20	-131.52	-37.29	1040	134.62	-53.40	-28.40	Y	N
1088	UB Mentholated	-1	240	1662.0	398.88	NA	NA	1670	143.71	NA	NA	Y	N
	VLN Mentholated	2	210	1236.2	259.60	-139.28	-34.92	1820	115.38	-28.33	-19.71	Y	N
		6	194	1670.0	323.98	-74.90	-18.78	1520	127.63	-16.08	-11.19	Y	N
1089	UB Non-mentholated	-1	181	1795.0	324.90	NA	NA	669	270.55	NA	NA	Y	Y
		2	96.9	2415.3	234.04	-90.85	-27.96	544	178.13	-92.43	-34.16	Y	Y
		6	109	2062.0	224.76	-100.14	-30.82	559	194.99	-75.56	-27.93	Y	Y
1092	UB Mentholated	-1	332	2383.0	791.16	NA	NA	734	452.32	NA	NA	Y	N
	VLN Mentholated	2	206	1551.7	319.65	-471.51	-59.60	898	229.40	-222.92	-49.28	Y	N
		6	199	1587.0	315.81	-475.34	-60.08	1150	173.04	-279.27	-61.74	Y	N
1094	UB Mentholated	-1	231	1930.0	445.83	NA	NA	1230	187.80	NA	NA	Y	N

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1094	VLN Mentholated	2	222	1307.6	290.29	-155.54	-34.89	1720	129.07	-58.74	-31.27	Y	N
		6	233	1040.0	242.32	-203.51	-45.65	1930	120.73	-67.08	-35.72	Y	N
1095	UB Mentholated	-1	75.8	2551.0	193.37	NA	NA	514	147.47	NA	NA	Y	N
	VLN Mentholated	2	129	430.3	55.51	-137.86	-71.29	982	131.36	-16.11	-10.92	N	N
		6	52.6	2131.0	112.09	-81.28	-42.03	390	134.87	-12.60	-8.54	Y	N
1096	UB Non-mentholated	-1	125	2532.0	316.50	NA	NA	634	197.16	NA	NA	Y	N
	VLN Non-mentholated	2	95.7	1934.5	185.13	-131.37	-41.51	679	140.94	-56.22	-28.51	Y	N
		6	81.6	2949.0	240.64	-75.86	-23.97	488	167.21	-29.95	-15.19	Y	N
1097	UB Mentholated	-1	268	1982.0	531.18	NA	NA	1250	214.40	NA	NA	Y	N
	VLN Mentholated	2	236	1598.3	377.20	-153.98	-28.99	1510	156.29	-58.11	-27.10	Y	N
		6	149	1814.0	270.29	-260.89	-49.12	1270	117.32	-97.08	-45.28	Y	N
1098	UB Non-mentholated	-1	243	1415.8	344.04	NA	NA	1060	229.25	NA	NA	Y	Y
	VLN Non-mentholated	2	148	1666.1	246.58	-97.46	-28.33	958	154.49	-74.76	-32.61	Y	Y
		6	148	1811.0	268.03	-76.01	-22.09	895	165.36	-63.88	-27.87	Y	Y
1099	UB Non-mentholated	-1	427	810.2	.	NA	NA	1420	300.70	NA	NA	N	N
	VLN Non-mentholated	2	247	1272.2	314.23	.	.	1060	233.02	.	.	Y	N
		6	361	1005.0	362.81	.	.	1250	288.80	.	.	Y	N
1100	UB Non-mentholated	-1	105	3350.7	351.82	NA	NA	550	190.91	NA	NA	Y	N

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1100	VLN Non-mentholated	2	121	2653.5	321.07	-30.75	-8.74	684	176.90	-14.01	-7.34	Y	N
		6	125	2576.0	322.00	-29.82	-8.48	772	161.92	-28.99	-15.19	Y	N
1101	UB Non-mentholated	-1	319	1814.1	578.70	NA	NA	827	385.73	NA	NA	Y	N
	VLN Non-mentholated	2	265	2317.4	614.11	35.41	6.12	805	329.19	-56.54	-14.66	Y	N
		6	150	3707.0	556.05	-22.65	-3.91	258	581.40	195.66	50.73	Y	N
1103	UB Non-mentholated	-1	137	3479.4	476.68	NA	NA	297	461.28	NA	NA	Y	N
	VLN Non-mentholated	2	164	2449.2	401.67	-75.01	-15.74	762	215.22	-246.06	-53.34	Y	N
		6	152	2601.0	395.35	-81.33	-17.06	763	199.21	-262.07	-56.81	Y	N
1105	UB Non-mentholated	-1	474	527.3	249.94	NA	NA	1680	282.14	NA	NA	Y	N
	VLN Non-mentholated	2	315	825.2	259.94	10.00	4.00	1010	311.88	29.74	10.54	Y	N
		6	305	677.0	206.49	-43.46	-17.39	1420	214.79	-67.35	-23.87	Y	N
1106	UB Non-mentholated	-1	237	1380.1	327.08	NA	NA	1870	126.74	NA	NA	Y	Y
		2	261	1113.7	290.68	-36.41	-11.13	2330	112.02	-14.72	-11.62	Y	Y
		6	114	2435.0	277.59	-49.49	-15.13	968	117.77	-8.97	-7.08	Y	Y
1107	UB Non-mentholated	-1	74.0	2365.5	175.05	NA	NA	913	81.05	NA	NA	Y	N
	VLN Non-mentholated	2	73.0	2512.8	183.43	8.39	4.79	854	85.48	4.43	5.46	Y	N
		6	73.6	2599.0	191.29	16.24	9.28	806	91.32	10.26	12.66	Y	N
1108	UB Non-mentholated	-1	116	1782.0	206.71	NA	NA	1150	100.87	NA	NA	Y	Y

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1108	UB Non-mentholated	2	85.9	2115.4	181.71	-25.00	-12.09	966	88.92	-11.95	-11.84	Y	Y
		6	111	1981.0	219.89	13.18	6.38	1030	107.77	6.90	6.84	Y	Y
1109	UB Non-mentholated	-1	231	1615.9	373.27	NA	NA	950	243.16	NA	NA	Y	Y
		2	171	1805.0	308.66	-64.62	-17.31	919	186.07	-57.09	-23.48	Y	Y
		6	289	1075.0	310.68	-62.60	-16.77	1490	193.96	-49.20	-20.23	Y	Y
1112	UB Non-mentholated VLN Non-mentholated	-1	126	2265.2	285.42	NA	NA	428	294.39	NA	NA	Y	N
		2	196	1829.3	358.54	73.13	25.62	613	319.74	25.35	8.61	Y	N
		6	130	2121.0	275.73	-9.69	-3.39	531	244.82	-49.57	-16.84	Y	N
1114	UB Non-mentholated	-1	169	1506.7	254.63	NA	NA	754	224.14	NA	NA	Y	Y
		2	44.7	2909.4	130.05	-124.58	-48.93	403	110.92	-113.22	-50.51	Y	Y
		6	81.6	1920.0	156.67	-97.96	-38.47	661	123.45	-100.69	-44.92	Y	Y
1115	UB Non-mentholated VLN Non-mentholated	-1	207	1785.7	369.64	NA	NA	1590	130.19	NA	NA	Y	Y
		2	175	1601.3	280.23	-89.41	-24.19	1770	98.87	-31.32	-24.06	Y	Y
2002	UB Mentholated	-1	162	2188.0	354.46	NA	NA	803	201.74	NA	NA	Y	Y
		2	169	1893.0	319.92	-34.54	-9.74	915	184.70	-17.04	-8.45	Y	Y
		6	111	3245.0	360.20	5.74	1.62	569	195.08	-6.66	-3.30	Y	Y
2003	UB Mentholated VLN Mentholated	-1	176	3036.0	534.34	NA	NA	342	514.62	NA	NA	Y	N
		2	125	4180.0	522.50	-11.84	-2.22	348	359.20	-155.42	-30.20	Y	N

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2003	VLN Mentholated	6	107	3245.0	347.22	-187.12	-35.02	373	286.86	-227.76	-44.26	Y	N
2007	UB Non-mentholated	-1	121	1535.0	185.74	NA	NA	696	173.85	NA	NA	Y	Y
	VLN Non-mentholated	2	113	1492.0	168.60	-17.14	-9.23	725	155.86	-17.99	-10.35	Y	Y
		6	108	1387.0	149.80	-35.94	-19.35	828	130.43	-43.42	-24.97	Y	Y
2008	UB Mentholated	-1	189	2663.0	503.31	NA	NA	900	210.00	NA	NA	Y	Y
	VLN Mentholated	2	112	3323.0	372.18	-131.13	-26.05	709	157.97	-52.03	-24.78	Y	Y
		6	229	1734.0	397.09	-106.22	-21.10	1300	176.15	-33.85	-16.12	Y	Y
2009	UB Non-mentholated	-1	50.8	2427.0	123.29	NA	NA	807	62.95	NA	NA	Y	N
	VLN Non-mentholated	2	107	1390.0	148.73	25.44	20.63	1420	75.35	12.40	19.70	Y	N
2010	UB Mentholated	-1	63.2	1673.0	105.73	NA	NA	1650	38.30	NA	NA	Y	Y
		2	52.5	1289.0	67.67	-38.06	-36.00	1390	37.77	-0.53	-1.39	Y	Y
		6	72.1	1158.0	83.49	-22.24	-21.04	2350	30.68	-7.62	-19.90	Y	Y
2011	UB Mentholated	-1	127	1639.0	208.15	NA	NA	1010	125.74	NA	NA	Y	N
	VLN Mentholated	2	97.5	1510.0	147.23	-60.93	-29.27	1110	87.84	-37.90	-30.14	Y	N
		6	153	1165.0	178.25	-29.91	-14.37	1510	101.32	-24.42	-19.42	Y	N
2014	UB Mentholated	-1	82.1	3009.0	247.04	NA	NA	738	111.25	NA	NA	Y	N
	VLN Mentholated	2	154	1438.0	221.45	-25.59	-10.36	1410	109.22	-2.03	-1.82	Y	N
		6	84.5	2776.0	234.57	-12.47	-5.05	718	117.69	6.44	5.79	Y	N

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2015	UB Mentholated	-1	156	1277.0	199.21	NA	NA	1080	144.44	NA	NA	Y	Y
		2	129	1774.0	228.85	29.63	14.88	800	161.25	16.81	11.63	Y	Y
		6	141	1070.0	150.87	-48.34	-24.27	1620	87.04	-57.41	-39.74	Y	Y
2016	UB Mentholated	-1	246	1787.0	439.60	NA	NA	642	383.18	NA	NA	Y	Y
2017	UB Mentholated VLN Mentholated	-1	185	1504.0	278.24	NA	NA	1290	143.41	NA	NA	Y	N
		2	95.6	1864.0	178.20	-100.04	-35.96	1110	86.13	-57.28	-39.94	Y	N
		6	183	1210.0	221.43	-56.81	-20.42	1530	119.61	-23.80	-16.60	Y	N
2018	UB Mentholated	-1	262	1191.0	312.04	NA	NA	1390	188.49	NA	NA	Y	Y
		2	222	1374.0	305.03	-7.01	-2.25	1120	198.21	9.73	5.16	Y	Y
		6	450	963.0	433.35	121.31	38.88	1620	277.78	89.29	47.37	Y	Y
2020	UB Mentholated VLN Mentholated	-1	106	1117.0	118.40	NA	NA	919	115.34	NA	NA	Y	N
		2	103	1155.0	118.97	0.56	0.48	1070	96.26	-19.08	-16.54	Y	N
		6	71.9	1300.0	93.47	-24.93	-21.06	929	77.40	-37.95	-32.90	Y	N
2021	UB Mentholated VLN Mentholated	-1	116	2086.0	241.98	NA	NA	1120	103.57	NA	NA	Y	Y
		2	55.4	2606.0	144.37	-97.60	-40.34	909	60.95	-42.63	-41.16	Y	Y
		6	47.2	2561.0	120.88	-121.10	-50.04	821	57.49	-46.08	-44.49	Y	Y
2023	UB Mentholated VLN Mentholated	-1	95.7	996.0	95.32	NA	NA	2220	43.11	NA	NA	Y	Y
		2	42.6	1252.0	53.34	-41.98	-44.04	1650	25.82	-17.29	-40.11	Y	Y

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2023	VLN Mentholated	6	59.4	999.0	59.34	-35.98	-37.74	2180	27.25	-15.86	-36.79	Y	Y
2024	UB Non-mentholated	-1	307	1112.0	341.38	NA	NA	1690	181.66	NA	NA	Y	Y
2025	UB Non-mentholated	-1	95.8	2766.0	264.98	NA	NA	674	142.14	NA	NA	Y	Y
		2	107	2484.0	265.79	0.81	0.30	844	126.78	-15.36	-10.81	Y	Y
		6	127	2746.0	348.74	83.76	31.61	866	146.65	4.51	3.18	Y	Y
2028	UB Non-mentholated VLN Non-mentholated	-1	242	1538.0	372.20	NA	NA	1270	190.55	NA	NA	Y	Y
		2	123	1876.0	230.75	-141.45	-38.00	834	147.48	-43.07	-22.60	Y	Y
		6	339	616.0	208.82	-163.37	-43.89	1780	190.45	-0.10	-0.05	Y	Y
2029	UB Mentholated	-1	115	1689.0	194.24	NA	NA	996	115.46	NA	NA	Y	Y
		2	109	1933.0	210.70	16.46	8.48	855	127.49	12.02	10.41	Y	Y
		6	95.3	2068.0	197.08	2.85	1.46	789	120.79	5.32	4.61	Y	Y
2039	UB Mentholated VLN Mentholated	-1	130	1765.0	229.45	NA	NA	762	170.60	NA	NA	Y	N
		2	107	1582.0	169.27	-60.18	-26.23	711	150.49	-20.11	-11.79	Y	N
		6	103	718.0	73.95	-155.50	-67.77	898	114.70	-55.90	-32.77	Y	N
2050	UB Mentholated	-1	142	1887.0	267.95	NA	NA	995	142.71	NA	NA	Y	Y
		2	71.8	1436.0	103.10	-164.85	-61.52	908	79.07	-63.64	-44.59	Y	Y
		6	85.3	1392.0	118.74	-149.22	-55.69	1300	65.62	-77.10	-54.02	Y	Y
2052	UB Mentholated	-1	103	2094.0	215.68	NA	NA	921	111.83	NA	NA	Y	Y

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

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ITT = Intent-to-treat, PP = Per-protocol.

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VLN mentholated = Mentholated VLN cigarettes

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2052	VLN Mentholated	2	112	1611.0	180.43	-35.25	-16.34	1190	94.12	-17.72	-15.84	Y	Y
		6	55.9	2735.0	152.89	-62.80	-29.11	664	84.19	-27.65	-24.72	Y	Y
2057	UB Mentholated	-1	104	3085.0	320.84	NA	NA	646	160.99	NA	NA	Y	N
	VLN Mentholated	2	62.4	3805.0	237.43	-83.41	-26.00	552	113.04	-47.95	-29.78	Y	N
		6	75.3	3820.0	287.65	-33.19	-10.35	592	127.20	-33.79	-20.99	Y	N
2058	UB Mentholated	-1	170	1240.0	210.80	NA	NA	1410	120.57	NA	NA	Y	N
	VLN Mentholated	2	92.7	1621.0	150.27	-60.53	-28.72	1000	92.70	-27.87	-23.11	Y	N
		6	72.4	2198.0	159.14	-51.66	-24.51	763	94.89	-25.68	-21.30	Y	N
2059	UB Mentholated	-1	172	1545.0	265.74	NA	NA	780	220.51	NA	NA	Y	Y
		2	176	1452.0	255.55	-10.19	-3.83	785	224.20	3.69	1.67	Y	Y
		6	185	1242.0	229.77	-35.97	-13.54	1100	168.18	-52.33	-23.73	Y	Y
2060	UB Mentholated	-1	563	773.0	435.20	NA	NA	1200	469.17	NA	NA	Y	N
	VLN Mentholated	2	350	684.0	239.40	-195.80	-44.99	1230	284.55	-184.61	-39.35	Y	N
		6	329	1465.0	481.99	46.79	10.75	971	338.83	-130.34	-27.78	Y	N
2064	UB Mentholated	-1	104	3404.0	354.02	NA	NA	450	231.11	NA	NA	Y	N
	VLN Mentholated	2	102	2844.0	290.09	-63.93	-18.06	649	157.16	-73.95	-32.00	Y	N
		6	106	2882.0	305.49	-48.52	-13.71	572	185.31	-45.80	-19.82	Y	N
2066	UB Mentholated	-1	95.1	1056.0	100.43	NA	NA	1810	52.54	NA	NA	Y	N

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2066	VLN Mentholated	2	62.8	912.0	57.27	-43.15	-42.97	1790	35.08	-17.46	-33.23	Y	N
		6	33.9	1617.0	54.82	-45.61	-45.42	1110	30.54	-22.00	-41.87	Y	N
2067	UB Non-mentholated	-1	48.4	2550.0	123.42	NA	NA	643	75.27	NA	NA	Y	N
	VLN Non-mentholated	2	60.6	1608.0	97.44	-25.98	-21.05	1070	56.64	-18.64	-24.76	Y	N
		6	47.8	2810.0	134.32	10.90	8.83	654	73.09	-2.18	-2.90	Y	N
2075	UB Mentholated	-1	200	3995.0	799.00	NA	NA	551	362.98	NA	NA	Y	Y
2076	UB Mentholated	-1	70.4	2036.0	143.33	NA	NA	943	74.66	NA	NA	Y	N
	VLN Mentholated	2	51.0	2229.0	113.68	-29.66	-20.69	928	54.96	-19.70	-26.39	Y	N
		6	44.6	2063.0	92.01	-51.32	-35.81	1030	43.30	-31.35	-42.00	Y	N
2086	UB Non-mentholated	-1	347	779.0	270.31	NA	NA	1640	211.59	NA	NA	Y	N
	VLN Non-mentholated	2	146	1692.0	247.03	-23.28	-8.61	1040	140.38	-71.20	-33.65	Y	N
2088	UB Mentholated	-1	102	3222.0	328.64	NA	NA	480	212.50	NA	NA	Y	N
	VLN Mentholated	2	70.9	2854.0	202.35	-126.30	-38.43	601	117.97	-94.53	-44.48	Y	N
		6	91.2	2370.0	216.14	-112.50	-34.23	680	134.12	-78.38	-36.89	Y	N
2092	UB Mentholated	-1	48.3	2002.0	96.70	NA	NA	445	108.54	NA	NA	Y	N
	VLN Mentholated	2	42.5	1940.0	82.45	-14.25	-14.73	457	93.00	-15.54	-14.32	Y	N
		6	20.2	2262.0	45.69	-51.00	-52.75	391	51.66	-56.88	-52.40	Y	N
2099	UB Non-mentholated	-1	150	1107.0	166.05	NA	NA	1350	111.11	NA	NA	Y	N

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2099	VLN Non-mentholated	2	81.8	1523.0	124.58	-41.47	-24.97	968	84.50	-26.61	-23.95	Y	N
		6	119	1051.0	125.07	-40.98	-24.68	1430	83.22	-27.89	-25.10	Y	N
2100	UB Mentholated	-1	558	577.0	321.97	NA	NA	2130	261.97	NA	NA	Y	Y
		2	366	1028.0	376.25	54.28	16.86	1200	305.00	43.03	16.42	Y	Y
		6	567	550.0	311.85	-10.12	-3.14	2170	261.29	-0.68	-0.26	Y	Y
2108	UB Non-mentholated VLN Non-mentholated	-1	69.9	2860.0	199.91	NA	NA	286	244.41	NA	NA	Y	N
		2	56.6	3150.0	178.29	-21.62	-10.82	255	221.96	-22.44	-9.18	Y	N
		6	54.7	3399.0	185.93	-13.99	-7.00	252	217.06	-27.34	-11.19	Y	N
2110	UB Mentholated	-1	199	1034.0	205.77	NA	NA	818	243.28	NA	NA	Y	Y
		2	243	799.0	194.16	-11.61	-5.64	1050	231.43	-11.85	-4.87	Y	Y
		6	223	653.0	145.62	-60.15	-29.23	1190	187.39	-55.88	-22.97	Y	Y
2113	UB Mentholated VLN Mentholated	-1	321	843.0	270.60	NA	NA	1120	286.61	NA	NA	Y	Y
		2	108	878.0	94.82	-175.78	-64.96	910	118.68	-167.93	-58.59	Y	Y
2115	UB Mentholated	-1	159	1626.0	258.53	NA	NA	906	175.50	NA	NA	Y	Y
2119	UB Mentholated VLN Mentholated	-1	416	650.0	270.40	NA	NA	2390	174.06	NA	NA	Y	Y
		2	214	786.0	168.20	-102.20	-37.79	1910	112.04	-62.02	-35.63	Y	Y
		6	183	902.0	165.07	-105.33	-38.95	1590	115.09	-58.96	-33.88	Y	Y
2120	UB Non-mentholated	-1	84.5	1243.0	105.03	NA	NA	634	133.28	NA	NA	Y	Y

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2120	VLN Non-mentholated	2	60.4	1147.0	69.28	-35.75	-34.04	646	93.50	-39.78	-29.85	Y	Y
		6	49.1	1735.0	85.19	-19.85	-18.89	488	100.61	-32.67	-24.51	Y	Y
2122	UB Non-mentholated	-1	225	1396.0	314.10	NA	NA	1050	214.29	NA	NA	Y	Y
		2	205	1487.0	304.84	-9.27	-2.95	1010	202.97	-11.32	-5.28	Y	Y
		6	159	1643.0	261.24	-52.86	-16.83	954	166.67	-47.62	-22.22	Y	Y
2125	UB Mentholated	-1	259	1819.0	471.12	NA	NA	1600	161.88	NA	NA	Y	Y
		2	104	3746.0	389.58	-81.54	-17.31	755	137.75	-24.13	-14.90	Y	Y
		6	157	3110.0	488.27	17.15	3.64	960	163.54	1.67	1.03	Y	Y
2126	UB Mentholated VLN Mentholated	-1	174	1339.0	232.99	NA	NA	1200	145.00	NA	NA	Y	N
		2	105	1234.0	129.57	-103.42	-44.39	1110	94.59	-50.41	-34.76	Y	N
		6	152	1047.0	159.14	-73.84	-31.69	1510	100.66	-44.34	-30.58	Y	N
2136	UB Non-mentholated VLN Non-mentholated	-1	83.1	2199.0	182.74	NA	NA	803	103.49	NA	NA	Y	N
		2	132	1100.0	145.20	-37.54	-20.54	1490	88.59	-14.90	-14.39	Y	N
2140	UB Non-mentholated	-1	173	800.0	138.40	NA	NA	1470	117.69	NA	NA	Y	Y
		2	154	763.0	117.50	-20.90	-15.10	1610	95.65	-22.03	-18.72	Y	Y
		6	137	939.0	128.64	-9.76	-7.05	1250	109.60	-8.09	-6.87	Y	Y
2142	UB Non-mentholated	-1	271	2406.0	652.03	NA	NA	500	542.00	NA	NA	Y	Y
2143	UB Non-mentholated	-1	179	2510.0	449.29	NA	NA	595	300.84	NA	NA	Y	Y

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2143	VLN Non-mentholated	2	174	2050.0	356.70	-92.59	-20.61	756	230.16	-70.68	-23.49	Y	Y
		6	136	2221.0	302.06	-147.23	-32.77	729	186.56	-114.28	-37.99	Y	Y
2158	UB Non-mentholated	-1	143	1684.0	240.81	NA	NA	843	169.63	NA	NA	Y	Y
		2	183	1211.0	221.61	-19.20	-7.97	1160	157.76	-11.87	-7.00	Y	Y
2159	UB Non-mentholated	-1	224	1506.0	337.34	NA	NA	795	281.76	NA	NA	Y	N
	VLN Non-mentholated	2	223	1042.0	232.37	-104.98	-31.12	1100	202.73	-79.03	-28.05	Y	N
		6	212	1311.0	277.93	-59.41	-17.61	1050	201.90	-79.86	-28.34	Y	N
2164	UB Non-mentholated	-1	203	2448.0	496.94	NA	NA	520	390.38	NA	NA	Y	Y
	VLN Non-mentholated	2	140	2822.0	395.08	-101.86	-20.50	464	301.72	-88.66	-22.71	Y	Y
		6	147	2302.0	338.39	-158.55	-31.91	568	258.80	-131.58	-33.71	Y	Y
2168	UB Non-mentholated	-1	151	1464.0	221.06	NA	NA	459	328.98	NA	NA	Y	N
	VLN Non-mentholated	2	134	1163.0	155.84	-65.22	-29.50	528	253.79	-75.19	-22.86	Y	N
		6	116	216.0	.	.	.	427	271.66	-57.31	-17.42	N	N
2170	UB Non-mentholated	-1	363	929.0	337.23	NA	NA	1190	305.04	NA	NA	Y	Y
		2	386	1105.0	426.53	89.30	26.48	1090	354.13	49.09	16.09	Y	Y
		6	427	1005.0	.	.	.	1550	275.48	-29.56	-9.69	N	N
2175	UB Mentholated	-1	219	1724.0	377.56	NA	NA	736	297.55	NA	NA	Y	Y
		2	185	1687.0	312.10	-65.46	-17.34	776	238.40	-59.15	-19.88	Y	Y

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2175	UB Mentholated	6	223	1431.0	319.11	-58.44	-15.48	916	243.45	-54.10	-18.18	Y	Y
2189	UB Mentholated	-1	50.8	2385.0	121.16	NA	NA	806	63.03	NA	NA	Y	Y
2211	UB Mentholated VLN Mentholated	-1	107	2088.0	223.42	NA	NA	517	206.96	NA	NA	Y	N
		2	101	1946.0	196.55	-26.87	-12.03	591	170.90	-36.07	-17.43	Y	N
		6	91.3	297.0	27.12	-196.30	-87.86	685	133.28	-73.68	-35.60	Y	N
2212	UB Mentholated	-1	130	1397.0	181.61	NA	NA	1470	88.44	NA	NA	Y	Y
		2	105	1514.0	158.97	-22.64	-12.47	1400	75.00	-13.44	-15.19	Y	Y
		6	148	1016.0	150.37	-31.24	-17.20	2070	71.50	-16.94	-19.15	Y	Y
2213	UB Mentholated VLN Mentholated	-1	154	2513.0	387.00	NA	NA	930	165.59	NA	NA	Y	N
		2	147	2301.0	338.25	-48.76	-12.60	969	151.70	-13.89	-8.39	Y	N
		6	197	1689.0	332.73	-54.27	-14.02	1350	145.93	-19.67	-11.88	Y	N
2215	UB Mentholated	-1	156	1494.0	233.06	NA	NA	753	207.17	NA	NA	Y	Y
		2	168	1644.0	276.19	43.13	18.50	669	251.12	43.95	21.21	Y	Y
		6	211	1321.0	278.73	45.67	19.59	846	249.41	42.24	20.39	Y	Y
2220	UB Non-mentholated VLN Non-mentholated	-1	126	547.0	68.92	NA	NA	3260	38.65	NA	NA	Y	N
		2	78.7	1054.0	82.95	14.03	20.35	2100	37.48	-1.17	-3.04	Y	N
		6	123	900.0	110.70	41.78	60.62	2470	49.80	11.15	28.84	Y	N
2235	UB Mentholated	-1	407	1046.0	425.72	NA	NA	2100	193.81	NA	NA	Y	N

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

CFB = Change from Baseline, PCFB = Percent change from baseline, Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Values reported as below the limit of quantitation (BLQ) were set to one-half of the LLOQ for summarization and statistical analysis.

. = Value missing or not reportable.

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2235	VLN Mentholated	2	230	1129.0	259.67	-166.05	-39.00	2020	113.86	-79.95	-41.25	Y	N
		6	383	448.0	171.58	-254.14	-59.70	2030	188.67	-5.14	-2.65	Y	N
2244	UB Non-mentholated	-1	207	1370.0	283.59	NA	NA	1230	168.29	NA	NA	Y	N
	VLN Non-mentholated	2	246	1012.0	248.95	-34.64	-12.21	1940	126.80	-41.49	-24.65	Y	N
		6	253	926.0	234.28	-49.31	-17.39	1870	135.29	-33.00	-19.61	Y	N
2247	UB Mentholated	-1	203	1591.0	322.97	NA	NA	1430	141.96	NA	NA	Y	Y
	VLN Mentholated	2	133	1612.0	214.40	-108.58	-33.62	1270	104.72	-37.23	-26.23	Y	Y
2251	UB Non-mentholated	-1	209	1872.0	391.25	NA	NA	1050	199.05	NA	NA	Y	Y
		2	224	1851.0	414.62	23.38	5.97	1140	196.49	-2.56	-1.28	Y	Y
		6	384	1192.0	457.73	66.48	16.99	1870	205.35	6.30	3.17	Y	Y
2257	UB Non-mentholated	-1	52.3	2851.0	149.11	NA	NA	393	133.08	NA	NA	Y	Y
		2	77.7	1989.0	154.55	5.44	3.65	497	156.34	23.26	17.48	Y	Y
		6	70.5	1988.0	140.15	-8.95	-6.00	427	165.11	32.03	24.07	Y	Y
2259	UB Mentholated	-1	141	1236.0	174.28	NA	NA	2220	63.51	NA	NA	Y	Y
		2	148	1039.0	153.77	-20.50	-11.77	2440	60.66	-2.86	-4.50	Y	Y
		6	179	999.0	178.82	4.55	2.61	2520	71.03	7.52	11.84	Y	Y
2269	UB Mentholated	-1	190	1468.0	278.92	NA	NA	1540	123.38	NA	NA	Y	N
	VLN Mentholated	2	134	353.0	47.30	-231.62	-83.04	1120	119.64	-3.73	-3.03	Y	N

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

CFB = Change from Baseline, PCFB = Percent change from baseline, Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Values reported as below the limit of quantitation (BLQ) were set to one-half of the LLOQ for summarization and statistical analysis.

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Appendix 16.2.6.7 Urinary 1-OHP (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Conc. (pg/mL)	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
					Amount (ng/24hrs)	CFB (ng/24hrs)	PCFB (%)		Amount (ng/g Creat.)	CFB (ng/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2269	VLN Mentholated	6	70.3	845.0	59.40	-219.52	-78.70	627	112.12	-11.26	-9.12	Y	N
2272	UB Mentholated	-1	107	889.0	95.12	NA	NA	2370	45.15	NA	NA	Y	N
	VLN Mentholated	2	53.1	1818.0	96.54	1.41	1.49	1070	49.63	4.48	9.92	Y	N
		6	47.4	1589.0	75.32	-19.80	-20.82	1290	36.74	-8.40	-18.61	Y	N

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

CFB = Change from Baseline, PCFB = Percent change from baseline, Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Values reported as below the limit of quantitation (BLQ) were set to one-half of the LLOQ for summarization and statistical analysis.

. = Value missing or not reportable.

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag
1001	UB Non-mentholated	-1	2171.0	1770	494	1640	2860	4900	5270	Y	N
	VLN Non-mentholated	2	1172.6	89.3	96.7	573	2110	3420	1550	Y	N
		6	1249.1	149	369	1260	3430	4600	2070	Y	N
1002	UB Non-mentholated	-1	4356.5	690	343	2170	1500	4720	3950	Y	N
	VLN Non-mentholated	2	4062.7	60.9	102	1060	1000	2770	2670	Y	N
		6	5759.6	BLQ<(50.0)	58.5	942	678	2310	1900	Y	N
1003	UB Mentholated	-1	1385.0	1200	1380	1760	5060	4830	3890	Y	N
	VLN Mentholated	2	410.0	127	449	814	3420	3420	2280	Y	N
		6	1017.7	238	881	1970	7130	7320	4860	Y	N
1007	UB Non-mentholated	-1	1935.0	1100	1060	846	2280	1300	1220	Y	Y
	VLN Non-mentholated	2	2199.9	BLQ<(50.0)	BLQ<(50.0)	BLQ<(50.0)	BLQ<(200)	79.3	BLQ<(200)	Y	Y
		6	1700.3	62.0	107	113	410	182	201	Y	Y
1008	UB Mentholated	-1	2014.0	802	925	2790	3430	3210	3570	Y	N
	VLN Mentholated	2	1435.9	87.1	68.7	666	1170	1340	1430	Y	N
		6	1122.0	55.3	50.7	1500	1510	1800	1720	N	N
1010	UB Mentholated	-1	2030.0	627	2030	2010	8650	5190	3760	Y	Y
		2	1539.6	365	1860	1540	8980	5350	4050	Y	Y
		6	1036.8	599	756	1140	3950	4140	2990	N	N
1011	UB Non-mentholated	-1	1059.0	962	3920	2340	12900	5750	2520	Y	Y
		2	1364.0	712	2770	1420	8410	2790	1360	Y	Y

Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Values reported as below the limit of quantitation (BLQ) were set to one-half of the LLOQ for summarization and statistical analysis.

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population ----- ITT PP Flag Flag	
1011	UB Non-mentholated	6	628.7	944	2260	1390	8470	3020	1680	N	N
1013	UB Non-mentholated VLN Non-mentholated	-1	1664.0	878	1590	2200	5650	5820	2570	Y	N
		2	1043.8	BLQ<(50.0)	519	1060	4140	5020	2450	N	N
		6	874.0	172	747	1320	6230	5390	2470	Y	N
1014	UB Mentholated VLN Mentholated	-1	2069.0	1630	2240	1480	3570	806	344	Y	N
		6	903.2	333	1480	1680	6580	2160	927	Y	N
1015	UB Mentholated VLN Mentholated	-1	3550.0	739	236	771	1010	2590	2250	Y	Y
		2	3406.2	BLQ<(50.0)	BLQ<(50.0)	BLQ<(50.0)	BLQ<(200)	59.3	BLQ<(200)	Y	Y
		6	3477.7	92.4	BLQ<(50.0)	BLQ<(50.0)	BLQ<(200)	136	BLQ<(200)	Y	Y
1016	UB Non-mentholated	-1	1853.0	880	1110	2130	5220	4310	3330	Y	Y
		2	2839.1	752	817	1890	3690	2930	1980	Y	Y
		6	1899.3	763	941	2360	3750	5260	3590	Y	Y
1017	UB Mentholated	-1	2490.0	336	1980	1090	6180	1670	1140	Y	Y
		2	2593.9	496	1540	1430	7300	2230	1630	Y	Y
		6	1399.2	418	2300	1760	9670	4200	2580	Y	Y
1018	UB Mentholated	-1	1721.0	1250	1210	1490	4460	4740	2740	Y	Y
1019	UB Non-mentholated VLN Non-mentholated	-1	1431.0	530	1600	2030	5400	6260	2550	Y	N
		2	3109.0	BLQ<(50.0)	55.3	322	704	884	369	Y	N
		6	2290.1	380	581	1490	3390	4420	1760	Y	N
1020	UB Non-mentholated	-1	1666.0	408	1650	2190	8750	5420	2440	Y	N

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Urine Study Week	Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag

Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Values reported as below the limit of quantitation (BLQ) were set to one-half of the LLOQ for summarization and statistical analysis.

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag
1020	VLN Non-mentholated	2	1240.9	87.1	532	508	3330	2000	1070	Y	N
		6	917.7	63.8	710	1050	7680	6390	3230	Y	N
1021	UB Non-mentholated	-1	1808.0	183	449	885	2360	2560	1520	N	N
		2	1842.4	231	723	944	2910	2410	1590	Y	Y
		6	2136.5	324	681	1010	2620	1980	1150	Y	Y
1023	UB Non-mentholated VLN Non-mentholated	-1	2894.0	258	278	537	1570	1590	733	Y	N
		2	3795.5	BLQ<(50.0)	BLQ<(50.0)	BLQ<(50.0)	BLQ<(200)	119	BLQ<(200)	Y	N
		6	3600.0	BLQ<(50.0)	139	243	1130	559	299	Y	N
1029	UB Mentholated VLN Mentholated	-1	2525.2	693	455	649	3510	2310	3710	Y	N
		2	3098.0	BLQ<(50.0)	55.4	212	953	1090	1380	Y	N
		6	2192.0	BLQ<(50.0)	254	303	3240	1920	3690	Y	N
1032	UB Mentholated VLN Mentholated	-1	3793.8	382	422	1570	1630	3450	1850	Y	Y
		2	3479.0	BLQ<(50.0)	BLQ<(50.0)	56.3	BLQ<(200)	155	BLQ<(200)	Y	Y
		6	2345.0	BLQ<(50.0)	BLQ<(50.0)	226	530	1080	651	Y	Y
1034	UB Non-mentholated VLN Non-mentholated	-1	1275.1	2760	1630	1690	5860	3810	3610	Y	N
		2	969.0	346	465	985	3670	3180	2780	Y	N
		6	1037.0	357	1020	1190	7750	3110	3330	Y	N
1035	UB Non-mentholated VLN Non-mentholated	-1	2182.4	334	1610	1280	4570	2360	779	Y	N
		2	2196.0	67.7	590	1060	3400	2930	1130	Y	N
		6	1204.0	119	1290	1580	6660	3930	1940	Y	N

Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag
1036	UB Mentholated	-1	1896.8	1240	417	1200	1560	2380	1920	Y	Y
		2	1841.0	856	503	1370	1960	2570	2330	Y	Y
		6	1475.0	960	832	1820	3380	3820	3460	Y	Y
1037	UB Mentholated	-1	5986.4	497	419	643	1830	1770	1880	Y	Y
		2	2822.0	418	839	1160	3600	3670	3820	Y	Y
		6	2712.0	667	1090	1320	4830	3990	4000	Y	Y
1038	UB Non-mentholated	-1	1610.1	1870	946	1890	4290	4490	1590	Y	N
	VLN Non-mentholated	2	1705.0	BLQ<(50.0)	BLQ<(50.0)	55.7	283	160	BLQ<(200)	Y	N
		6	1641.0	132	309	664	3020	2830	1250	Y	N
1042	UB Non-mentholated	-1	5646.2	1000	289	760	1130	1330	1700	Y	N
	VLN Non-mentholated	2	3586.0	BLQ<(50.0)	BLQ<(50.0)	BLQ<(50.0)	BLQ<(200)	148	261	Y	N
		6	2769.0	BLQ<(50.0)	BLQ<(50.0)	152	401	570	684	Y	N
1045	UB Non-mentholated	-1	3025.5	1770	2780	841	3070	111	BLQ<(200)	Y	Y
		2	2443.0	1470	3090	693	2840	98.3	BLQ<(200)	Y	Y
		6	1894.0	1950	4330	860	3720	140	BLQ<(200)	Y	Y
1046	UB Mentholated	-1	3780.8	326	289	972	1570	2800	1400	Y	Y
		2	2832.0	670	378	1120	1840	3730	1890	Y	Y
		6	2830.0	539	491	1030	2220	3590	1830	Y	Y
1050	UB Non-mentholated	-1	1520.3	1530	1570	2130	4220	3450	3360	Y	N
	VLN Non-mentholated	2	3144.1	55.0	BLQ<(50.0)	126	317	233	BLQ<(200)	Y	N

Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Values reported as below the limit of quantitation (BLQ) were set to one-half of the LLOQ for summarization and statistical analysis.

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag
1050	VLN Non-mentholated	6	1578.0	293	525	1360	4250	3820	3280	Y	N
1051	UB Mentholated	-1	2216.8	586	835	1550	3220	3790	1220	Y	Y
		2	2040.0	721	908	1740	3270	3650	1010	Y	Y
		6	1784.0	298	820	1710	3790	4360	1290	Y	Y
1052	UB Mentholated VLN Mentholated	-1	1539.8	489	168	3490	245	4130	6130	Y	N
		2	1602.0	BLQ<(50.0)	BLQ<(50.0)	1280	BLQ<(200)	1500	1840	Y	N
		6	1065.0	644	250	4050	372	4210	6020	Y	N
1053	UB Mentholated VLN Mentholated	-1	2902.3	1040	651	1190	1500	1630	1440	Y	N
		2	2790.0	BLQ<(50.0)	BLQ<(50.0)	110	216	230	250	Y	N
		6	2523.0	203	94.5	211	394	359	352	Y	N
1054	UB Non-mentholated	-1	956.9	3980	2950	2020	14100	13300	10000	Y	Y
		2	1844.0	1150	1610	1590	6510	4920	3270	Y	Y
		6	1089.0	2540	2060	1640	11100	8650	6450	Y	Y
1055	UB Mentholated VLN Mentholated	-1	3328.9	673	719	1320	2720	3510	1400	Y	N
		2	3391.6	BLQ<(50.0)	BLQ<(50.0)	BLQ<(50.0)	BLQ<(200)	95.3	BLQ<(200)	Y	N
		6	1581.0	63.0	506	739	3530	3090	1520	Y	N
1056	UB Non-mentholated VLN Non-mentholated	-1	3925.2	488	401	707	1830	2490	1590	Y	N
		2	1334.0	BLQ<(50.0)	59.1	110	624	844	524	Y	N
		6	1152.0	BLQ<(50.0)	249	542	2060	2840	1970	Y	N
1058	UB Non-mentholated	-1	3355.1	957	830	1810	2540	1890	1430	Y	N

Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Values reported as below the limit of quantitation (BLQ) were set to one-half of the LLOQ for summarization and statistical analysis.

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag
1058	VLN Non-mentholated	2	2869.0	BLQ<(50.0)	BLQ<(50.0)	57.8	BLQ<(200)	68.7	BLQ<(200)	Y	N
		6	1927.0	667	969	2170	4370	3450	2520	Y	N
1059	UB Non-mentholated	-1	956.0	2020	7320	1910	22800	7220	4300	Y	Y
		2	2124.7	1210	2950	1250	8170	3060	1320	Y	Y
		6	1507.0	861	5770	1760	15600	4410	2040	Y	Y
1060	UB Mentholated VLN Mentholated	-1	2414.0	966	1310	2520	3390	3290	1450	Y	N
		2	2361.4	68.9	64.5	601	859	1320	628	Y	N
		6	1742.0	167	466	1880	3150	3560	1530	Y	N
1063	UB Mentholated VLN Mentholated	-1	7095.2	376	359	813	1490	1690	1160	Y	Y
		2	3891.4	BLQ<(50.0)	BLQ<(50.0)	BLQ<(50.0)	BLQ<(200)	50.6	BLQ<(200)	Y	Y
		6	3208.0	BLQ<(50.0)	BLQ<(50.0)	BLQ<(50.0)	BLQ<(200)	BLQ<(50.0)	BLQ<(200)	Y	Y
1064	UB Non-mentholated	-1	3268.0	499	447	1390	1930	5450	3100	Y	Y
		2	2273.1	1100	980	2230	3640	6280	3680	Y	Y
1066	UB Non-mentholated VLN Non-mentholated	-1	967.0	1940	5990	1530	7810	1080	966	Y	Y
		2	1744.8	71.5	96.1	79.1	BLQ<(200)	BLQ<(50.0)	BLQ<(200)	Y	Y
		6	1725.0	BLQ<(50.0)	65.2	61.8	BLQ<(200)	BLQ<(50.0)	BLQ<(200)	Y	Y
1069	UB Non-mentholated	-1	2554.0	969	1120	1320	4120	2490	1010	Y	Y
		2	2465.9	867	1350	1200	4870	2380	962	Y	Y
		6	2162.0	2510	1620	1240	5610	3010	1310	Y	Y
1070	UB Non-mentholated	-1	3393.0	591	1370	1080	4190	1560	1810	Y	Y

Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Values reported as below the limit of quantitation (BLQ) were set to one-half of the LLOQ for summarization and statistical analysis.

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag
1070	VLN Non-mentholated	2	2687.1	BLQ<(50.0)	124	162	480	339	294	Y	Y
		6	1316.0	66.3	317	218	1450	632	685	Y	Y
1071	UB Non-mentholated	-1	2129.0	1330	615	1400	3150	2900	2710	Y	N
	VLN Non-mentholated	2	2212.3	413	248	942	2200	1730	1560	Y	N
1072	UB Mentholated	-1	2181.0	314	670	846	3600	3800	2340	Y	Y
	VLN Mentholated	2	1779.7	BLQ<(50.0)	62.5	77.9	521	420	290	Y	Y
1074	UB Non-mentholated	-1	2211.0	665	105	2360	BLQ<(200)	4050	4080	Y	N
	VLN Non-mentholated	2	1464.3	161	58.9	1710	BLQ<(200)	2840	3170	Y	N
		6	1677.0	92.0	54.8	1910	BLQ<(200)	2810	2890	Y	N
1075	UB Non-mentholated	-1	2163.0	208	998	1140	3610	2580	1230	Y	Y
		2	1890.7	293	1470	1320	4350	2520	1300	Y	Y
		6	1263.0	500	1970	1350	7670	3930	2510	Y	Y
1077	UB Non-mentholated	-1	3102.1	1280	1730	1800	3690	1440	1010	Y	Y
	VLN Non-mentholated	2	3008.3	BLQ<(50.0)	59.8	70.4	209	64.9	BLQ<(200)	Y	Y
		6	2743.0	BLQ<(50.0)	BLQ<(50.0)	61.5	BLQ<(200)	55.6	BLQ<(200)	Y	Y
1078	UB Non-mentholated	-1	1991.0	889	748	1320	3290	4160	2730	Y	N
	VLN Non-mentholated	2	3513.1	70.3	109	244	705	710	412	Y	N
		6	2384.0	119	418	945	2950	3480	2240	Y	N
1079	UB Mentholated	-1	2154.0	724	1170	1620	3990	3870	1280	Y	Y
	VLN Mentholated	2	3647.6	BLQ<(50.0)	BLQ<(50.0)	BLQ<(50.0)	BLQ<(200)	BLQ<(50.0)	BLQ<(200)	Y	Y

Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag
1079	VLN Mentholated	6	2605.0	BLQ<(50.0)	BLQ<(50.0)	BLQ<(50.0)	BLQ<(200)	BLQ<(50.0)	BLQ<(200)	Y	Y
1082	UB Non-mentholated	-1	2790.0	301	1480	1380	4490	2870	1110	Y	N
	VLN Non-mentholated	2	2629.9	BLQ<(50.0)	157	307	1280	1040	386	Y	N
		6	2013.0	BLQ<(50.0)	757	627	3790	2130	944	Y	N
1083	UB Non-mentholated	-1	1708.0	1500	3360	1810	7530	2520	2010	Y	N
	VLN Non-mentholated	2	1788.0	351	1200	1050	5160	1800	1270	Y	N
		6	2017.0	498	1400	1430	5810	2330	1590	Y	N
1084	UB Non-mentholated	-1	1467.0	740	1450	1670	4920	4490	3380	Y	N
	VLN Non-mentholated	2	1158.4	117	156	469	2330	2030	1880	Y	N
1086	UB Non-mentholated	-1	1938.0	1150	1550	3060	6090	6480	2170	Y	N
	VLN Non-mentholated	2	1255.9	55.4	228	869	3020	2810	1060	Y	N
		6	1580.0	97.1	704	1510	4770	3780	1630	Y	N
1088	UB Mentholated	-1	1662.0	473	1470	1580	5940	5730	3270	Y	N
	VLN Mentholated	2	1236.2	BLQ<(50.0)	158	791	3340	4980	3050	Y	N
		6	1670.0	BLQ<(50.0)	586	780	4800	3740	3000	Y	N
1089	UB Non-mentholated	-1	1795.0	867	480	950	1710	3800	980	Y	Y
		2	2415.3	628	286	730	1170	3310	824	Y	Y
		6	2062.0	697	315	777	1370	3160	780	Y	Y
1092	UB Mentholated	-1	2383.0	445	463	1980	1640	5040	2570	Y	N
	VLN Mentholated	2	1551.7	454	560	1760	1870	4200	2570	Y	N

Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag
1092	VLN Mentholated	6	1587.0	241	405	1660	2550	7350	5410	Y	N
1094	UB Mentholated	-1	1930.0	564	2040	1490	4120	2050	1600	Y	N
	VLN Mentholated	2	1307.6	BLQ<(50.0)	132	233	1120	489	436	Y	N
		6	1040.0	BLQ<(50.0)	300	479	2310	1070	931	Y	N
1095	UB Mentholated	-1	2551.0	1020	731	1130	2400	2210	838	Y	N
	VLN Mentholated	2	430.3	170	505	488	2560	1090	501	N	N
		6	2131.0	94.0	151	559	1450	1330	557	Y	N
1096	UB Non-mentholated	-1	2532.0	725	1030	931	4000	2430	1890	Y	N
	VLN Non-mentholated	2	1934.5	398	859	924	4240	1980	1460	Y	N
		6	2949.0	417	882	891	2910	1860	1290	Y	N
1097	UB Mentholated	-1	1982.0	1400	71.3	2320	BLQ<(200)	6240	7250	Y	N
	VLN Mentholated	2	1598.3	BLQ<(50.0)	BLQ<(50.0)	1530	BLQ<(200)	3970	5820	Y	N
		6	1814.0	60.5	BLQ<(50.0)	1780	BLQ<(200)	3940	4370	Y	N
1098	UB Non-mentholated	-1	1415.8	853	2970	940	10300	2060	2240	Y	Y
	VLN Non-mentholated	2	1666.1	52.6	181	63.5	898	144	BLQ<(200)	Y	Y
		6	1811.0	BLQ<(50.0)	131	51.9	580	93.9	BLQ<(200)	Y	Y
1099	UB Non-mentholated	-1	810.2	1020	1690	2140	8380	8720	5060	N	N
	VLN Non-mentholated	2	1272.2	BLQ<(50.0)	154	358	2110	2030	1050	Y	N
		6	1005.0	77.3	602	972	5450	4410	2300	Y	N
1100	UB Non-mentholated	-1	3350.7	728	1040	915	2310	1450	603	Y	N

Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag
1100	VLN Non-mentholated	2	2653.5	80.7	464	650	2530	2270	1050	Y	N
		6	2576.0	438	763	1060	3260	2670	1190	Y	N
1101	UB Non-mentholated VLN Non-mentholated	-1	1814.1	125	668	1180	3350	5860	1610	Y	N
		2	2317.4	BLQ<(50.0)	72.7	264	1660	3190	1060	Y	N
		6	3707.0	BLQ<(50.0)	177	651	1230	2330	747	Y	N
1103	UB Non-mentholated VLN Non-mentholated	-1	3479.4	667	864	1530	2930	3050	1840	Y	N
		2	2449.2	BLQ<(50.0)	193	521	1620	1650	1030	Y	N
		6	2601.0	132	948	1710	3950	2870	1780	Y	N
1105	UB Non-mentholated VLN Non-mentholated	-1	527.3	3440	1590	1700	11000	14100	11800	Y	N
		2	825.2	71.1	328	891	5650	5660	5610	Y	N
		6	677.0	195	790	1130	7630	4710	4790	Y	N
1106	UB Non-mentholated	-1	1380.1	1090	1300	2140	5840	11300	9170	Y	Y
		2	1113.7	903	1540	2380	7210	14500	10000	Y	Y
		6	2435.0	499	775	1710	3890	6510	6490	Y	Y
1107	UB Non-mentholated VLN Non-mentholated	-1	2365.5	572	505	625	1520	1170	1030	Y	N
		2	2512.8	BLQ<(50.0)	120	251	934	753	763	Y	N
		6	2599.0	BLQ<(50.0)	316	693	2010	1390	1180	Y	N
1108	UB Non-mentholated	-1	1782.0	288	1020	1570	4360	5960	3530	Y	Y
		2	2115.4	365	1450	1430	4530	3420	2230	Y	Y
		6	1981.0	425	1260	1410	4280	3730	2360	Y	Y

Subjects used their own usual brand cigarettes at Week -1.

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VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag
1109	UB Non-mentholated	-1	1615.9	2020	2070	1730	7620	4740	3790	Y	Y
		2	1805.0	1590	1370	1520	6710	5070	4100	Y	Y
		6	1075.0	1840	2260	1670	11400	7240	6600	Y	Y
1112	UB Non-mentholated VLN Non-mentholated	-1	2265.2	859	625	1380	2120	2410	1210	Y	N
		2	1829.3	95.8	249	549	1330	1330	719	Y	N
		6	2121.0	125	534	1140	1890	2180	1030	Y	N
1114	UB Non-mentholated	-1	1506.7	550	663	671	2880	2870	2500	Y	Y
		2	2909.4	164	214	409	1300	1380	1050	Y	Y
		6	1920.0	343	381	554	1610	2380	1660	Y	Y
1115	UB Non-mentholated VLN Non-mentholated	-1	1785.7	711	1420	1330	8080	6240	2850	Y	Y
		2	1601.3	BLQ<(50.0)	52.2	53.9	506	427	202	Y	Y
2002	UB Mentholated	-1	2188.0	1930	585	1590	2330	3760	3760	Y	Y
		2	1893.0	2460	579	1500	2090	3570	3500	Y	Y
		6	3245.0	1200	591	1630	1630	2550	2540	Y	Y
2003	UB Mentholated VLN Mentholated	-1	3036.0	407	267	1090	1260	3900	2100	Y	N
		2	4180.0	BLQ<(50.0)	BLQ<(50.0)	411	577	1660	1040	Y	N
		6	3245.0	69.8	BLQ<(50.0)	581	566	2210	1170	Y	N
2007	UB Non-mentholated VLN Non-mentholated	-1	1535.0	278	985	841	3700	1930	1410	Y	Y
		2	1492.0	BLQ<(50.0)	72.4	147	1020	588	440	Y	Y
		6	1387.0	BLQ<(50.0)	BLQ<(50.0)	106	577	376	275	Y	Y

Subjects used their own usual brand cigarettes at Week -1.

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag
2008	UB Mentholated	-1	2663.0	793	147	2790	BLQ<(200)	2450	1260	Y	Y
	VLN Mentholated	2	3323.0	BLQ<(50.0)	BLQ<(50.0)	65.8	BLQ<(200)	58.5	BLQ<(200)	Y	Y
		6	1734.0	BLQ<(50.0)	BLQ<(50.0)	539	BLQ<(200)	654	404	Y	Y
2009	UB Non-mentholated	-1	2427.0	244	318	917	1630	2280	1010	Y	N
	VLN Non-mentholated	2	1390.0	BLQ<(50.0)	146	836	2370	3280	1650	Y	N
2010	UB Mentholated	-1	1673.0	1230	403	1020	2170	3170	3470	Y	Y
		2	1289.0	1140	488	1040	2090	2440	2520	Y	Y
		6	1158.0	1180	488	973	2170	2790	3010	Y	Y
2011	UB Mentholated	-1	1639.0	1520	1830	1500	2820	1040	550	Y	N
	VLN Mentholated	2	1510.0	78.4	201	801	2020	706	385	Y	N
		6	1165.0	BLQ<(50.0)	411	987	3280	1510	784	Y	N
2014	UB Mentholated	-1	3009.0	624	258	2360	842	3460	3350	Y	N
	VLN Mentholated	2	1438.0	BLQ<(50.0)	BLQ<(50.0)	976	721	2100	2590	Y	N
		6	2776.0	105	BLQ<(50.0)	1100	580	2420	2860	Y	N
2015	UB Mentholated	-1	1277.0	942	515	1500	2890	4200	2690	Y	Y
		2	1774.0	819	490	911	1840	2920	2040	Y	Y
		6	1070.0	172	BLQ<(50.0)	1380	1260	3440	2250	Y	Y
2016	UB Mentholated	-1	1787.0	1150	106	1830	BLQ<(200)	3750	1920	Y	Y
2017	UB Mentholated	-1	1504.0	2910	1050	4260	2710	5670	3310	Y	N
	VLN Mentholated	2	1864.0	112	BLQ<(50.0)	204	BLQ<(200)	227	BLQ<(200)	Y	N

Subjects used their own usual brand cigarettes at Week -1.

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag
2017	VLN Mentholated	6	1210.0	1050	623	1510	3240	5240	3560	Y	N
2018	UB Mentholated	-1	1191.0	746	86.3	2140	BLQ<(200)	4150	3860	Y	Y
		2	1374.0	378	100	2220	BLQ<(200)	4610	4060	Y	Y
		6	963.0	596	150	2440	BLQ<(200)	6770	6500	Y	Y
2020	UB Mentholated VLN Mentholated	-1	1117.0	247	409	1800	2040	2790	1390	Y	N
		2	1155.0	BLQ<(50.0)	BLQ<(50.0)	774	1330	1390	950	Y	N
		6	1300.0	75.5	122	1280	1810	2100	1260	Y	N
2021	UB Mentholated VLN Mentholated	-1	2086.0	422	BLQ<(50.0)	1310	BLQ<(200)	1780	1610	Y	Y
		2	2606.0	BLQ<(50.0)	BLQ<(50.0)	159	BLQ<(200)	222	BLQ<(200)	Y	Y
		6	2561.0	BLQ<(50.0)	BLQ<(50.0)	148	BLQ<(200)	304	240	Y	Y
2023	UB Mentholated VLN Mentholated	-1	996.0	1590	247	2090	221	4790	3050	Y	Y
		2	1252.0	BLQ<(50.0)	BLQ<(50.0)	57.3	BLQ<(200)	102	BLQ<(200)	Y	Y
		6	999.0	BLQ<(50.0)	BLQ<(50.0)	BLQ<(50.0)	BLQ<(200)	93.0	BLQ<(200)	Y	Y
2024	UB Non-mentholated	-1	1112.0	467	3200	1290	8780	4410	4020	Y	Y
2025	UB Non-mentholated	-1	2766.0	164	606	1360	4030	3860	1840	Y	Y
		2	2484.0	377	872	1540	5700	3750	1930	Y	Y
		6	2746.0	222	641	1330	4830	6140	3090	Y	Y
2028	UB Non-mentholated VLN Non-mentholated	-1	1538.0	274	828	1270	3590	3320	2950	Y	Y
		2	1876.0	BLQ<(50.0)	BLQ<(50.0)	157	283	390	325	Y	Y
		6	616.0	BLQ<(50.0)	BLQ<(50.0)	82.1	229	342	278	Y	Y

Subjects used their own usual brand cigarettes at Week -1.

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag
2029	UB Mentholated	-1	1689.0	407	835	876	2760	1630	1510	Y	Y
		2	1933.0	491	598	780	2940	2170	2150	Y	Y
		6	2068.0	177	600	825	2600	1740	1500	Y	Y
2039	UB Mentholated VLN Mentholated	-1	1765.0	887	1490	1590	4320	1710	1330	Y	N
		2	1582.0	301	722	1210	3220	1380	1040	Y	N
		6	718.0	292	680	1390	3910	1860	1360	Y	N
2050	UB Mentholated	-1	1887.0	2540	93.6	3780	BLQ<(200)	5390	4890	Y	Y
		2	1436.0	2090	87.0	3340	BLQ<(200)	4520	4060	Y	Y
		6	1392.0	1500	75.4	3440	BLQ<(200)	4810	4070	Y	Y
2052	UB Mentholated VLN Mentholated	-1	2094.0	918	688	888	1950	1870	1570	Y	Y
		2	1611.0	BLQ<(50.0)	BLQ<(50.0)	50.6	BLQ<(200)	164	BLQ<(200)	Y	Y
		6	2735.0	BLQ<(50.0)	BLQ<(50.0)	52.9	BLQ<(200)	96.6	BLQ<(200)	Y	Y
2057	UB Mentholated VLN Mentholated	-1	3085.0	967	444	772	1090	1230	1600	Y	N
		2	3805.0	BLQ<(50.0)	BLQ<(50.0)	165	329	294	360	Y	N
		6	3820.0	103	107	558	858	872	1090	Y	N
2058	UB Mentholated VLN Mentholated	-1	1240.0	471	758	1660	3300	2990	1440	Y	N
		2	1621.0	BLQ<(50.0)	BLQ<(50.0)	238	230	242	BLQ<(200)	Y	N
		6	2198.0	BLQ<(50.0)	55.2	339	310	347	BLQ<(200)	Y	N
2059	UB Mentholated	-1	1545.0	1090	672	1900	1910	3220	2220	Y	Y
		2	1452.0	1260	882	2200	2300	3070	2250	Y	Y

Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Values reported as below the limit of quantitation (BLQ) were set to one-half of the LLOQ for summarization and statistical analysis.

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag
2059	UB Mentholated	6	1242.0	2280	872	1950	1980	2840	2100	Y	Y
2060	UB Mentholated	-1	773.0	1780	3430	2130	10300	6600	2870	Y	N
	VLN Mentholated	2	684.0	99.4	386	740	4980	2930	1750	Y	N
		6	1465.0	970	1960	1920	7210	4980	2200	Y	N
2064	UB Mentholated	-1	3404.0	979	671	883	3890	2600	3160	Y	N
	VLN Mentholated	2	2844.0	96.2	265	562	3290	1590	1860	Y	N
		6	2882.0	76.0	149	477	2540	1820	1840	Y	N
2066	UB Mentholated	-1	1056.0	1080	4170	2130	10100	3440	2670	Y	N
	VLN Mentholated	2	912.0	208	957	1240	4770	1920	1580	Y	N
		6	1617.0	111	390	901	3010	1000	807	Y	N
2067	UB Non-mentholated	-1	2550.0	241	419	1100	2130	3180	2740	Y	N
	VLN Non-mentholated	2	1608.0	BLQ<(50.0)	182	886	2480	2830	2210	Y	N
		6	2810.0	237	309	886	1660	3030	2380	Y	N
2075	UB Mentholated	-1	3995.0	450	150	641	1210	3720	1420	Y	Y
2076	UB Mentholated	-1	2036.0	279	253	882	1100	2720	2610	Y	N
	VLN Mentholated	2	2229.0	BLQ<(50.0)	BLQ<(50.0)	106	BLQ<(200)	379	415	Y	N
		6	2063.0	BLQ<(50.0)	BLQ<(50.0)	418	961	2130	2700	Y	N
2086	UB Non-mentholated	-1	779.0	1760	1810	1370	6810	6410	5500	Y	N
	VLN Non-mentholated	2	1692.0	66.5	119	348	1440	767	694	Y	N
2088	UB Mentholated	-1	3222.0	429	732	948	2510	1430	2280	Y	N

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Urine Study Week	Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag

Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Values reported as below the limit of quantitation (BLQ) were set to one-half of the LLOQ for summarization and statistical analysis.

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag
2088	VLN Mentholated	2	2854.0	BLQ<(50.0)	BLQ<(50.0)	145	508	354	543	Y	N
		6	2370.0	BLQ<(50.0)	BLQ<(50.0)	255	809	776	1250	Y	N
2092	UB Mentholated	-1	2002.0	118	128	396	943	1810	1130	Y	N
	VLN Mentholated	2	1940.0	BLQ<(50.0)	BLQ<(50.0)	BLQ<(50.0)	BLQ<(200)	175	BLQ<(200)	Y	N
		6	2262.0	BLQ<(50.0)	BLQ<(50.0)	122	426	634	389	Y	N
2099	UB Non-mentholated	-1	1107.0	117	1600	1120	7640	4150	2290	Y	N
	VLN Non-mentholated	2	1523.0	BLQ<(50.0)	162	333	2280	1450	856	Y	N
		6	1051.0	BLQ<(50.0)	719	640	5340	2510	1560	Y	N
2100	UB Mentholated	-1	577.0	2620	3280	2260	22000	10700	13600	Y	Y
		2	1028.0	1910	1760	1550	13400	7150	12600	Y	Y
		6	550.0	3010	3320	2170	25900	13900	19300	Y	Y
2108	UB Non-mentholated	-1	2860.0	635	266	694	1090	2550	1860	Y	N
	VLN Non-mentholated	2	3150.0	BLQ<(50.0)	BLQ<(50.0)	88.1	BLQ<(200)	204	BLQ<(200)	Y	N
		6	3399.0	68.8	87.9	426	711	1210	907	Y	N
2110	UB Mentholated	-1	1034.0	940	689	807	3160	5360	5500	Y	Y
		2	799.0	1560	1170	957	3620	4230	4410	Y	Y
		6	653.0	504	1330	1080	4870	4760	6200	Y	Y
2113	UB Mentholated	-1	843.0	1430	999	2050	3220	4180	2540	Y	Y
	VLN Mentholated	2	878.0	94.1	76.1	373	606	482	299	Y	Y
2115	UB Mentholated	-1	1626.0	843	98.7	2450	BLQ<(200)	3860	4130	Y	Y

Subjects used their own usual brand cigarettes at Week -1.

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VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag
2119	UB Mentholated	-1	650.0	3110	4580	3240	18400	7240	9820	Y	Y
	VLN Mentholated	2	786.0	69.9	256	224	1780	639	1060	Y	Y
		6	902.0	73.8	191	139	938	386	493	Y	Y
2120	UB Non-mentholated	-1	1243.0	757	751	1070	4170	3350	2530	Y	Y
	VLN Non-mentholated	2	1147.0	BLQ<(50.0)	BLQ<(50.0)	BLQ<(50.0)	BLQ<(200)	85.2	BLQ<(200)	Y	Y
		6	1735.0	BLQ<(50.0)	BLQ<(50.0)	BLQ<(50.0)	BLQ<(200)	104	BLQ<(200)	Y	Y
2122	UB Non-mentholated	-1	1396.0	403	1450	1330	6850	3720	3850	Y	Y
		2	1487.0	234	1300	1270	6430	2790	2840	Y	Y
		6	1643.0	221	1490	1110	6010	2420	2870	Y	Y
2125	UB Mentholated	-1	1819.0	501	BLQ<(50.0)	623	BLQ<(200)	3270	2970	Y	Y
		2	3746.0	101	BLQ<(50.0)	869	BLQ<(200)	2320	1900	Y	Y
		6	3110.0	842	BLQ<(50.0)	1240	BLQ<(200)	2950	2560	Y	Y
2126	UB Mentholated	-1	1339.0	1610	2880	1680	8440	2510	2330	Y	N
	VLN Mentholated	2	1234.0	BLQ<(50.0)	121	144	770	314	323	Y	N
		6	1047.0	78.0	164	473	3540	1240	1550	Y	N
2136	UB Non-mentholated	-1	2199.0	1170	1120	806	4390	3030	1730	Y	N
	VLN Non-mentholated	2	1100.0	51.9	408	433	4630	3250	2830	Y	N
2140	UB Non-mentholated	-1	800.0	288	1030	676	3150	2730	1650	Y	Y
		2	763.0	145	526	590	2850	2760	1750	Y	Y
		6	939.0	391	601	791	2660	2820	1600	Y	Y

Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

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VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag
2142	UB Non-mentholated	-1	2406.0	598	467	1440	2030	7130	5360	Y	Y
2143	UB Non-mentholated VLN Non-mentholated	-1	2510.0	191	1160	1800	5590	4270	4570	Y	Y
		2	2050.0	BLQ<(50.0)	BLQ<(50.0)	60.7	220	228	207	Y	Y
		6	2221.0	BLQ<(50.0)	BLQ<(50.0)	62.9	BLQ<(200)	174	BLQ<(200)	Y	Y
2158	UB Non-mentholated	-1	1684.0	1160	1810	1530	4830	2390	923	Y	Y
		2	1211.0	1360	2150	1650	6690	3530	1310	Y	Y
2159	UB Non-mentholated VLN Non-mentholated	-1	1506.0	356	3060	2830	9500	4860	2100	Y	N
		2	1042.0	70.8	806	1340	7780	3590	1890	Y	N
		6	1311.0	BLQ<(50.0)	1180	2000	9580	5150	2370	Y	N
2164	UB Non-mentholated VLN Non-mentholated	-1	2448.0	2030	1160	2080	2760	1630	1390	Y	Y
		2	2822.0	BLQ<(50.0)	BLQ<(50.0)	137	BLQ<(200)	97.6	BLQ<(200)	Y	Y
		6	2302.0	64.9	66.7	202	253	239	BLQ<(200)	Y	Y
2168	UB Non-mentholated VLN Non-mentholated	-1	1464.0	1560	1020	2140	4730	3820	3170	Y	N
		2	1163.0	225	133	660	1640	1590	1330	Y	N
		6	216.0	BLQ<(50.0)	BLQ<(50.0)	794	2020	2260	2120	N	N
2170	UB Non-mentholated	-1	929.0	1540	1560	2760	7420	7200	4250	Y	Y
		2	1105.0	1010	1440	3040	8140	7490	4960	Y	Y
		6	1005.0	1800	1450	2930	9900	9750	6720	N	N
2175	UB Mentholated	-1	1724.0	1760	3460	2470	8360	3190	1510	Y	Y
		2	1687.0	830	3060	1740	8560	2510	1230	Y	Y

Subjects used their own usual brand cigarettes at Week -1.

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VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag
2175	UB Mentholated	6	1431.0	1340	2640	1590	9880	4000	1960	Y	Y
2189	UB Mentholated	-1	2385.0	336	93.6	1250	BLQ<(200)	3000	1740	Y	Y
2211	UB Mentholated VLN Mentholated	-1	2088.0	1340	140	2090	BLQ<(200)	2260	1610	Y	N
		2	1946.0	BLQ<(50.0)	BLQ<(50.0)	131	BLQ<(200)	184	BLQ<(200)	Y	N
		6	297.0	BLQ<(50.0)	BLQ<(50.0)	1360	BLQ<(200)	2210	1710	Y	N
2212	UB Mentholated	-1	1397.0	688	1510	1720	5540	4000	4720	Y	Y
		2	1514.0	1280	1250	1380	4050	3030	3410	Y	Y
		6	1016.0	839	1110	1220	4970	4610	5570	Y	Y
2213	UB Mentholated VLN Mentholated	-1	2513.0	1230	195	3670	226	3950	2350	Y	N
		2	2301.0	80.4	BLQ<(50.0)	913	BLQ<(200)	1250	707	Y	N
		6	1689.0	82.0	BLQ<(50.0)	2360	256	5300	3530	Y	N
2215	UB Mentholated	-1	1494.0	1580	1420	2540	3120	3820	2030	Y	Y
		2	1644.0	2550	1170	2340	3170	3830	2360	Y	Y
		6	1321.0	1370	1080	2390	3590	4310	2720	Y	Y
2220	UB Non-mentholated VLN Non-mentholated	-1	547.0	5840	9850	1400	7100	546	BLQ<(200)	Y	N
		2	1054.0	1480	3130	243	1150	65.5	BLQ<(200)	Y	N
		6	900.0	1220	7860	849	4390	280	BLQ<(200)	Y	N
2235	UB Mentholated VLN Mentholated	-1	1046.0	4870	3220	2270	10800	6070	3150	Y	N
		2	1129.0	986	863	733	4340	2160	1060	Y	N
		6	448.0	968	2800	1830	11800	5350	2520	Y	N

Subjects used their own usual brand cigarettes at Week -1.

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VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.8.1 Urine Nicotine and Metabolites Concentrations (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	Nicotine (ng/mL)	Nicotine Glucuronide (ng/mL)	Cotinine (ng/mL)	Cotinine Glucuronide (ng/mL)	Trans-3-hydroxy Cotinine (ng/mL)	Trans-3-hydroxy Cotinine Glucuronide (ng/mL)	Population	
										ITT Flag	PP Flag
2244	UB Non-mentholated	-1	1370.0	2640	2640	1820	8960	4750	2750	Y	N
	VLN Non-mentholated	2	1012.0	1470	1880	1510	10800	6820	4570	Y	N
		6	926.0	1250	2090	1580	11700	6430	3520	Y	N
2247	UB Mentholated	-1	1591.0	1200	74.2	2050	BLQ<(200)	3470	2760	Y	Y
	VLN Mentholated	2	1612.0	BLQ<(50.0)	BLQ<(50.0)	252	BLQ<(200)	759	689	Y	Y
2251	UB Non-mentholated	-1	1872.0	903	1200	1700	5550	4020	2920	Y	Y
		2	1851.0	1220	1120	1240	5420	5080	4590	Y	Y
		6	1192.0	2110	1950	1760	10600	7900	8560	Y	Y
2257	UB Non-mentholated	-1	2851.0	367	442	1450	1410	1860	445	Y	Y
		2	1989.0	493	501	1770	2290	3740	966	Y	Y
		6	1988.0	440	392	1500	1890	3410	841	Y	Y
2259	UB Mentholated	-1	1236.0	1880	297	2990	BLQ<(200)	2480	1910	Y	Y
		2	1039.0	2330	318	3890	237	3990	3520	Y	Y
		6	999.0	2260	314	2920	212	3790	3740	Y	Y
2269	UB Mentholated	-1	1468.0	723	1470	2060	4580	2860	2800	Y	N
	VLN Mentholated	2	353.0	78.3	99.2	137	534	467	358	Y	N
		6	845.0	127	204	229	886	601	463	Y	N
2272	UB Mentholated	-1	889.0	4140	380	2730	636	2180	3100	Y	N
	VLN Mentholated	2	1818.0	BLQ<(50.0)	BLQ<(50.0)	210	BLQ<(200)	190	252	Y	N
		6	1589.0	514	50.6	1040	289	1140	1740	Y	N

Subjects used their own usual brand cigarettes at Week -1.

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VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.8.2 Urinary Theq (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1001	UB Non-mentholated	-1	2171.0	24.51	NA	NA	499	22.63	NA	NA	Y	N
	VLN Non-mentholated	2	1172.6	6.10	-18.41	-75.11	804	6.47	-16.15	-71.39	Y	N
		6	1249.1	9.82	-14.69	-59.95	843	9.32	-13.30	-58.79	Y	N
1002	UB Non-mentholated	-1	4356.5	40.37	NA	NA	424	21.85	NA	NA	Y	N
	VLN Non-mentholated	2	4062.7	20.56	-19.81	-49.08	414	12.22	-9.63	-44.07	Y	N
		6	5759.6	23.15	-17.22	-42.66	333	12.07	-9.79	-44.78	Y	N
1003	UB Mentholated	-1	1385.0	16.07	NA	NA	1770	6.55	NA	NA	Y	N
	VLN Mentholated	2	410.0	2.69	-13.38	-83.27	2280	2.88	-3.68	-56.12	Y	N
		6	1017.7	14.32	-1.74	-10.85	2250	6.26	-0.30	-4.56	Y	N
1007	UB Non-mentholated	-1	1935.0	9.81	NA	NA	890	5.70	NA	NA	Y	Y
	VLN Non-mentholated	2	2199.9	0.48	-9.34	-95.13	947	0.23	-5.47	-95.98	Y	Y
		6	1700.3	1.10	-8.71	-88.77	1330	0.49	-5.21	-91.45	Y	Y
1008	UB Mentholated	-1	2014.0	19.49	NA	NA	1120	8.64	NA	NA	Y	N
	VLN Mentholated	2	1435.9	4.35	-15.13	-77.65	1550	1.96	-6.68	-77.35	Y	N
		6	1122.0	4.97	-14.51	-74.48	701	6.32	-2.32	-26.80	N	N
1010	UB Mentholated	-1	2030.0	27.34	NA	NA	941	14.31	NA	NA	Y	Y
		2	1539.6	20.18	-7.16	-26.19	1120	11.70	-2.61	-18.24	Y	Y
		6	1036.8	8.96	-18.39	-67.24	741	11.66	-2.65	-18.54	N	N

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Appendix 16.2.6.8.2 Urinary Theq (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1011	UB Non-mentholated	-1	1059.0	17.90	NA	NA	2360	7.16	NA	NA	Y	Y
		2	1364.0	13.88	-4.02	-22.46	1590	6.40	-0.76	-10.64	Y	Y
		6	628.7	6.60	-11.30	-63.13	1060	9.90	2.74	38.29	N	N
1013	UB Non-mentholated VLN Non-mentholated	-1	1664.0	20.49	NA	NA	1060	11.61	NA	NA	Y	N
		2	1043.8	.	.	.	1450	5.84	-5.77	-49.69	N	N
		6	874.0	8.96	-11.53	-56.27	1970	5.20	-6.41	-55.20	Y	N
1014	UB Mentholated VLN Mentholated	-1	2069.0	13.54	NA	NA	476	13.74	NA	NA	Y	N
		6	903.2	7.09	-6.45	-47.62	1330	5.90	-7.84	-57.05	Y	N
1015	UB Mentholated VLN Mentholated	-1	3550.0	18.47	NA	NA	371	14.03	NA	NA	Y	Y
		2	3406.2	0.68	-17.79	-96.31	373	0.54	-13.49	-96.17	Y	Y
		6	3477.7	1.16	-17.32	-93.74	392	0.85	-13.18	-93.96	Y	Y
1016	UB Non-mentholated	-1	1853.0	20.16	NA	NA	873	12.46	NA	NA	Y	Y
		2	2839.1	22.51	2.35	11.63	528	15.01	2.55	20.47	Y	Y
		6	1899.3	21.15	0.98	4.88	908	12.26	-0.20	-1.62	Y	Y
1017	UB Mentholated	-1	2490.0	17.54	NA	NA	507	13.90	NA	NA	Y	Y
		2	2593.9	22.08	4.54	25.85	529	16.09	2.19	15.78	Y	Y
		6	1399.2	17.17	-0.37	-2.11	920	13.34	-0.56	-4.00	Y	Y
1018	UB Mentholated	-1	1721.0	18.01	NA	NA	672	15.57	NA	NA	Y	Y

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Appendix 16.2.6.8.2 Urinary Theq (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1019	UB Non-mentholated	-1	1431.0	17.26	NA	NA	1750	6.89	NA	NA	Y	N
	VLN Non-mentholated	2	3109.0	4.91	-12.34	-71.52	762	2.07	-4.82	-69.90	Y	N
		6	2290.1	18.54	1.29	7.45	1110	7.29	0.40	5.86	Y	N
1020	UB Non-mentholated	-1	1666.0	21.48	NA	NA	773	16.68	NA	NA	Y	N
	VLN Non-mentholated	2	1240.9	5.59	-15.89	-73.99	1430	3.15	-13.53	-81.12	Y	N
		6	917.7	10.76	-10.72	-49.92	1280	9.16	-7.52	-45.09	Y	N
1021	UB Non-mentholated	-1	1808.0	9.27	NA	NA	681	7.53	NA	NA	N	N
		2	1842.4	10.17	.	.	710	7.78	.	.	Y	Y
		6	2136.5	10.61	.	.	637	7.79	.	.	Y	Y
1023	UB Non-mentholated	-1	2894.0	9.47	NA	NA	367	8.92	NA	NA	Y	N
	VLN Non-mentholated	2	3795.5	0.95	-8.52	-89.96	274	0.91	-8.00	-89.75	Y	N
		6	3600.0	5.18	-4.29	-45.31	334	4.31	-4.61	-51.69	Y	N
1029	UB Mentholated	-1	2525.2	16.94	NA	NA	554	12.11	NA	NA	Y	N
	VLN Mentholated	2	3098.0	6.86	-10.08	-59.52	505	4.38	-7.73	-63.81	Y	N
		6	2192.0	11.32	-5.62	-33.19	753	6.86	-5.25	-43.37	Y	N
1032	UB Mentholated	-1	3793.8	24.69	NA	NA	319	20.40	NA	NA	Y	Y
	VLN Mentholated	2	3479.0	1.08	-23.61	-95.63	411	0.75	-19.64	-96.31	Y	Y
		6	2345.0	3.96	-20.73	-83.97	602	2.80	-17.59	-86.26	Y	Y

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Appendix 16.2.6.8.2 Urinary Theq (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1034	UB Non-mentholated	-1	1275.1	16.07	NA	NA	1080	11.67	NA	NA	Y	N
	VLN Non-mentholated	2	969.0	6.85	-9.21	-57.34	1210	5.85	-5.82	-49.89	Y	N
		6	1037.0	9.96	-6.11	-38.03	1550	6.19	-5.47	-46.91	Y	N
1035	UB Non-mentholated	-1	2182.4	14.67	NA	NA	1180	5.70	NA	NA	Y	N
	VLN Non-mentholated	2	2196.0	12.87	-1.80	-12.26	726	8.08	2.38	41.72	Y	N
		6	1204.0	11.35	-3.32	-22.62	1400	6.74	1.04	18.21	Y	N
1036	UB Mentholated	-1	1896.8	11.60	NA	NA	761	8.04	NA	NA	Y	Y
		2	1841.0	11.89	0.28	2.43	793	8.14	0.10	1.28	Y	Y
		6	1475.0	13.77	2.17	18.71	1110	8.41	0.37	4.66	Y	Y
1037	UB Mentholated	-1	5986.4	26.67	NA	NA	350	12.73	NA	NA	Y	Y
		2	2822.0	23.49	-3.17	-11.89	698	11.93	-0.80	-6.28	Y	Y
		6	2712.0	26.46	-0.20	-0.76	651	14.99	2.26	17.78	Y	Y
1038	UB Non-mentholated	-1	1610.1	16.95	NA	NA	802	13.13	NA	NA	Y	N
	VLN Non-mentholated	2	1705.0	0.68	-16.27	-96.00	830	0.48	-12.65	-96.35	Y	N
		6	1641.0	8.57	-8.38	-49.46	894	5.84	-7.29	-55.51	Y	N
1042	UB Non-mentholated	-1	5646.2	23.88	NA	NA	353	11.98	NA	NA	Y	N
	VLN Non-mentholated	2	3586.0	1.24	-22.64	-94.81	380	0.91	-11.07	-92.40	Y	N
		6	2769.0	3.17	-20.71	-86.74	429	2.67	-9.32	-77.75	Y	N

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Appendix 16.2.6.8.2 Urinary Theq (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1045	UB Non-mentholated	-1	3025.5	16.42	NA	NA	613	8.86	NA	NA	Y	Y
		2	2443.0	12.27	-4.15	-25.27	654	7.68	-1.17	-13.25	Y	Y
		6	1894.0	12.68	-3.75	-22.82	921	7.27	-1.59	-17.94	Y	Y
1046	UB Mentholated	-1	3780.8	19.14	NA	NA	570	8.88	NA	NA	Y	Y
		2	2832.0	19.00	-0.14	-0.71	670	10.01	1.13	12.77	Y	Y
		6	2830.0	18.62	-0.52	-2.69	806	8.16	-0.72	-8.06	Y	Y
1050	UB Non-mentholated VLN Non-mentholated	-1	1520.3	16.08	NA	NA	781	13.54	NA	NA	Y	N
		2	3144.1	1.79	-14.29	-88.86	472	1.21	-12.34	-91.09	Y	N
		6	1578.0	13.29	-2.79	-17.36	825	10.21	-3.34	-24.63	Y	N
1051	UB Mentholated	-1	2216.8	16.92	NA	NA	762	10.02	NA	NA	Y	Y
		2	2040.0	15.89	-1.03	-6.08	789	9.87	-0.14	-1.43	Y	Y
		6	1784.0	14.73	-2.19	-12.92	1050	7.87	-2.15	-21.47	Y	Y
1052	UB Mentholated VLN Mentholated	-1	1539.8	15.52	NA	NA	1300	7.75	NA	NA	Y	N
		2	1602.0	5.35	-10.18	-65.55	1130	2.95	-4.80	-61.91	Y	N
		6	1065.0	11.57	-3.95	-25.43	1850	5.87	-1.88	-24.24	Y	N
1053	UB Mentholated VLN Mentholated	-1	2902.3	14.94	NA	NA	795	6.48	NA	NA	Y	N
		2	2790.0	1.51	-13.43	-89.88	933	0.58	-5.89	-91.03	Y	N
		6	2523.0	2.73	-12.21	-81.73	914	1.18	-5.29	-81.72	Y	N

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Appendix 16.2.6.8.2 Urinary Theq (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1054	UB Non-mentholated	-1	956.9	28.11	NA	NA	2550	11.52	NA	NA	Y	Y
		2	1844.0	22.08	-6.03	-21.44	1180	10.15	-1.37	-11.90	Y	Y
		6	1089.0	22.10	-6.01	-21.40	2130	9.53	-1.99	-17.31	Y	Y
1055	UB Mentholated VLN Mentholated	-1	3328.9	23.52	NA	NA	451	15.66	NA	NA	Y	N
		2	3391.6	0.78	-22.73	-96.68	495	0.47	-15.20	-97.03	Y	N
		6	1581.0	9.31	-14.21	-60.41	955	6.17	-9.50	-60.63	Y	N
1056	UB Non-mentholated VLN Non-mentholated	-1	3925.2	19.53	NA	NA	416	11.96	NA	NA	Y	N
		2	1334.0	1.85	-17.68	-90.54	799	1.73	-10.23	-85.51	Y	N
		6	1152.0	5.59	-13.94	-71.35	785	6.19	-5.77	-48.28	Y	N
1058	UB Non-mentholated VLN Non-mentholated	-1	3355.1	21.53	NA	NA	518	12.39	NA	NA	Y	N
		2	2869.0	0.68	-20.84	-96.82	520	0.46	-11.93	-96.30	Y	N
		6	1927.0	17.66	-3.87	-17.97	1190	7.70	-4.69	-37.83	Y	N
1059	UB Non-mentholated	-1	956.0	24.64	NA	NA	2300	11.21	NA	NA	Y	Y
		2	2124.7	22.74	-1.90	-7.72	1040	10.29	-0.92	-8.18	Y	Y
		6	1507.0	25.70	1.06	4.29	1750	9.74	-1.46	-13.05	Y	Y
1060	UB Mentholated VLN Mentholated	-1	2414.0	21.46	NA	NA	751	11.84	NA	NA	Y	N
		2	2361.4	5.76	-15.70	-73.16	782	3.12	-8.72	-73.65	Y	N
		6	1742.0	12.63	-8.83	-41.15	950	7.63	-4.21	-35.53	Y	N

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Appendix 16.2.6.8.2 Urinary Theq (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1063	UB Mentholated	-1	7095.2	27.81	NA	NA	306	12.81	NA	NA	Y	Y
	VLN Mentholated	2	3891.4	0.75	-27.06	-97.30	569	0.34	-12.47	-97.35	Y	Y
		6	3208.0	0.55	-27.26	-98.03	787	0.22	-12.59	-98.30	Y	Y
1064	UB Non-mentholated	-1	3268.0	28.91	NA	NA	749	11.81	NA	NA	Y	Y
		2	2273.1	27.78	-1.13	-3.92	1060	11.53	-0.28	-2.40	Y	Y
1066	UB Non-mentholated	-1	967.0	10.79	NA	NA	2190	5.09	NA	NA	Y	Y
	VLN Non-mentholated	2	1744.8	0.53	-10.26	-95.12	1050	0.29	-4.81	-94.36	Y	Y
		6	1725.0	0.39	-10.40	-96.41	1220	0.18	-4.91	-96.39	Y	Y
1069	UB Non-mentholated	-1	2554.0	18.30	NA	NA	793	9.03	NA	NA	Y	Y
		2	2465.9	17.99	-0.31	-1.71	783	9.32	0.28	3.10	Y	Y
		6	2162.0	21.90	3.60	19.67	973	10.41	1.38	15.22	Y	Y
1070	UB Non-mentholated	-1	3393.0	21.33	NA	NA	633	9.93	NA	NA	Y	Y
	VLN Non-mentholated	2	2687.1	2.34	-18.99	-89.04	752	1.16	-8.77	-88.35	Y	Y
		6	1316.0	2.53	-18.80	-88.14	1800	1.07	-8.86	-89.25	Y	Y
1071	UB Non-mentholated	-1	2129.0	17.04	NA	NA	700	11.44	NA	NA	Y	N
	VLN Non-mentholated	2	2212.3	10.09	-6.96	-40.82	1230	3.71	-7.73	-67.59	Y	N
1072	UB Mentholated	-1	2181.0	15.94	NA	NA	806	9.07	NA	NA	Y	Y
	VLN Mentholated	2	1779.7	1.51	-14.43	-90.52	955	0.89	-8.18	-90.20	Y	Y

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Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1074	UB Non-mentholated	-1	2211.0	18.02	NA	NA	876	9.30	NA	NA	Y	N
	VLN Non-mentholated	2	1464.3	8.20	-9.81	-54.47	1350	4.15	-5.15	-55.39	Y	N
		6	1677.0	9.34	-8.68	-48.18	1310	4.25	-5.05	-54.32	Y	N
1075	UB Non-mentholated	-1	2163.0	13.23	NA	NA	773	7.91	NA	NA	Y	Y
		2	1890.7	13.07	-0.16	-1.19	845	8.18	0.27	3.41	Y	Y
		6	1263.0	13.44	0.21	1.57	1340	7.94	0.03	0.35	Y	Y
1077	UB Non-mentholated	-1	3102.1	22.10	NA	NA	493	14.45	NA	NA	Y	Y
	VLN Non-mentholated	2	3008.3	0.94	-21.16	-95.73	596	0.53	-13.93	-96.36	Y	Y
		6	2743.0	0.63	-21.47	-97.14	693	0.33	-14.12	-97.70	Y	Y
1078	UB Non-mentholated	-1	1991.0	17.30	NA	NA	597	14.56	NA	NA	Y	N
	VLN Non-mentholated	2	3513.1	5.10	-12.20	-70.51	352	4.13	-10.43	-71.66	Y	N
		6	2384.0	15.43	-1.88	-10.84	654	9.89	-4.66	-32.03	Y	N
1079	UB Mentholated	-1	2154.0	18.19	NA	NA	1370	6.16	NA	NA	Y	Y
	VLN Mentholated	2	3647.6	0.62	-17.56	-96.57	802	0.21	-5.95	-96.54	Y	Y
		6	2605.0	0.45	-17.74	-97.55	1040	0.16	-6.00	-97.33	Y	Y
1082	UB Non-mentholated	-1	2790.0	20.25	NA	NA	843	8.61	NA	NA	Y	N
	VLN Non-mentholated	2	2629.9	5.31	-14.94	-73.77	926	2.18	-6.43	-74.67	Y	N
		6	2013.0	9.91	-10.34	-51.06	1200	4.10	-4.51	-52.35	Y	N

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

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Appendix 16.2.6.8.2 Urinary Theq (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1083	UB Non-mentholated	-1	1708.0	19.23	NA	NA	762	14.77	NA	NA	Y	N
	VLN Non-mentholated	2	1788.0	11.35	-7.88	-40.97	892	7.12	-7.66	-51.83	Y	N
		6	2017.0	15.79	-3.44	-17.88	804	9.74	-5.04	-34.09	Y	N
1084	UB Non-mentholated	-1	1467.0	15.43	NA	NA	1380	7.62	NA	NA	Y	N
	VLN Non-mentholated	2	1158.4	4.91	-10.52	-68.18	1630	2.60	-5.02	-65.88	Y	N
1086	UB Non-mentholated	-1	1938.0	27.01	NA	NA	968	14.40	NA	NA	Y	N
	VLN Non-mentholated	2	1255.9	6.52	-20.49	-75.85	1410	3.68	-10.72	-74.42	Y	N
		6	1580.0	12.53	-14.49	-53.62	1040	7.62	-6.78	-47.05	Y	N
1088	UB Mentholated	-1	1662.0	19.35	NA	NA	1670	6.97	NA	NA	Y	N
	VLN Mentholated	2	1236.2	9.78	-9.57	-49.45	1820	4.35	-2.62	-37.64	Y	N
		6	1670.0	12.88	-6.47	-33.45	1520	5.07	-1.90	-27.23	Y	N
1089	UB Non-mentholated	-1	1795.0	11.48	NA	NA	669	9.56	NA	NA	Y	Y
		2	2415.3	12.40	0.91	7.94	544	9.43	-0.13	-1.35	Y	Y
		6	2062.0	10.73	-0.75	-6.55	559	9.31	-0.25	-2.64	Y	Y
1092	UB Mentholated	-1	2383.0	20.57	NA	NA	734	11.76	NA	NA	Y	N
	VLN Mentholated	2	1551.7	12.23	-8.34	-40.54	898	8.78	-2.98	-25.37	Y	N
		6	1587.0	18.61	-1.96	-9.54	1150	10.19	-1.56	-13.30	Y	N
1094	UB Mentholated	-1	1930.0	13.98	NA	NA	1230	5.89	NA	NA	Y	N

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Appendix 16.2.6.8.2 Urinary Theq (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1094	VLN Mentholated	2	1307.6	1.86	-12.12	-86.69	1720	0.83	-5.06	-85.95	Y	N
		6	1040.0	3.11	-10.88	-77.79	1930	1.55	-4.34	-73.73	Y	N
1095	UB Mentholated	-1	2551.0	14.67	NA	NA	514	11.19	NA	NA	Y	N
	VLN Mentholated	2	430.3	1.37	-13.30	-90.67	982	3.24	-7.95	-71.05	N	N
		6	2131.0	5.79	-8.88	-60.54	390	6.97	-4.22	-37.74	Y	N
1096	UB Non-mentholated	-1	2532.0	17.22	NA	NA	634	10.73	NA	NA	Y	N
	VLN Non-mentholated	2	1934.5	11.47	-5.75	-33.42	679	8.73	-2.00	-18.63	Y	N
		6	2949.0	15.15	-2.07	-12.01	488	10.53	-0.20	-1.85	Y	N
1097	UB Mentholated	-1	1982.0	23.93	NA	NA	1250	9.66	NA	NA	Y	N
	VLN Mentholated	2	1598.3	11.84	-12.10	-50.55	1510	4.90	-4.76	-49.23	Y	N
		6	1814.0	12.71	-11.22	-46.89	1270	5.52	-4.14	-42.89	Y	N
1098	UB Non-mentholated	-1	1415.8	15.02	NA	NA	1060	10.01	NA	NA	Y	Y
	VLN Non-mentholated	2	1666.1	1.29	-13.73	-91.38	958	0.81	-9.20	-91.90	Y	Y
		6	1811.0	0.95	-14.07	-93.66	895	0.59	-9.42	-94.13	Y	Y
1099	UB Non-mentholated	-1	810.2	.	NA	NA	1420	12.15	NA	NA	N	N
	VLN Non-mentholated	2	1272.2	4.55	.	.	1060	3.37	.	.	Y	N
		6	1005.0	8.55	.	.	1250	6.80	.	.	Y	N
1100	UB Non-mentholated	-1	3350.7	15.49	NA	NA	550	8.40	NA	NA	Y	N

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Appendix 16.2.6.8.2 Urinary Theq (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1100	VLN Non-mentholated	2	2653.5	11.79	-3.69	-23.84	684	6.50	-1.91	-22.67	Y	N
		6	2576.0	15.61	0.12	0.77	772	7.85	-0.56	-6.62	Y	N
1101	UB Non-mentholated VLN Non-mentholated	-1	1814.1	15.84	NA	NA	827	10.55	NA	NA	Y	N
		2	2317.4	9.79	-6.04	-38.15	805	5.25	-5.30	-50.26	Y	N
		6	3707.0	13.24	-2.60	-16.40	258	13.84	3.29	31.13	Y	N
1103	UB Non-mentholated VLN Non-mentholated	-1	3479.4	25.13	NA	NA	297	24.32	NA	NA	Y	N
		2	2449.2	7.81	-17.32	-68.92	762	4.19	-20.14	-82.79	Y	N
		6	2601.0	18.69	-6.44	-25.64	763	9.42	-14.90	-61.28	Y	N
1105	UB Non-mentholated VLN Non-mentholated	-1	527.3	14.73	NA	NA	1680	16.62	NA	NA	Y	N
		2	825.2	8.99	-5.73	-38.94	1010	10.79	-5.83	-35.10	Y	N
		6	677.0	7.59	-7.14	-48.46	1420	7.90	-8.73	-52.51	Y	N
1106	UB Non-mentholated	-1	1380.1	27.53	NA	NA	1870	10.67	NA	NA	Y	Y
		2	1113.7	26.50	-1.03	-3.74	2330	10.21	-0.46	-4.27	Y	Y
		6	2435.0	30.65	3.12	11.34	968	13.00	2.34	21.91	Y	Y
1107	UB Non-mentholated VLN Non-mentholated	-1	2365.5	8.35	NA	NA	913	3.87	NA	NA	Y	N
		2	2512.8	4.31	-4.04	-48.39	854	2.01	-1.86	-48.06	Y	N
		6	2599.0	8.92	0.57	6.83	806	4.26	0.39	10.14	Y	N
1108	UB Non-mentholated	-1	1782.0	19.27	NA	NA	1150	9.40	NA	NA	Y	Y

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Appendix 16.2.6.8.2 Urinary Theq (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
1108	UB Non-mentholated	2	2115.4	17.62	-1.65	-8.55	966	8.62	-0.78	-8.29	Y	Y
		6	1981.0	16.81	-2.46	-12.78	1030	8.24	-1.17	-12.40	Y	Y
1109	UB Non-mentholated	-1	1615.9	22.27	NA	NA	950	14.51	NA	NA	Y	Y
		2	1805.0	23.14	0.87	3.90	919	13.95	-0.56	-3.85	Y	Y
		6	1075.0	20.13	-2.14	-9.61	1490	12.57	-1.94	-13.37	Y	Y
1112	UB Non-mentholated VLN Non-mentholated	-1	2265.2	13.53	NA	NA	428	13.95	NA	NA	Y	N
		2	1829.3	5.07	-8.46	-62.51	613	4.52	-9.43	-67.59	Y	N
		6	2121.0	9.74	-3.78	-27.97	531	8.65	-5.30	-37.99	Y	N
1114	UB Non-mentholated	-1	1506.7	9.54	NA	NA	754	8.40	NA	NA	Y	Y
		2	2909.4	8.35	-1.20	-12.55	403	7.12	-1.28	-15.27	Y	Y
		6	1920.0	8.67	-0.87	-9.14	661	6.83	-1.57	-18.67	Y	Y
1115	UB Non-mentholated VLN Non-mentholated	-1	1785.7	22.96	NA	NA	1590	8.09	NA	NA	Y	Y
		2	1601.3	1.25	-21.71	-94.55	1770	0.44	-7.65	-94.54	Y	Y
2002	UB Mentholated	-1	2188.0	20.95	NA	NA	803	11.93	NA	NA	Y	Y
		2	1893.0	18.24	-2.71	-12.95	915	10.53	-1.40	-11.70	Y	Y
		6	3245.0	22.73	1.78	8.49	569	12.31	0.39	3.23	Y	Y
2003	UB Mentholated VLN Mentholated	-1	3036.0	19.23	NA	NA	342	18.52	NA	NA	Y	N
		2	4180.0	10.62	-8.62	-44.80	348	7.30	-11.22	-60.60	Y	N

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Appendix 16.2.6.8.2 Urinary Theq (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2003	VLN Mentholated	6	3245.0	10.57	-8.66	-45.04	373	8.73	-9.79	-52.85	Y	N
2007	UB Non-mentholated	-1	1535.0	8.41	NA	NA	696	7.87	NA	NA	Y	Y
	VLN Non-mentholated	2	1492.0	2.02	-6.39	-75.96	725	1.87	-6.00	-76.26	Y	Y
		6	1387.0	1.16	-7.25	-86.17	828	1.01	-6.86	-87.13	Y	Y
2008	UB Mentholated	-1	2663.0	16.25	NA	NA	900	6.78	NA	NA	Y	Y
	VLN Mentholated	2	3323.0	0.79	-15.46	-95.15	709	0.33	-6.44	-95.07	Y	Y
		6	1734.0	2.27	-13.98	-86.03	1300	1.01	-5.77	-85.14	Y	Y
2009	UB Non-mentholated	-1	2427.0	10.58	NA	NA	807	5.40	NA	NA	Y	N
	VLN Non-mentholated	2	1390.0	7.58	-3.01	-28.40	1420	3.84	-1.56	-28.96	Y	N
2010	UB Mentholated	-1	1673.0	12.66	NA	NA	1650	4.58	NA	NA	Y	Y
		2	1289.0	8.33	-4.33	-34.18	1390	4.65	0.06	1.41	Y	Y
		6	1158.0	8.09	-4.56	-36.05	2350	2.97	-1.61	-35.13	Y	Y
2011	UB Mentholated	-1	1639.0	10.16	NA	NA	1010	6.14	NA	NA	Y	N
	VLN Mentholated	2	1510.0	3.94	-6.22	-61.23	1110	2.35	-3.79	-61.71	Y	N
		6	1165.0	4.96	-5.19	-51.13	1510	2.82	-3.31	-54.01	Y	N
2014	UB Mentholated	-1	3009.0	23.18	NA	NA	738	10.44	NA	NA	Y	N
	VLN Mentholated	2	1438.0	6.01	-17.17	-74.07	1410	2.96	-7.47	-71.60	Y	N
		6	2776.0	13.04	-10.14	-43.73	718	6.54	-3.89	-37.31	Y	N

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Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2015	UB Mentholated	-1	1277.0	11.02	NA	NA	1080	7.99	NA	NA	Y	Y
		2	1774.0	10.83	-0.19	-1.76	800	7.63	-0.36	-4.53	Y	Y
		6	1070.0	6.34	-4.68	-42.44	1620	3.66	-4.33	-54.20	Y	Y
2016	UB Mentholated	-1	1787.0	12.41	NA	NA	642	10.81	NA	NA	Y	Y
2017	UB Mentholated VLN Mentholated	-1	1504.0	22.30	NA	NA	1290	11.49	NA	NA	Y	N
		2	1864.0	1.11	-21.19	-95.04	1110	0.53	-10.96	-95.35	Y	N
		6	1210.0	12.37	-9.93	-44.54	1530	6.68	-4.81	-41.87	Y	N
2018	UB Mentholated	-1	1191.0	9.54	NA	NA	1390	5.76	NA	NA	Y	Y
		2	1374.0	11.26	1.72	18.08	1120	7.32	1.56	27.03	Y	Y
		6	963.0	11.11	1.57	16.51	1620	7.12	1.36	23.64	Y	Y
2020	UB Mentholated VLN Mentholated	-1	1117.0	6.71	NA	NA	919	6.54	NA	NA	Y	N
		2	1155.0	3.41	-3.30	-49.16	1070	2.76	-3.78	-57.77	Y	N
		6	1300.0	5.81	-0.89	-13.33	929	4.81	-1.72	-26.33	Y	N
2021	UB Mentholated VLN Mentholated	-1	2086.0	8.13	NA	NA	1120	3.48	NA	NA	Y	Y
		2	2606.0	1.20	-6.93	-85.23	909	0.51	-2.97	-85.43	Y	Y
		6	2561.0	1.49	-6.64	-81.68	821	0.71	-2.77	-79.64	Y	Y
2023	UB Mentholated VLN Mentholated	-1	996.0	9.08	NA	NA	2220	4.11	NA	NA	Y	Y
		2	1252.0	0.33	-8.75	-96.34	1650	0.16	-3.95	-96.08	Y	Y

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Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2023	VLN Mentholated	6	999.0	0.23	-8.86	-97.49	2180	0.10	-4.00	-97.45	Y	Y
2024	UB Non-mentholated	-1	1112.0	14.15	NA	NA	1690	7.53	NA	NA	Y	Y
2025	UB Non-mentholated	-1	2766.0	21.11	NA	NA	674	11.32	NA	NA	Y	Y
		2	2484.0	21.99	0.88	4.19	844	10.49	-0.83	-7.35	Y	Y
		6	2746.0	28.89	7.78	36.88	866	12.15	0.83	7.31	Y	Y
2028	UB Non-mentholated VLN Non-mentholated	-1	1538.0	11.68	NA	NA	1270	5.98	NA	NA	Y	Y
		2	1876.0	1.47	-10.21	-87.41	834	0.94	-5.04	-84.28	Y	Y
		6	616.0	0.39	-11.29	-96.68	1780	0.35	-5.63	-94.09	Y	Y
2029	UB Mentholated	-1	1689.0	8.32	NA	NA	996	4.95	NA	NA	Y	Y
		2	1933.0	10.88	2.56	30.77	855	6.58	1.64	33.11	Y	Y
		6	2068.0	9.41	1.09	13.12	789	5.77	0.82	16.63	Y	Y
2039	UB Mentholated VLN Mentholated	-1	1765.0	12.50	NA	NA	762	9.30	NA	NA	Y	N
		2	1582.0	7.70	-4.80	-38.42	711	6.84	-2.45	-26.37	Y	N
		6	718.0	4.21	-8.29	-66.31	898	6.53	-2.76	-29.72	Y	N
2050	UB Mentholated	-1	1887.0	24.18	NA	NA	995	12.88	NA	NA	Y	Y
		2	1436.0	15.59	-8.59	-35.53	908	11.96	-0.92	-7.16	Y	Y
		6	1392.0	14.76	-9.42	-38.97	1300	8.15	-4.72	-36.68	Y	Y
2052	UB Mentholated	-1	2094.0	10.96	NA	NA	921	5.68	NA	NA	Y	Y

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

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ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

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Appendix 16.2.6.8.2 Urinary Theq (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2052	VLN Mentholated	2	1611.0	0.50	-10.46	-95.41	1190	0.26	-5.42	-95.38	Y	Y
		6	2735.0	0.70	-10.25	-93.58	664	0.39	-5.29	-93.18	Y	Y
2057	UB Mentholated	-1	3085.0	12.76	NA	NA	646	6.40	NA	NA	Y	N
	VLN Mentholated	2	3805.0	2.84	-9.91	-77.72	552	1.35	-5.05	-78.86	Y	N
		6	3820.0	8.71	-4.05	-31.76	592	3.85	-2.55	-39.86	Y	N
2058	UB Mentholated	-1	1240.0	8.73	NA	NA	1410	4.99	NA	NA	Y	N
	VLN Mentholated	2	1621.0	0.99	-7.74	-88.67	1000	0.61	-4.38	-87.78	Y	N
		6	2198.0	1.85	-6.88	-78.77	763	1.11	-3.89	-77.87	Y	N
2059	UB Mentholated	-1	1545.0	11.95	NA	NA	780	9.92	NA	NA	Y	Y
		2	1452.0	12.12	0.17	1.43	785	10.64	0.72	7.24	Y	Y
		6	1242.0	10.84	-1.11	-9.32	1100	7.93	-1.98	-20.01	Y	Y
2060	UB Mentholated	-1	773.0	13.11	NA	NA	1200	14.14	NA	NA	Y	N
	VLN Mentholated	2	684.0	4.45	-8.66	-66.08	1230	5.29	-8.85	-62.60	Y	N
		6	1465.0	17.83	4.72	35.97	971	12.53	-1.60	-11.34	Y	N
2064	UB Mentholated	-1	3404.0	25.50	NA	NA	450	16.65	NA	NA	Y	N
	VLN Mentholated	2	2844.0	12.56	-12.94	-50.74	649	6.81	-9.84	-59.12	Y	N
		6	2882.0	11.82	-13.68	-53.63	572	7.17	-9.47	-56.91	Y	N
2066	UB Mentholated	-1	1056.0	14.54	NA	NA	1810	7.61	NA	NA	Y	N

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Appendix 16.2.6.8.2 Urinary Theq (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2066	VLN Mentholated	2	912.0	5.76	-8.78	-60.36	1790	3.53	-4.08	-53.58	Y	N
		6	1617.0	6.00	-8.54	-58.71	1110	3.34	-4.26	-56.03	Y	N
2067	UB Non-mentholated VLN Non-mentholated	-1	2550.0	16.13	NA	NA	643	9.84	NA	NA	Y	N
		2	1608.0	8.73	-7.40	-45.86	1070	5.08	-4.76	-48.40	Y	N
		6	2810.0	15.65	-0.48	-2.96	654	8.52	-1.32	-13.42	Y	N
2075	UB Mentholated	-1	3995.0	21.71	NA	NA	551	9.86	NA	NA	Y	Y
2076	UB Mentholated VLN Mentholated	-1	2036.0	10.51	NA	NA	943	5.48	NA	NA	Y	N
		2	2229.0	1.52	-8.99	-85.51	928	0.74	-4.74	-86.55	Y	N
		6	2063.0	7.94	-2.57	-24.43	1030	3.74	-1.74	-31.72	Y	N
2086	UB Non-mentholated VLN Non-mentholated	-1	779.0	11.57	NA	NA	1640	9.06	NA	NA	Y	N
		2	1692.0	3.49	-8.09	-69.88	1040	1.98	-7.08	-78.14	Y	N
2088	UB Mentholated VLN Mentholated	-1	3222.0	16.17	NA	NA	480	10.46	NA	NA	Y	N
		2	2854.0	2.69	-13.48	-83.37	601	1.57	-8.89	-85.01	Y	N
		6	2370.0	4.38	-11.79	-72.89	680	2.72	-7.74	-73.99	Y	N
2092	UB Mentholated VLN Mentholated	-1	2002.0	6.01	NA	NA	445	6.75	NA	NA	Y	N
		2	1940.0	0.58	-5.44	-90.39	457	0.65	-6.10	-90.35	Y	N
		6	2262.0	2.38	-3.63	-60.43	391	2.69	-4.06	-60.14	Y	N
2099	UB Non-mentholated	-1	1107.0	11.01	NA	NA	1350	7.37	NA	NA	Y	N

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Appendix 16.2.6.8.2 Urinary Theq (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2099	VLN Non-mentholated	2	1523.0	4.66	-6.35	-57.67	968	3.16	-4.21	-57.09	Y	N
		6	1051.0	6.54	-4.47	-40.58	1430	4.35	-3.01	-40.92	Y	N
2100	UB Mentholated	-1	577.0	18.13	NA	NA	2130	14.75	NA	NA	Y	Y
		2	1028.0	22.55	4.42	24.36	1200	18.28	3.53	23.90	Y	Y
		6	550.0	21.32	3.18	17.57	2170	17.86	3.11	21.06	Y	Y
2108	UB Non-mentholated VLN Non-mentholated	-1	2860.0	13.94	NA	NA	286	17.04	NA	NA	Y	N
		2	3150.0	1.20	-12.74	-91.41	255	1.49	-15.55	-91.25	Y	N
		6	3399.0	7.65	-6.29	-45.12	252	8.93	-8.11	-47.59	Y	N
2110	UB Mentholated	-1	1034.0	10.77	NA	NA	818	12.73	NA	NA	Y	Y
		2	799.0	8.13	-2.63	-24.46	1050	9.70	-3.04	-23.84	Y	Y
		6	653.0	7.27	-3.50	-32.53	1190	9.35	-3.38	-26.56	Y	Y
2113	UB Mentholated VLN Mentholated	-1	843.0	8.37	NA	NA	1120	8.86	NA	NA	Y	Y
		2	878.0	1.13	-7.23	-86.45	910	1.42	-7.44	-83.99	Y	Y
2115	UB Mentholated	-1	1626.0	13.44	NA	NA	906	9.13	NA	NA	Y	Y
2119	UB Mentholated VLN Mentholated	-1	650.0	17.68	NA	NA	2390	11.38	NA	NA	Y	Y
		2	786.0	1.75	-15.93	-90.11	1910	1.16	-10.21	-89.76	Y	Y
		6	902.0	1.14	-16.53	-93.53	1590	0.80	-10.58	-92.99	Y	Y
2120	UB Non-mentholated	-1	1243.0	9.90	NA	NA	634	12.56	NA	NA	Y	Y

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Appendix 16.2.6.8.2 Urinary Theq (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2120	VLN Non-mentholated	2	1147.0	0.25	-9.64	-97.43	646	0.34	-12.22	-97.26	Y	Y
		6	1735.0	0.41	-9.49	-95.83	488	0.49	-12.07	-96.12	Y	Y
2122	UB Non-mentholated	-1	1396.0	14.40	NA	NA	1050	9.82	NA	NA	Y	Y
		2	1487.0	12.78	-1.62	-11.24	1010	8.51	-1.31	-13.37	Y	Y
		6	1643.0	13.19	-1.20	-8.34	954	8.42	-1.40	-14.28	Y	Y
2125	UB Mentholated	-1	1819.0	9.46	NA	NA	1600	3.25	NA	NA	Y	Y
		2	3746.0	14.06	4.60	48.65	755	4.97	1.72	52.97	Y	Y
		6	3110.0	17.60	8.14	86.04	960	5.89	2.64	81.36	Y	Y
2126	UB Mentholated VLN Mentholated	-1	1339.0	15.49	NA	NA	1200	9.64	NA	NA	Y	N
		2	1234.0	1.21	-14.28	-92.21	1110	0.88	-8.76	-90.87	Y	N
		6	1047.0	4.14	-11.35	-73.29	1510	2.62	-7.02	-72.86	Y	N
2136	UB Non-mentholated VLN Non-mentholated	-1	2199.0	17.13	NA	NA	803	9.70	NA	NA	Y	N
		2	1100.0	7.44	-9.69	-56.54	1490	4.54	-5.16	-53.18	Y	N
2140	UB Non-mentholated	-1	800.0	4.71	NA	NA	1470	4.00	NA	NA	Y	Y
		2	763.0	4.08	-0.62	-13.26	1610	3.32	-0.68	-16.96	Y	Y
		6	939.0	5.37	0.66	14.01	1250	4.57	0.57	14.23	Y	Y
2142	UB Non-mentholated	-1	2406.0	27.57	NA	NA	500	22.92	NA	NA	Y	Y
2143	UB Non-mentholated	-1	2510.0	26.59	NA	NA	595	17.81	NA	NA	Y	Y

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Appendix 16.2.6.8.2 Urinary Theq (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2143	VLN Non-mentholated	2	2050.0	0.98	-25.61	-96.32	756	0.63	-17.17	-96.45	Y	Y
		6	2221.0	0.74	-25.86	-97.23	729	0.46	-17.35	-97.44	Y	Y
2158	UB Non-mentholated	-1	1684.0	13.61	NA	NA	843	9.59	NA	NA	Y	Y
		2	1211.0	12.77	-0.84	-6.18	1160	9.09	-0.50	-5.19	Y	Y
2159	UB Non-mentholated VLN Non-mentholated	-1	1506.0	20.83	NA	NA	795	17.40	NA	NA	Y	N
		2	1042.0	9.52	-11.31	-54.29	1100	8.30	-9.09	-52.26	Y	N
		6	1311.0	16.04	-4.79	-22.99	1050	11.65	-5.74	-33.02	Y	N
2164	UB Non-mentholated VLN Non-mentholated	-1	2448.0	19.00	NA	NA	520	14.92	NA	NA	Y	Y
		2	2822.0	0.95	-18.05	-95.01	464	0.72	-14.20	-95.15	Y	Y
		6	2302.0	1.48	-17.51	-92.18	568	1.14	-13.79	-92.39	Y	Y
2168	UB Non-mentholated VLN Non-mentholated	-1	1464.0	15.84	NA	NA	459	23.57	NA	NA	Y	N
		2	1163.0	4.16	-11.67	-73.71	528	6.78	-16.79	-71.24	Y	N
		6	216.0	.	.	.	427	10.63	-12.94	-54.89	N	N
2170	UB Non-mentholated	-1	929.0	15.04	NA	NA	1190	13.61	NA	NA	Y	Y
		2	1105.0	18.51	3.47	23.05	1090	15.37	1.76	12.94	Y	Y
		6	1005.0	.	.	.	1550	13.51	-0.10	-0.73	N	N
2175	UB Mentholated	-1	1724.0	22.24	NA	NA	736	17.53	NA	NA	Y	Y
		2	1687.0	17.71	-4.52	-20.34	776	13.53	-3.99	-22.79	Y	Y

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Appendix 16.2.6.8.2 Urinary Theq (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2175	UB Mentholated	6	1431.0	18.40	-3.84	-17.26	916	14.04	-3.49	-19.91	Y	Y
2189	UB Mentholated	-1	2385.0	11.63	NA	NA	806	6.05	NA	NA	Y	Y
2211	UB Mentholated VLN Mentholated	-1	2088.0	12.51	NA	NA	517	11.59	NA	NA	Y	N
		2	1946.0	0.78	-11.73	-93.73	591	0.68	-10.91	-94.12	Y	N
		6	297.0	1.17	-11.34	-90.62	685	5.77	-5.82	-50.22	Y	N
2212	UB Mentholated	-1	1397.0	15.37	NA	NA	1470	7.48	NA	NA	Y	Y
		2	1514.0	13.74	-1.63	-10.61	1400	6.48	-1.00	-13.40	Y	Y
		6	1016.0	11.30	-4.06	-26.44	2070	5.38	-2.11	-28.17	Y	Y
2213	UB Mentholated VLN Mentholated	-1	2513.0	23.06	NA	NA	930	9.87	NA	NA	Y	N
		2	2301.0	5.40	-17.66	-76.59	969	2.42	-7.45	-75.47	Y	N
		6	1689.0	14.21	-8.85	-38.38	1350	6.23	-3.63	-36.84	Y	N
2215	UB Mentholated	-1	1494.0	15.17	NA	NA	753	13.48	NA	NA	Y	Y
		2	1644.0	18.08	2.91	19.17	669	16.44	2.95	21.90	Y	Y
		6	1321.0	13.97	-1.20	-7.90	846	12.50	-0.98	-7.29	Y	Y
2220	UB Non-mentholated VLN Non-mentholated	-1	547.0	8.55	NA	NA	3260	4.79	NA	NA	Y	N
		2	1054.0	4.04	-4.51	-52.73	2100	1.83	-2.97	-61.92	Y	N
		6	900.0	7.26	-1.28	-15.01	2470	3.27	-1.53	-31.82	Y	N
2235	UB Mentholated	-1	1046.0	20.91	NA	NA	2100	9.52	NA	NA	Y	N

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Appendix 16.2.6.8.2 Urinary Theq (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2235	VLN Mentholated	2	1129.0	7.18	-13.72	-65.64	2020	3.15	-6.37	-66.90	Y	N
		6	448.0	6.74	-14.16	-67.74	2030	7.42	-2.10	-22.08	Y	N
2244	UB Non-mentholated VLN Non-mentholated	-1	1370.0	20.45	NA	NA	1230	12.14	NA	NA	Y	N
		2	1012.0	16.70	-3.75	-18.33	1940	8.51	-3.63	-29.90	Y	N
		6	926.0	14.88	-5.57	-27.23	1870	8.59	-3.54	-29.18	Y	N
2247	UB Mentholated VLN Mentholated	-1	1591.0	11.64	NA	NA	1430	5.11	NA	NA	Y	Y
		2	1612.0	2.03	-9.61	-82.56	1270	0.99	-4.12	-80.61	Y	Y
2251	UB Non-mentholated	-1	1872.0	19.24	NA	NA	1050	9.79	NA	NA	Y	Y
		2	1851.0	21.66	2.42	12.59	1140	10.27	0.48	4.88	Y	Y
		6	1192.0	23.82	4.58	23.81	1870	10.69	0.90	9.17	Y	Y
2257	UB Non-mentholated	-1	2851.0	12.34	NA	NA	393	11.01	NA	NA	Y	Y
		2	1989.0	13.92	1.58	12.80	497	14.08	3.07	27.85	Y	Y
		6	1988.0	12.18	-0.16	-1.30	427	14.35	3.34	30.28	Y	Y
2259	UB Mentholated	-1	1236.0	9.59	NA	NA	2220	3.49	NA	NA	Y	Y
		2	1039.0	11.52	1.94	20.21	2440	4.55	1.05	30.11	Y	Y
		6	999.0	10.03	0.45	4.66	2520	3.99	0.49	14.07	Y	Y
2269	UB Mentholated VLN Mentholated	-1	1468.0	13.33	NA	NA	1540	5.90	NA	NA	Y	N
		2	353.0	0.37	-12.96	-97.22	1120	0.94	-4.96	-84.10	Y	N

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

CFB = Change from Baseline, PCFB = Percent change from baseline, Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Values reported as below the limit of quantitation (BLQ) were set to one-half of the LLOQ for summarization and statistical analysis.

. = Value missing or not reportable.

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Appendix 16.2.6.8.2 Urinary Theq (Safety Population)

Subject Number	Study Product	Study Week	Urine Volume (mL)	24-Hour Amount Excreted			Creatinine Conc. (ug/mL)	Creatinine Adjusted Values			Population	
				Amount (mg/24hrs)	CFB (mg/24hrs)	PCFB (%)		Amount (mg/g Creat.)	CFB (mg/g Creat.)	PCFB (%)	ITT Flag	PP Flag
2269	VLN Mentholated	6	845.0	1.31	-12.02	-90.14	627	2.48	-3.42	-57.94	Y	N
2272	UB Mentholated	-1	889.0	9.19	NA	NA	2370	4.36	NA	NA	Y	N
	VLN Mentholated	2	1818.0	1.00	-8.19	-89.16	1070	0.51	-3.85	-88.26	Y	N
		6	1589.0	5.33	-3.85	-41.93	1290	2.60	-1.76	-40.31	Y	N

Baseline: Week -1, NA = Not applicable, Conc. = Concentration, Creat. = Creatinine

CFB = Change from Baseline, PCFB = Percent change from baseline, Subjects used their own usual brand cigarettes at Week -1.

ITT = Intent-to-treat, PP = Per-protocol.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

Values reported as below the limit of quantitation (BLQ) were set to one-half of the LLOQ for summarization and statistical analysis.

. = Value missing or not reportable.

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Appendix 16.2.6.9 Blood COHb (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (% Saturation)	CFB (% Saturation)	PCFB (%)
1001	UB Non-mentholated	-1	7.9	NA	NA
	VLN Non-mentholated	2	9	1.1	13.92
		6	7	-0.9	-11.39
1002	UB Non-mentholated	-1	12.2	NA	NA
	VLN Non-mentholated	2	19.5	7.3	59.84
		6	11.9	-0.3	-2.46
1003	UB Mentholated	-1	6.9	NA	NA
	VLN Mentholated	2	7.1	0.2	2.90
		6	7.7	0.8	11.59
1007	UB Non-mentholated	-1	5.3	NA	NA
	VLN Non-mentholated	2	5.5	0.2	3.77
		6	3.8	-1.5	-28.30
1008	UB Mentholated	-1	5.6	NA	NA
	VLN Mentholated	2	5.5	-0.1	-1.79
		6	4.3	-1.3	-23.21
1010	UB Mentholated	-1	7.4	NA	NA
		2	6.7	-0.7	-9.46
		6	6.5	-0.9	-12.16
1011	UB Non-mentholated	-1	5.5	NA	NA
		2	5.9	0.4	7.27
		6	5.6	0.1	1.82

Note: NA = Not applicable

Baseline = Week -1, CFB = Change from baseline, PCFB = Percent change from baseline

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.9 Blood COHb (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (% Saturation)	CFB (% Saturation)	PCFB (%)
1013	UB Non-mentholated	-1	4.8	NA	NA
	VLN Non-mentholated	2	8.8	4.0	83.33
		6	6.9	2.1	43.75
1014	UB Mentholated	-1	5.3	NA	NA
	VLN Mentholated	2	7.4	2.1	39.62
		6	5	-0.3	-5.66
1015	UB Mentholated	-1	6.5	NA	NA
	VLN Mentholated	2	6.8	0.3	4.62
		6	4.6	-1.9	-29.23
1016	UB Non-mentholated	-1	5.5	NA	NA
		2	7	1.5	27.27
		6	7	1.5	27.27
1017	UB Mentholated	-1	5.8	NA	NA
		2	7.1	1.3	22.41
		6	5	-0.8	-13.79
1018	UB Mentholated	-1	7.9	NA	NA
1019	UB Non-mentholated	-1	5.5	NA	NA
	VLN Non-mentholated	2	5.9	0.4	7.27
		6	5.4	-0.1	-1.82
1020	UB Non-mentholated	-1	6.1	NA	NA
	VLN Non-mentholated	2	7	0.9	14.75

Note: NA = Not applicable

Baseline = Week -1, CFB = Change from baseline, PCFB = Percent change from baseline

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.9 Blood COHb (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (% Saturation)	CFB (% Saturation)	PCFB (%)
1020	VLN Non-mentholated	6	4.4	-1.7	-27.87
1021	UB Non-mentholated	-1	2.7	NA	NA
		2	4.7	2.0	74.07
		6	3.7	1.0	37.04
1023	UB Non-mentholated VLN Non-mentholated	-1	5.6	NA	NA
		2	5.3	-0.3	-5.36
		6	4.5	-1.1	-19.64
1029	UB Mentholated VLN Mentholated	-1	5.1	NA	NA
		2	2.9	-2.2	-43.14
		6	3.4	-1.7	-33.33
1032	UB Mentholated VLN Mentholated	-1	7.8	NA	NA
		2	11.6	3.8	48.72
		6	9.9	2.1	26.92
1034	UB Non-mentholated VLN Non-mentholated	-1	8.4	NA	NA
		2	8.9	0.5	5.95
		6	6.5	-1.9	-22.62
1035	UB Non-mentholated VLN Non-mentholated	-1	6.2	NA	NA
		2	6	-0.2	-3.23
		6	5.7	-0.5	-8.06
1036	UB Mentholated	-1	5.3	NA	NA
		2	4.3	-1.0	-18.87

Note: NA = Not applicable

Baseline = Week -1, CFB = Change from baseline, PCFB = Percent change from baseline

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.9 Blood COHb (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (% Saturation)	CFB (% Saturation)	PCFB (%)
1036	UB Mentholated	6	4.8	-0.5	-9.43
1037	UB Mentholated	-1	6.4	NA	NA
		2	7.1	0.7	10.94
		6	7.4	1.0	15.63
1038	UB Non-mentholated VLN Non-mentholated	-1	5.8	NA	NA
		2	3.3	-2.5	-43.10
		6	3.3	-2.5	-43.10
1042	UB Non-mentholated VLN Non-mentholated	-1	6.1	NA	NA
		2	7.3	1.2	19.67
		6	3.9	-2.2	-36.07
1045	UB Non-mentholated	-1	6.5	NA	NA
		2	5.3	-1.2	-18.46
		6	6.9	0.4	6.15
1046	UB Mentholated	-1	5.6	NA	NA
		2	5.2	-0.4	-7.14
		6	5.1	-0.5	-8.93
1050	UB Non-mentholated VLN Non-mentholated	-1	5.7	NA	NA
		2	7.5	1.8	31.58
		6	5.7	0.0	0.00
1051	UB Mentholated	-1	5.3	NA	NA
		2	4.8	-0.5	-9.43

Note: NA = Not applicable

Baseline = Week -1, CFB = Change from baseline, PCFB = Percent change from baseline

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.9 Blood COHb (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (% Saturation)	CFB (% Saturation)	PCFB (%)
1051	UB Mentholated	6	3.7	-1.6	-30.19
1052	UB Mentholated	-1	7	NA	NA
	VLN Mentholated	2	7.5	0.5	7.14
		6	4.9	-2.1	-30.00
1053	UB Mentholated	-1	5.7	NA	NA
	VLN Mentholated	2	5.1	-0.6	-10.53
		6	3.9	-1.8	-31.58
1054	UB Non-mentholated	-1	8.8	NA	NA
		2	7.5	-1.3	-14.77
		6	7	-1.8	-20.45
1055	UB Mentholated	-1	8	NA	NA
	VLN Mentholated	2	9.8	1.8	22.50
		6	4.9	-3.1	-38.75
1056	UB Non-mentholated	-1	5.8	NA	NA
	VLN Non-mentholated	2	8.6	2.8	48.28
		6	6.9	1.1	18.97
1058	UB Non-mentholated	-1	6.5	NA	NA
	VLN Non-mentholated	2	5.6	-0.9	-13.85
		6	4.9	-1.6	-24.62
1059	UB Non-mentholated	-1	7.1	NA	NA
		2	5.4	-1.7	-23.94

Note: NA = Not applicable

Baseline = Week -1, CFB = Change from baseline, PCFB = Percent change from baseline

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.9 Blood COHb (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (% Saturation)	CFB (% Saturation)	PCFB (%)
1059	UB Non-mentholated	6	7.8	0.7	9.86
1060	UB Mentholated	-1	8.7	NA	NA
	VLN Mentholated	2	9.5	0.8	9.20
		6	9.1	0.4	4.60
1063	UB Mentholated	-1	6.1	NA	NA
	VLN Mentholated	2	5.7	-0.4	-6.56
		6	4.5	-1.6	-26.23
1064	UB Non-mentholated	-1	6.6	NA	NA
		2	6.7	0.1	1.52
1066	UB Non-mentholated	-1	6.3	NA	NA
	VLN Non-mentholated	2	8	1.7	26.98
		6	6.9	0.6	9.52
1069	UB Non-mentholated	-1	4.9	NA	NA
		2	5.5	0.6	12.24
		6	5.3	0.4	8.16
1070	UB Non-mentholated	-1	8	NA	NA
	VLN Non-mentholated	2	7.5	-0.5	-6.25
		6	6.3	-1.7	-21.25
1071	UB Non-mentholated	-1	5.5	NA	NA
	VLN Non-mentholated	2	3.1	-2.4	-43.64

Note: NA = Not applicable

Baseline = Week -1, CFB = Change from baseline, PCFB = Percent change from baseline

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.9 Blood COHb (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (% Saturation)	CFB (% Saturation)	PCFB (%)
1072	UB Mentholated	-1	4.7	NA	NA
	VLN Mentholated	2	4.9	0.2	4.26
1074	UB Non-mentholated	-1	5.6	NA	NA
	VLN Non-mentholated	2	5	-0.6	-10.71
		6	3.7	-1.9	-33.93
1075	UB Non-mentholated	-1	5.1	NA	NA
		2	4.4	-0.7	-13.73
		6	4.9	-0.2	-3.92
1077	UB Non-mentholated	-1	6.3	NA	NA
	VLN Non-mentholated	2	7.5	1.2	19.05
		6	6.5	0.2	3.17
1078	UB Non-mentholated	-1	8.4	NA	NA
	VLN Non-mentholated	2	7.4	-1.0	-11.90
		6	5.8	-2.6	-30.95
1079	UB Mentholated	-1	5.7	NA	NA
	VLN Mentholated	2	4.1	-1.6	-28.07
		6	3.4	-2.3	-40.35
1082	UB Non-mentholated	-1	7.1	NA	NA
	VLN Non-mentholated	2	6.5	-0.6	-8.45
		6	4.5	-2.6	-36.62
1083	UB Non-mentholated	-1	5.7	NA	NA

Note: NA = Not applicable

Baseline = Week -1, CFB = Change from baseline, PCFB = Percent change from baseline

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.9 Blood COHb (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (% Saturation)	CFB (% Saturation)	PCFB (%)
1083	VLN Non-mentholated	2	8.6	2.9	50.88
		6	7.6	1.9	33.33
1084	UB Non-mentholated	-1	4.9	NA	NA
	VLN Non-mentholated	2	5.7	0.8	16.33
1086	UB Non-mentholated	-1	5.6	NA	NA
	VLN Non-mentholated	2	8	2.4	42.86
		6	7.4	1.8	32.14
1088	UB Mentholated	-1	4.6	NA	NA
	VLN Mentholated	2	4	-0.6	-13.04
		6	6	1.4	30.43
1089	UB Non-mentholated	-1	5	NA	NA
		2	5	0.0	0.00
		6	4.8	-0.2	-4.00
1092	UB Mentholated	-1	8.3	NA	NA
	VLN Mentholated	2	6.1	-2.2	-26.51
		6	4.9	-3.4	-40.96
1094	UB Mentholated	-1	5.7	NA	NA
	VLN Mentholated	2	7.1	1.4	24.56
		6	6.3	0.6	10.53
1095	UB Mentholated	-1	7.4	NA	NA
	VLN Mentholated	2	8.2	0.8	10.81

Note: NA = Not applicable

Baseline = Week -1, CFB = Change from baseline, PCFB = Percent change from baseline

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.9 Blood COHb (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (% Saturation)	CFB (% Saturation)	PCFB (%)
1095	VLN Mentholated	6	8.7	1.3	17.57
1096	UB Non-mentholated	-1	6.1	NA	NA
	VLN Non-mentholated	2	5.7	-0.4	-6.56
		6	6.2	0.1	1.64
1097	UB Mentholated	-1	5.9	NA	NA
	VLN Mentholated	2	3.2	-2.7	-45.76
		6	2.6	-3.3	-55.93
1098	UB Non-mentholated	-1	5.6	NA	NA
	VLN Non-mentholated	2	6.5	0.9	16.07
		6	5.8	0.2	3.57
1099	UB Non-mentholated	-1	5.3	NA	NA
	VLN Non-mentholated	2	6.5	1.2	22.64
		6	5.6	0.3	5.66
1100	UB Non-mentholated	-1	5.9	NA	NA
	VLN Non-mentholated	2	7	1.1	18.64
		6	5.9	0.0	0.00
1101	UB Non-mentholated	-1	6.6	NA	NA
	VLN Non-mentholated	2	8.4	1.8	27.27
		6	10.3	3.7	56.06
1103	UB Non-mentholated	-1	8.2	NA	NA
	VLN Non-mentholated	2	9.8	1.6	19.51

Note: NA = Not applicable

Baseline = Week -1, CFB = Change from baseline, PCFB = Percent change from baseline

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.9 Blood COHb (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (% Saturation)	CFB (% Saturation)	PCFB (%)
1103	VLN Non-mentholated	6	9.4	1.2	14.63
1105	UB Non-mentholated	-1	4.8	NA	NA
	VLN Non-mentholated	2	7.1	2.3	47.92
		6	4.7	-0.1	-2.08
1106	UB Non-mentholated	-1	6	NA	NA
		2	6.1	0.1	1.67
		6	6.8	0.8	13.33
1107	UB Non-mentholated	-1	6.8	NA	NA
	VLN Non-mentholated	2	6.7	-0.1	-1.47
		6	4.5	-2.3	-33.82
1108	UB Non-mentholated	-1	4.8	NA	NA
		2	5.6	0.8	16.67
		6	5.1	0.3	6.25
1109	UB Non-mentholated	-1	4.7	NA	NA
		2	4.3	-0.4	-8.51
		6	4.3	-0.4	-8.51
1112	UB Non-mentholated	-1	5.7	NA	NA
	VLN Non-mentholated	2	8	2.3	40.35
		6	4.5	-1.2	-21.05
1114	UB Non-mentholated	-1	3.8	NA	NA
		2	2.8	-1.0	-26.32

Note: NA = Not applicable

Baseline = Week -1, CFB = Change from baseline, PCFB = Percent change from baseline

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.9 Blood COHb (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (% Saturation)	CFB (% Saturation)	PCFB (%)
1114	UB Non-mentholated	6	2.5	-1.3	-34.21
1115	UB Non-mentholated	-1	4.6	NA	NA
	VLN Non-mentholated	2	6.1	1.5	32.61
2002	UB Mentholated	-1	6.5	NA	NA
		2	5.6	-0.9	-13.85
		6	6.3	-0.2	-3.08
2003	UB Mentholated VLN Mentholated	-1	8.6	NA	NA
		2	7.1	-1.5	-17.44
		6	3.9	-4.7	-54.65
2007	UB Non-mentholated VLN Non-mentholated	-1	4.8	NA	NA
		2	5.8	1.0	20.83
		6	4.1	-0.7	-14.58
2008	UB Mentholated VLN Mentholated	-1	6.1	NA	NA
		2	4	-2.1	-34.43
		6	4.5	-1.6	-26.23
2009	UB Non-mentholated VLN Non-mentholated	-1	1.3	NA	NA
		2	2.3	1.0	76.92
2010	UB Mentholated	-1	3.8	NA	NA
		2	4.3	0.5	13.16
		6	3.3	-0.5	-13.16

Note: NA = Not applicable

Baseline = Week -1, CFB = Change from baseline, PCFB = Percent change from baseline

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.9 Blood COHb (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (% Saturation)	CFB (% Saturation)	PCFB (%)
2011	UB Mentholated	-1	4.1	NA	NA
	VLN Mentholated	2	3.4	-0.7	-17.07
		6	3.3	-0.8	-19.51
2014	UB Mentholated	-1	7.5	NA	NA
	VLN Mentholated	2	9.2	1.7	22.67
		6	5.6	-1.9	-25.33
2015	UB Mentholated	-1	4	NA	NA
		2	4.1	0.1	2.50
		6	3.6	-0.4	-10.00
2016	UB Mentholated	-1	5.3	NA	NA
2017	UB Mentholated	-1	7	NA	NA
	VLN Mentholated	2	6.6	-0.4	-5.71
		6	4.6	-2.4	-34.29
2018	UB Mentholated	-1	5.4	NA	NA
		2	5.2	-0.2	-3.70
		6	3.5	-1.9	-35.19
2020	UB Mentholated	-1	6.2	NA	NA
	VLN Mentholated	2	5.1	-1.1	-17.74
		6	3.7	-2.5	-40.32
2021	UB Mentholated	-1	2.4	NA	NA
	VLN Mentholated	2	3.2	0.8	33.33

Note: NA = Not applicable

Baseline = Week -1, CFB = Change from baseline, PCFB = Percent change from baseline

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.9 Blood COHb (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (% Saturation)	CFB (% Saturation)	PCFB (%)
2021	VLN Mentholated	6	2.4	0.0	0.00
2023	UB Mentholated	-1	5.8	NA	NA
	VLN Mentholated	2	3	-2.8	-48.28
		6	3	-2.8	-48.28
2024	UB Non-mentholated	-1	3.4	NA	NA
2025	UB Non-mentholated	-1	4.6	NA	NA
		2	5.9	1.3	28.26
		6	6.1	1.5	32.61
2028	UB Non-mentholated	-1	4.8	NA	NA
	VLN Non-mentholated	2	5.6	0.8	16.67
		6	3.9	-0.9	-18.75
2029	UB Mentholated	-1	4.1	NA	NA
		2	4.5	0.4	9.76
		6	3.4	-0.7	-17.07
2039	UB Mentholated	-1	4	NA	NA
	VLN Mentholated	2	3.2	-0.8	-20.00
		6	2.6	-1.4	-35.00
2050	UB Mentholated	-1	7.6	NA	NA
		2	5.9	-1.7	-22.37
		6	3.8	-3.8	-50.00

Note: NA = Not applicable

Baseline = Week -1, CFB = Change from baseline, PCFB = Percent change from baseline

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.9 Blood COHb (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (% Saturation)	CFB (% Saturation)	PCFB (%)
2052	UB Mentholated	-1	4.6	NA	NA
	VLN Mentholated	2	5.6	1.0	21.74
		6	5	0.4	8.70
2057	UB Mentholated	-1	5.2	NA	NA
	VLN Mentholated	2	3.8	-1.4	-26.92
		6	4	-1.2	-23.08
2058	UB Mentholated	-1	2.9	NA	NA
	VLN Mentholated	2	2.6	-0.3	-10.34
		6	2.6	-0.3	-10.34
2059	UB Mentholated	-1	6.6	NA	NA
		2	4.7	-1.9	-28.79
		6	5.3	-1.3	-19.70
2060	UB Mentholated	-1	7.3	NA	NA
	VLN Mentholated	2	4.2	-3.1	-42.47
		6	4.1	-3.2	-43.84
2064	UB Mentholated	-1	6.2	NA	NA
	VLN Mentholated	2	8.4	2.2	35.48
		6	7.4	1.2	19.35
2066	UB Mentholated	-1	5.6	NA	NA
	VLN Mentholated	2	4.2	-1.4	-25.00
		6	3.2	-2.4	-42.86

Note: NA = Not applicable

Baseline = Week -1, CFB = Change from baseline, PCFB = Percent change from baseline

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.9 Blood COHb (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (% Saturation)	CFB (% Saturation)	PCFB (%)
2067	UB Non-mentholated	-1	5.9	NA	NA
	VLN Non-mentholated	2	6.1	0.2	3.39
		6	5.3	-0.6	-10.17
2075	UB Mentholated	-1	6.1	NA	NA
2076	UB Mentholated	-1	4.8	NA	NA
	VLN Mentholated	2	3.9	-0.9	-18.75
		6	2.5	-2.3	-47.92
2086	UB Non-mentholated	-1	5	NA	NA
	VLN Non-mentholated	2	5.8	0.8	16.00
2088	UB Mentholated	-1	4.7	NA	NA
	VLN Mentholated	2	3.2	-1.5	-31.91
		6	2.9	-1.8	-38.30
2092	UB Mentholated	-1	3.6	NA	NA
	VLN Mentholated	2	4.3	0.7	19.44
		6	2.5	-1.1	-30.56
2099	UB Non-mentholated	-1	4.6	NA	NA
	VLN Non-mentholated	2	4.8	0.2	4.35
		6	4.1	-0.5	-10.87
2100	UB Mentholated	-1	6.3	NA	NA
		2	7	0.7	11.11
		6	5.9	-0.4	-6.35

Note: NA = Not applicable

Baseline = Week -1, CFB = Change from baseline, PCFB = Percent change from baseline

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.9 Blood COHb (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (% Saturation)	CFB (% Saturation)	PCFB (%)
2108	UB Non-mentholated	-1	6.1	NA	NA
	VLN Non-mentholated	2	8.3	2.2	36.07
		6	6.6	0.5	8.20
2110	UB Mentholated	-1	4.2	NA	NA
		2	4.6	0.4	9.52
		6	3.2	-1.0	-23.81
2113	UB Mentholated	-1	5.9	NA	NA
	VLN Mentholated	2	4.9	-1.0	-16.95
2115	UB Mentholated	-1	4.2	NA	NA
2119	UB Mentholated	-1	7.2	NA	NA
	VLN Mentholated	2	6.9	-0.3	-4.17
		6	8.2	1.0	13.89
2120	UB Non-mentholated	-1	6.1	NA	NA
	VLN Non-mentholated	2	4.3	-1.8	-29.51
		6	4.3	-1.8	-29.51
2122	UB Non-mentholated	-1	5.3	NA	NA
		2	5.7	0.4	7.55
		6	4.5	-0.8	-15.09
2125	UB Mentholated	-1	3.3	NA	NA
		2	3.7	0.4	12.12
		6	3.7	0.4	12.12

Note: NA = Not applicable

Baseline = Week -1, CFB = Change from baseline, PCFB = Percent change from baseline

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.9 Blood COHb (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (% Saturation)	CFB (% Saturation)	PCFB (%)
2126	UB Mentholated	-1	4.7	NA	NA
	VLN Mentholated	2	5.3	0.6	12.77
		6	4.2	-0.5	-10.64
2136	UB Non-mentholated	-1	4.3	NA	NA
	VLN Non-mentholated	2	4.6	0.3	6.98
2140	UB Non-mentholated	-1	4.2	NA	NA
		2	2.7	-1.5	-35.71
		6	6.4	2.2	52.38
2142	UB Non-mentholated	-1	8.1	NA	NA
2143	UB Non-mentholated	-1	8.4	NA	NA
	VLN Non-mentholated	2	9.3	0.9	10.71
		6	9.1	0.7	8.33
2158	UB Non-mentholated	-1	4.5	NA	NA
		2	5.2	0.7	15.56
2159	UB Non-mentholated	-1	7.8	NA	NA
	VLN Non-mentholated	2	11.1	3.3	42.31
		6	8.3	0.5	6.41
2164	UB Non-mentholated	-1	8.2	NA	NA
	VLN Non-mentholated	2	10.8	2.6	31.71
		6	7.4	-0.8	-9.76

Note: NA = Not applicable

Baseline = Week -1, CFB = Change from baseline, PCFB = Percent change from baseline

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.9 Blood COHb (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (% Saturation)	CFB (% Saturation)	PCFB (%)
2168	UB Non-mentholated	-1	11.5	NA	NA
	VLN Non-mentholated	2	13.4	1.9	16.52
		6	8.3	-3.2	-27.83
2170	UB Non-mentholated	-1	5.3	NA	NA
		2	5	-0.3	-5.66
		6	4.8	-0.5	-9.43
2175	UB Mentholated	-1	6.6	NA	NA
		2	5	-1.6	-24.24
		6	4.1	-2.5	-37.88
2189	UB Mentholated	-1	3.7	NA	NA
2211	UB Mentholated	-1	3.9	NA	NA
	VLN Mentholated	2	5.1	1.2	30.77
		6	2.8	-1.1	-28.21
2212	UB Mentholated	-1	4	NA	NA
		2	4.7	0.7	17.50
		6	3.6	-0.4	-10.00
2213	UB Mentholated	-1	6.2	NA	NA
	VLN Mentholated	2	8.2	2.0	32.26
		6	5.2	-1.0	-16.13
2215	UB Mentholated	-1	6.4	NA	NA
		2	13.1	6.7	104.69

Note: NA = Not applicable

Baseline = Week -1, CFB = Change from baseline, PCFB = Percent change from baseline

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.9 Blood COHb (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (% Saturation)	CFB (% Saturation)	PCFB (%)
2215	UB Mentholated	6	6	-0.4	-6.25
2220	UB Non-mentholated	-1	3.7	NA	NA
	VLN Non-mentholated	2	3.7	0.0	0.00
		6	3.1	-0.6	-16.22
2235	UB Mentholated	-1	3.9	NA	NA
	VLN Mentholated	2	2.6	-1.3	-33.33
		6	3.9	0.0	0.00
2244	UB Non-mentholated	-1	4.4	NA	NA
	VLN Non-mentholated	2	4.5	0.1	2.27
		6	6	1.6	36.36
2247	UB Mentholated	-1	4.8	NA	NA
	VLN Mentholated	2	4.7	-0.1	-2.08
2251	UB Non-mentholated	-1	5.6	NA	NA
		2	6.7	1.1	19.64
		6	5.8	0.2	3.57
2257	UB Non-mentholated	-1	5.6	NA	NA
		2	6.1	0.5	8.93
		6	6.3	0.7	12.50
2259	UB Mentholated	-1	3.6	NA	NA
		2	4.1	0.5	13.89
		6	4	0.4	11.11

Note: NA = Not applicable

Baseline = Week -1, CFB = Change from baseline, PCFB = Percent change from baseline

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.9 Blood COHb (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (% Saturation)	CFB (% Saturation)	PCFB (%)
2269	UB Mentholated	-1	6.4	NA	NA
	VLN Mentholated	2	3.9	-2.5	-39.06
		6	3.5	-2.9	-45.31
2272	UB Mentholated	-1	2.9	NA	NA
	VLN Mentholated	2	6.6	3.7	127.59
		6	4.9	2.0	68.97

Note: NA = Not applicable

Baseline = Week -1, CFB = Change from baseline, PCFB = Percent change from baseline

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes

VLN mentholated = Mentholated VLN cigarettes

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes

UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.10 Plasma Cotinine (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (ng/mL)
1001	UB Non-mentholated	-1	337
	VLN Non-mentholated	2	74.2
		6	122
1002	UB Non-mentholated	-1	457
	VLN Non-mentholated	2	293
		6	243
1003	UB Mentholated	-1	247
	VLN Mentholated	2	91.8
		6	187
1007	UB Non-mentholated	-1	109
	VLN Non-mentholated	2	4.94
		6	8.88
1008	UB Mentholated	-1	338
	VLN Mentholated	2	62.8
		6	241
1010	UB Mentholated	-1	294
		2	284
		6	189
1011	UB Non-mentholated	-1	214
		2	173
		6	181
1013	UB Non-mentholated	-1	288
	VLN Non-mentholated	2	104

Note: Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.10 Plasma Cotinine (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (ng/mL)
1013	VLN Non-mentholated	6	153
1014	UB Mentholated	-1	269
	VLN Mentholated	2	76.5
		6	152
1015	UB Mentholated	-1	174
	VLN Mentholated	2	4.71
		6	5.11
1016	UB Non-mentholated	-1	275
		2	336
		6	354
1017	UB Mentholated	-1	171
		2	203
		6	197
1018	UB Mentholated	-1	244
1019	UB Non-mentholated	-1	242
	VLN Non-mentholated	2	38.3
		6	188
1020	UB Non-mentholated	-1	255
	VLN Non-mentholated	2	45.7
		6	87.6
1021	UB Non-mentholated	-1	106
		2	132

Note: Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.10 Plasma Cotinine (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (ng/mL)
1021	UB Non-mentholated	6	132
1023	UB Non-mentholated	-1	110
	VLN Non-mentholated	2	5.37
		6	32.9
1029	UB Mentholated	-1	83.7
	VLN Mentholated	2	10.1
		6	15.2
1032	UB Mentholated	-1	320
	VLN Mentholated	2	11.4
		6	29.6
1034	UB Non-mentholated	-1	283
	VLN Non-mentholated	2	87.0
		6	125
1035	UB Non-mentholated	-1	204
	VLN Non-mentholated	2	141
		6	201
1036	UB Mentholated	-1	184
		2	149
		6	172
1037	UB Mentholated	-1	170
		2	185
		6	208

Note: Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.10 Plasma Cotinine (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (ng/mL)
1038	UB Non-mentholated	-1	203
	VLN Non-mentholated	2	5.01
		6	44.0
1042	UB Non-mentholated	-1	179
	VLN Non-mentholated	2	9.18
		6	18.9
1045	UB Non-mentholated	-1	160
		2	141
		6	134
1046	UB Mentholated	-1	174
		2	152
		6	144
1050	UB Non-mentholated	-1	327
	VLN Non-mentholated	2	17.5
		6	134
1051	UB Mentholated	-1	250
		2	203
		6	171
1052	UB Mentholated	-1	563
	VLN Mentholated	2	177
		6	529
1053	UB Mentholated	-1	216
	VLN Mentholated	2	16.7

Note: Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.10 Plasma Cotinine (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (ng/mL)
1053	VLN Mentholated	6	33.9
1054	UB Non-mentholated	-1	247
		2	221
		6	163
1055	UB Mentholated	-1	7.30
	VLN Mentholated	2	275
		6	82.8
1056	UB Non-mentholated	-1	166
	VLN Non-mentholated	2	11.6
		6	43.6
1058	UB Non-mentholated	-1	315
	VLN Non-mentholated	2	8.24
		6	260
1059	UB Non-mentholated	-1	193
		2	150
		6	197
1060	UB Mentholated	-1	354
	VLN Mentholated	2	57.9
		6	190
1063	UB Mentholated	-1	213
	VLN Mentholated	2	4.68
		6	3.09

Note: Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.10 Plasma Cotinine (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (ng/mL)
1064	UB Non-mentholated	-1 2	244 317
1066	UB Non-mentholated VLN Non-mentholated	-1 2 6	242 14.4 14.2
1069	UB Non-mentholated	-1 2 6	149 141 141
1070	UB Non-mentholated VLN Non-mentholated	-1 2 6	231 26.5 21.9
1071	UB Non-mentholated VLN Non-mentholated	-1 2	150 76.2
1072	UB Mentholated VLN Mentholated	-1 2	142 10.9
1074	UB Non-mentholated VLN Non-mentholated	-1 2 6	402 204 253
1075	UB Non-mentholated	-1 2 6	151 172 143
1077	UB Non-mentholated	-1	285

Note: Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.10 Plasma Cotinine (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (ng/mL)
1077	VLN Non-mentholated	2	11.6
		6	7.05
1078	UB Non-mentholated VLN Non-mentholated	-1	198
		2	37.3
		6	88.5
1079	UB Mentholated VLN Mentholated	-1	181
		2	3.45
		6	1.68
1082	UB Non-mentholated VLN Non-mentholated	-1	217
		2	36.6
		6	72.3
1083	UB Non-mentholated VLN Non-mentholated	-1	258
		2	112
		6	175
1084	UB Non-mentholated VLN Non-mentholated	-1	177
		2	41.7
1086	UB Non-mentholated VLN Non-mentholated	-1	375
		2	81.6
		6	158
1088	UB Mentholated VLN Mentholated	-1	145
		2	68.4
		6	64.4

Note: Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

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Appendix 16.2.6.10 Plasma Cotinine (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (ng/mL)
1089	UB Non-mentholated	-1	126
		2	117
		6	110
1092	UB Mentholated VLN Mentholated	-1	254
		2	186
		6	190
1094	UB Mentholated VLN Mentholated	-1	278
		2	26.5
		6	55.6
1095	UB Mentholated VLN Mentholated	-1	265
		2	48.9
		6	85.1
1096	UB Non-mentholated VLN Non-mentholated	-1	173
		2	131
		6	162
1097	UB Mentholated VLN Mentholated	-1	279
		2	139
		6	135
1098	UB Non-mentholated VLN Non-mentholated	-1	123
		2	7.23
		6	5.63
1099	UB Non-mentholated VLN Non-mentholated	-1	213
		2	28.1

Note: Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/pksas/pdblood/adam_lis_conc.sas 12JUN2019 9:42

Appendix 16.2.6.10 Plasma Cotinine (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (ng/mL)
1099	VLN Non-mentholated	6	63.5
1100	UB Non-mentholated	-1	212
	VLN Non-mentholated	2	86.6
		6	134
1101	UB Non-mentholated	-1	151
	VLN Non-mentholated	2	27.4
		6	69.5
1103	UB Non-mentholated	-1	259
	VLN Non-mentholated	2	57.8
		6	185
1105	UB Non-mentholated	-1	176
	VLN Non-mentholated	2	83.5
		6	85.0
1106	UB Non-mentholated	-1	264
		2	317
		6	302
1107	UB Non-mentholated	-1	82.2
	VLN Non-mentholated	2	25.8
		6	64.8
1108	UB Non-mentholated	-1	194
		2	195
		6	179

Note: Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/pksas/pdblood/adam_lis_conc.sas 12JUN2019 9:42

Appendix 16.2.6.10 Plasma Cotinine (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (ng/mL)
1109	UB Non-mentholated	-1	252
		2	178
		6	194
1112	UB Non-mentholated VLN Non-mentholated	-1	262
		2	74.3
		6	150
1114	UB Non-mentholated	-1	91.0
		2	52.1
		6	65.0
1115	UB Non-mentholated VLN Non-mentholated	-1	146
		2	6.58
2002	UB Mentholated	-1	211
		2	172
		6	245
2003	UB Mentholated VLN Mentholated	-1	248
		2	37.2
		6	78.4
2007	UB Non-mentholated VLN Non-mentholated	-1	179
		2	22.2
		6	17.1
2008	UB Mentholated VLN Mentholated	-1	353
		2	9.15
		6	74.6

Note: Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/pksas/pdblood/adam_lis_conc.sas 12JUN2019 9:42

Appendix 16.2.6.10 Plasma Cotinine (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (ng/mL)
2009	UB Non-mentholated	-1	124
	VLN Non-mentholated	2	65.0
2010	UB Mentholated	-1	129
		2	176
		6	120
2011	UB Mentholated VLN Mentholated	-1	157
		2	51.9
		6	88.8
2014	UB Mentholated VLN Mentholated	-1	353
		2	76.8
		6	177
2015	UB Mentholated	-1	185
		2	161
		6	175
2016	UB Mentholated	-1	334
2017	UB Mentholated VLN Mentholated	-1	453
		2	23.3
		6	152
2018	UB Mentholated	-1	238
		2	288
		6	256
2020	UB Mentholated	-1	281

Note: Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/pksas/pdblood/adam_lis_conc.sas 12JUN2019 9:42

Appendix 16.2.6.10 Plasma Cotinine (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (ng/mL)
2020	VLN Mentholated	2	83.9
		6	186
2021	UB Mentholated VLN Mentholated	-1	164
		2	16.0
		6	18.1
2023	UB Mentholated VLN Mentholated	-1	255
		2	6.27
		6	5.37
2024	UB Non-mentholated	-1	129
2025	UB Non-mentholated	-1	196
		2	173
		6	206
2028	UB Non-mentholated VLN Non-mentholated	-1	213
		2	20.4
		6	8.38
2029	UB Mentholated	-1	124
		2	121
		6	123
2039	UB Mentholated VLN Mentholated	-1	211
		2	197
		6	168
2050	UB Mentholated	-1	655

Note: Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/pksas/pdblood/adam_lis_conc.sas 12JUN2019 9:42

Appendix 16.2.6.10 Plasma Cotinine (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (ng/mL)
2050	UB Mentholated	2	494
		6	410
2052	UB Mentholated VLN Mentholated	-1	154
		2	7.31
		6	7.26
2057	UB Mentholated VLN Mentholated	-1	188
		2	30.8
		6	90.7
2058	UB Mentholated VLN Mentholated	-1	152
		2	23.4
		6	33.6
2059	UB Mentholated	-1	324
		2	348
		6	288
2060	UB Mentholated VLN Mentholated	-1	364
		2	132
		6	329
2064	UB Mentholated VLN Mentholated	-1	156
		2	62.4
		6	57.2
2066	UB Mentholated VLN Mentholated	-1	265
		2	136
		6	110

Note: Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/pksas/pdblood/adam_lis_conc.sas 12JUN2019 9:42

Appendix 16.2.6.10 Plasma Cotinine (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (ng/mL)
2067	UB Non-mentholated	-1	208
	VLN Non-mentholated	2	111
		6	181
2075	UB Mentholated	-1	131
2076	UB Mentholated	-1	164
	VLN Mentholated	2	13.6
		6	52.7
2086	UB Non-mentholated	-1	182
	VLN Non-mentholated	2	43.8
2088	UB Mentholated	-1	172
	VLN Mentholated	2	18.3
		6	38.3
2092	UB Mentholated	-1	89.4
	VLN Mentholated	2	7.82
		6	22.8
2099	UB Non-mentholated	-1	152
	VLN Non-mentholated	2	39.6
		6	67.3
2100	UB Mentholated	-1	195
		2	198
		6	177
2108	UB Non-mentholated	-1	167

Note: Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/pksas/pdblood/adam_lis_conc.sas 12JUN2019 9:42

Appendix 16.2.6.10 Plasma Cotinine (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (ng/mL)
2108	VLN Non-mentholated	2	16.2
		6	65.5
2110	UB Mentholated	-1	116
		2	128
		6	96.2
2113	UB Mentholated	-1	261
	VLN Mentholated	2	48.6
2115	UB Mentholated	-1	337
2119	UB Mentholated VLN Mentholated	-1	306
		2	24.9
		6	12.2
2120	UB Non-mentholated VLN Non-mentholated	-1	188
		2	5.54
		6	6.71
2122	UB Non-mentholated	-1	149
		2	159
		6	150
2125	UB Mentholated	-1	86.2
		2	129
		6	198
2126	UB Mentholated	-1	192
	VLN Mentholated	2	15.1

Note: Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/pksas/pdblood/adam_lis_conc.sas 12JUN2019 9:42

Appendix 16.2.6.10 Plasma Cotinine (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (ng/mL)
2126	VLN Mentholated	6	44.7
2136	UB Non-mentholated	-1	164
	VLN Non-mentholated	2	59.0
2140	UB Non-mentholated	-1	136
		2	90.5
		6	128
2142	UB Non-mentholated	-1	314
2143	UB Non-mentholated	-1	387
	VLN Non-mentholated	2	11.8
		6	10.8
2158	UB Non-mentholated	-1	235
		2	243
2159	UB Non-mentholated	-1	372
	VLN Non-mentholated	2	129
		6	214
2164	UB Non-mentholated	-1	372
	VLN Non-mentholated	2	22.4
		6	27.7
2168	UB Non-mentholated	-1	453
	VLN Non-mentholated	2	124
		6	207

Note: Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/pksas/pdblood/adam_lis_conc.sas 12JUN2019 9:42

Appendix 16.2.6.10 Plasma Cotinine (Safety Population)

Subject Number	Study Product	Study Week	Biomarker Concentration (ng/mL)
2170	UB Non-mentholated	-1	327
		2	317
		6	302
2175	UB Mentholated	-1	287
		2	193
		6	171
2189	UB Mentholated	-1	185
2211	UB Mentholated	-1	448
	VLN Mentholated	2	20.7
		6	187
2212	UB Mentholated	-1	180
		2	148
		6	123
2213	UB Mentholated	-1	458
	VLN Mentholated	2	89.5
		6	239
2215	UB Mentholated	-1	418
		2	413
		6	376
2220	UB Non-mentholated	-1	107
	VLN Non-mentholated	2	23.3
		6	70.3

Note: Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/pksas/pdblood/adam_lis_conc.sas 12JUN2019 9:42

Appendix 16.2.6.10 Plasma Cotinine (Safety Population)

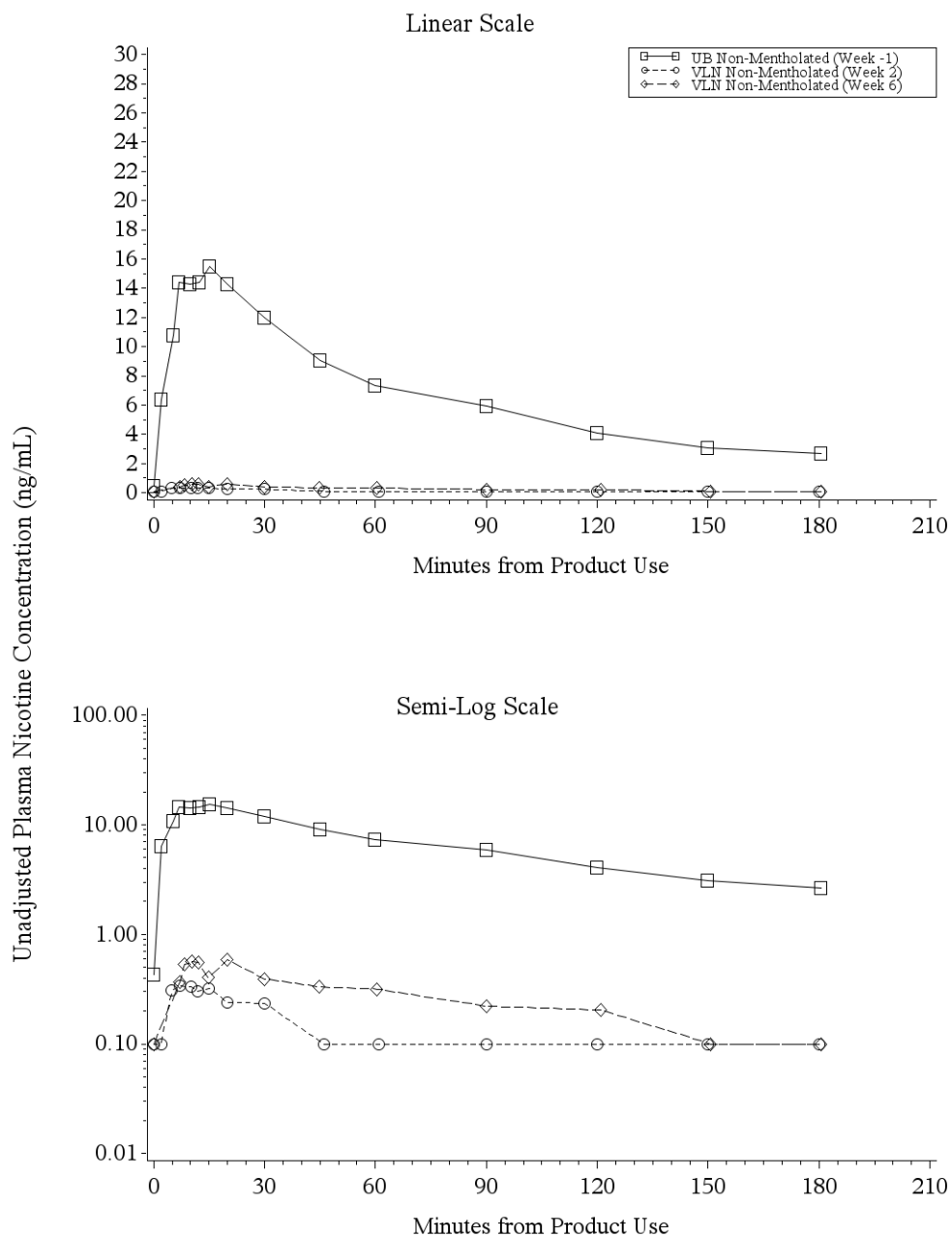
Subject Number	Study Product	Study Week	Biomarker Concentration (ng/mL)
2235	UB Mentholated	-1	157
	VLN Mentholated	2	59.7
		6	106
2244	UB Non-mentholated	-1	208
	VLN Non-mentholated	2	176
		6	140
2247	UB Mentholated	-1	241
	VLN Mentholated	2	28.2
2251	UB Non-mentholated	-1	266
		2	241
		6	263
2257	UB Non-mentholated	-1	241
		2	247
		6	223
2259	UB Mentholated	-1	270
		2	334
		6	304
2269	UB Mentholated	-1	209
	VLN Mentholated	2	116
		6	186
2272	UB Mentholated	-1	269
	VLN Mentholated	2	33.6
		6	160

Note: Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/pksas/pdblood/adam_lis_conc.sas 12JUN2019 9:42

Appendix 16.2.6.11.1

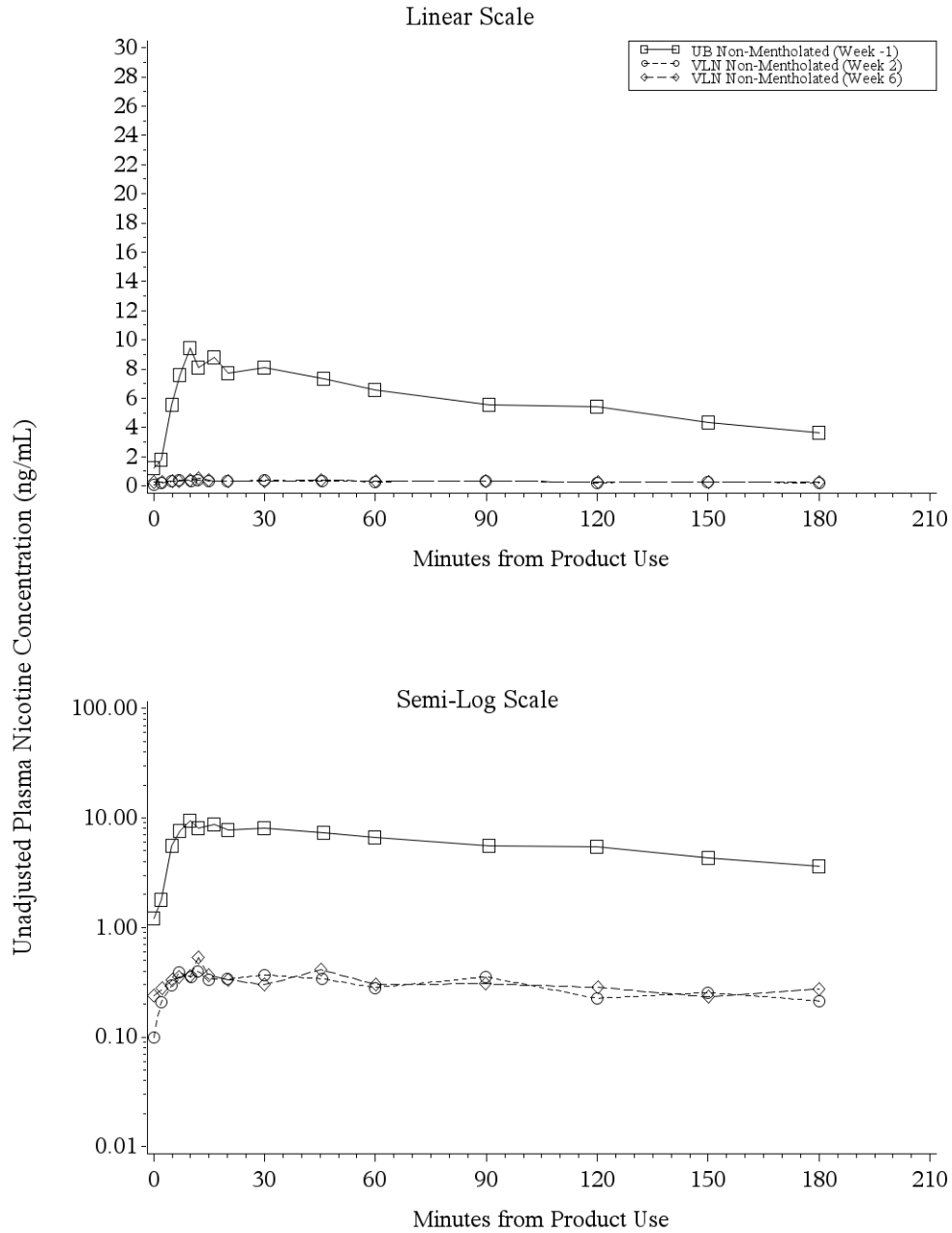
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1001



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.1

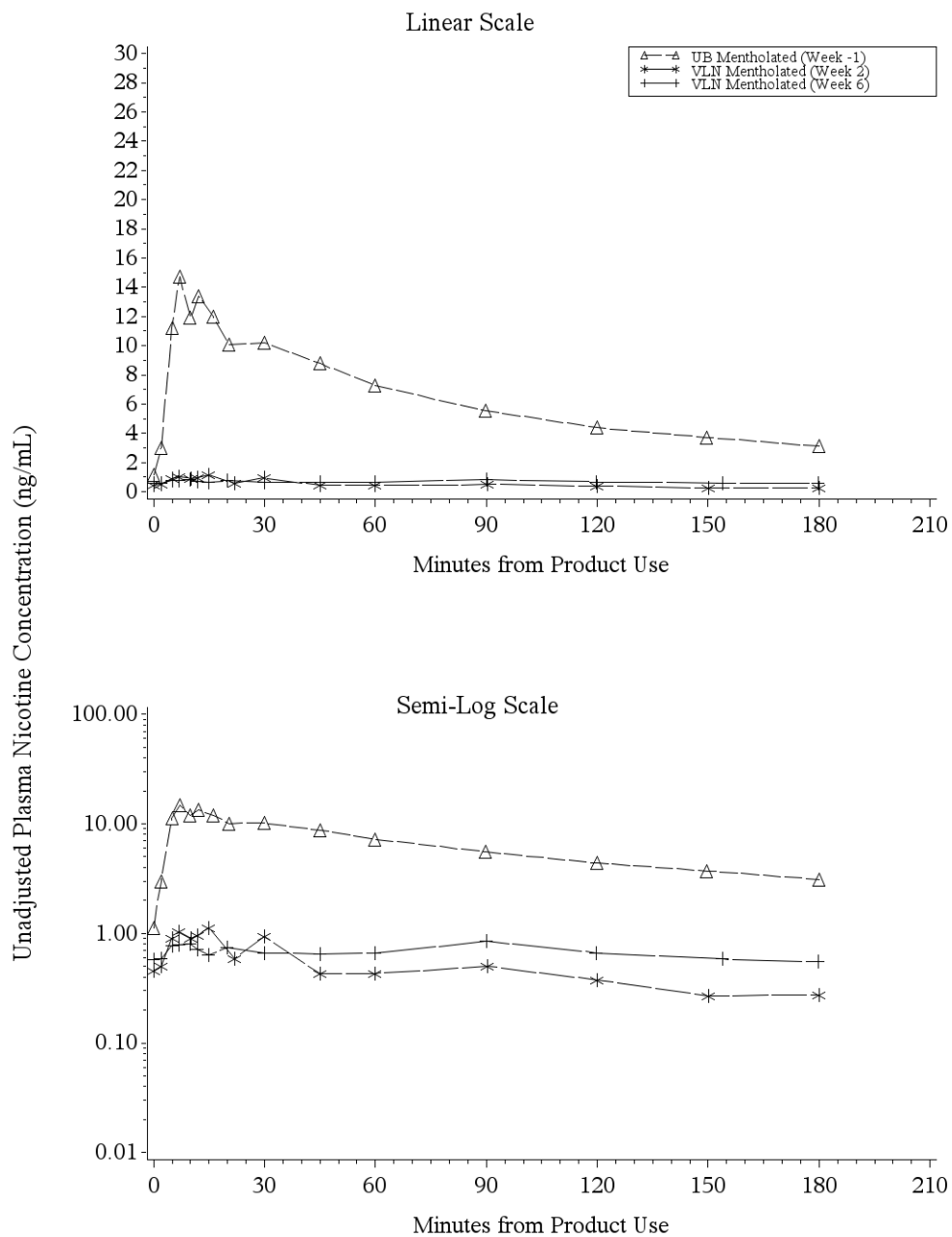
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1002



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.1

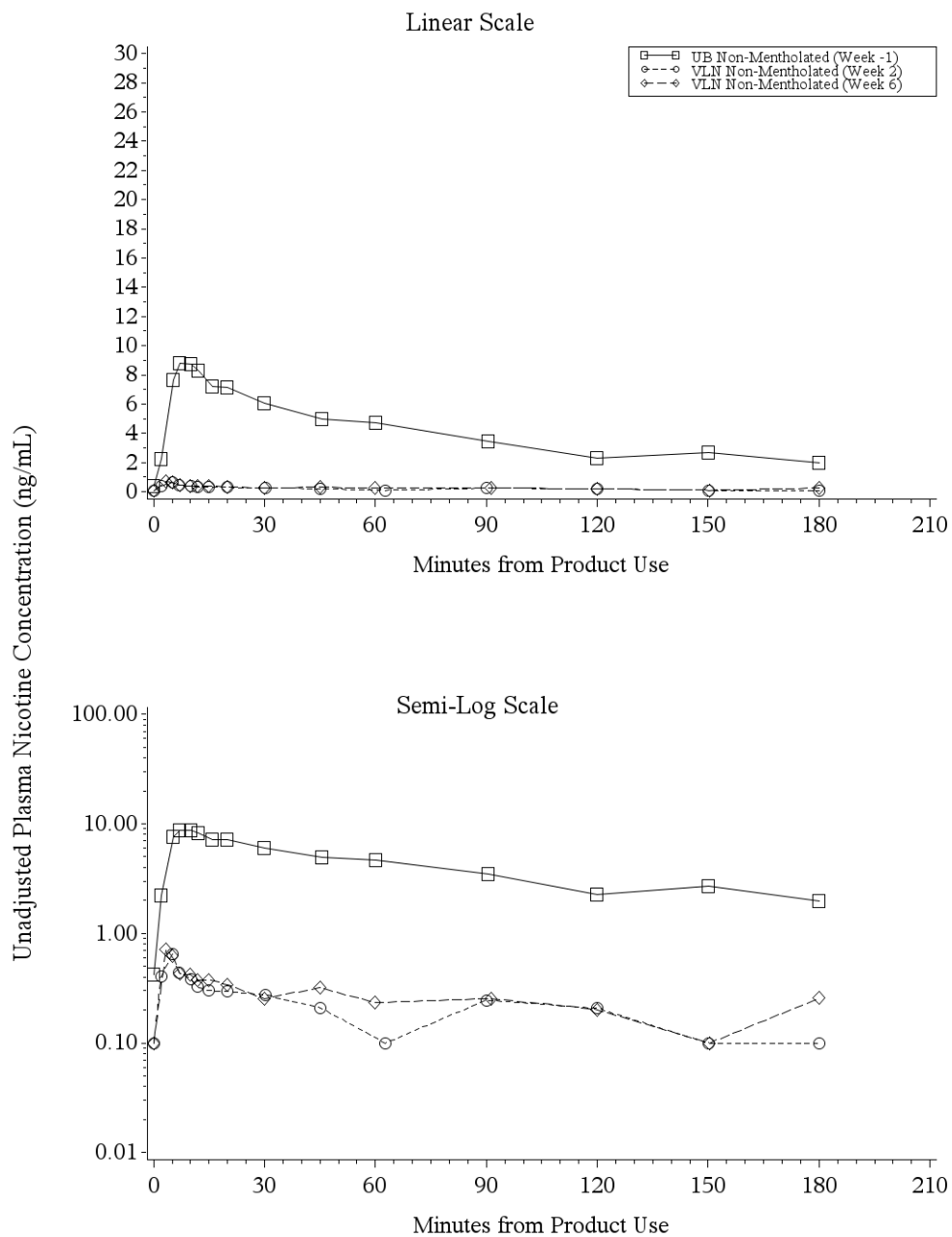
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1003



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.1

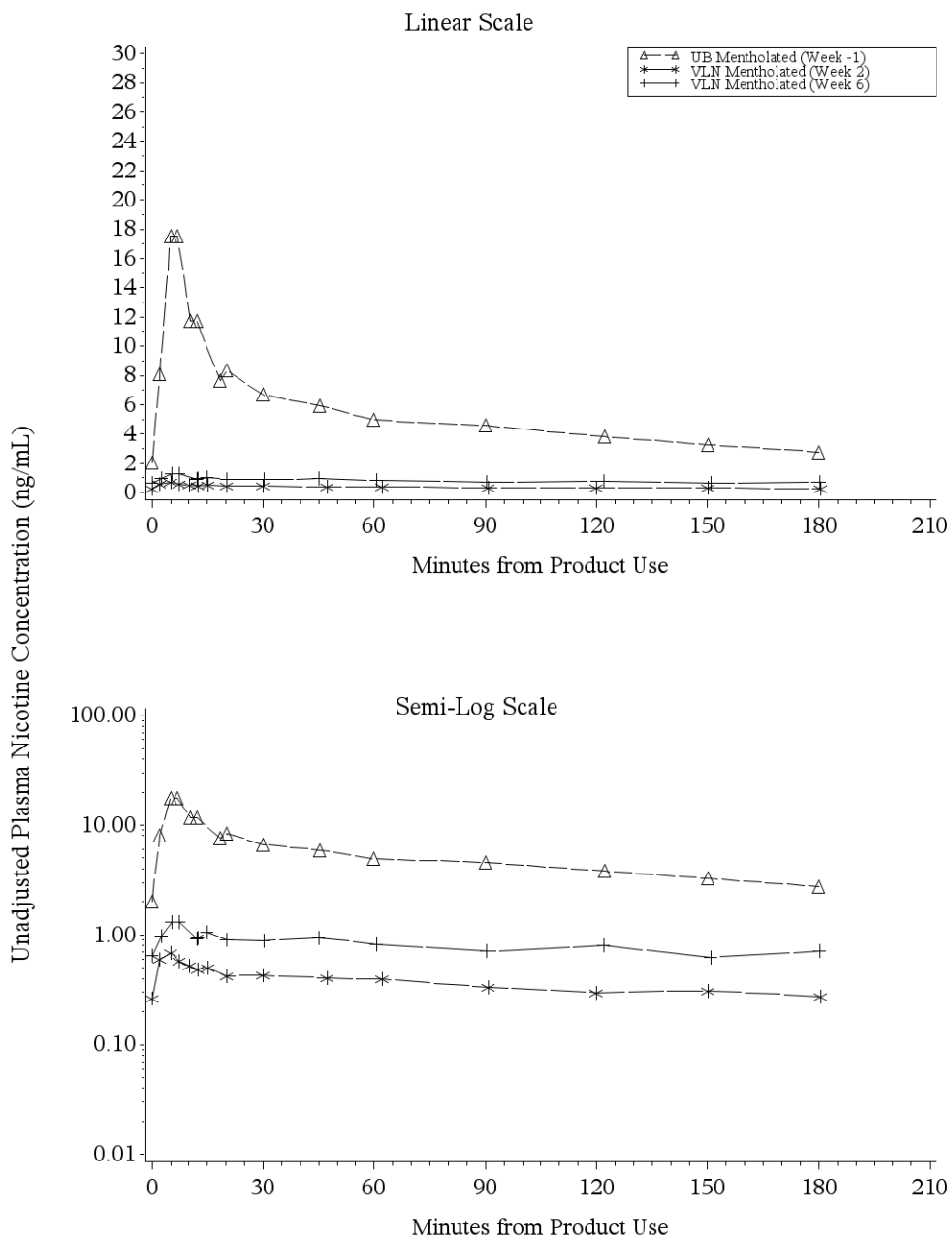
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1007



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.1

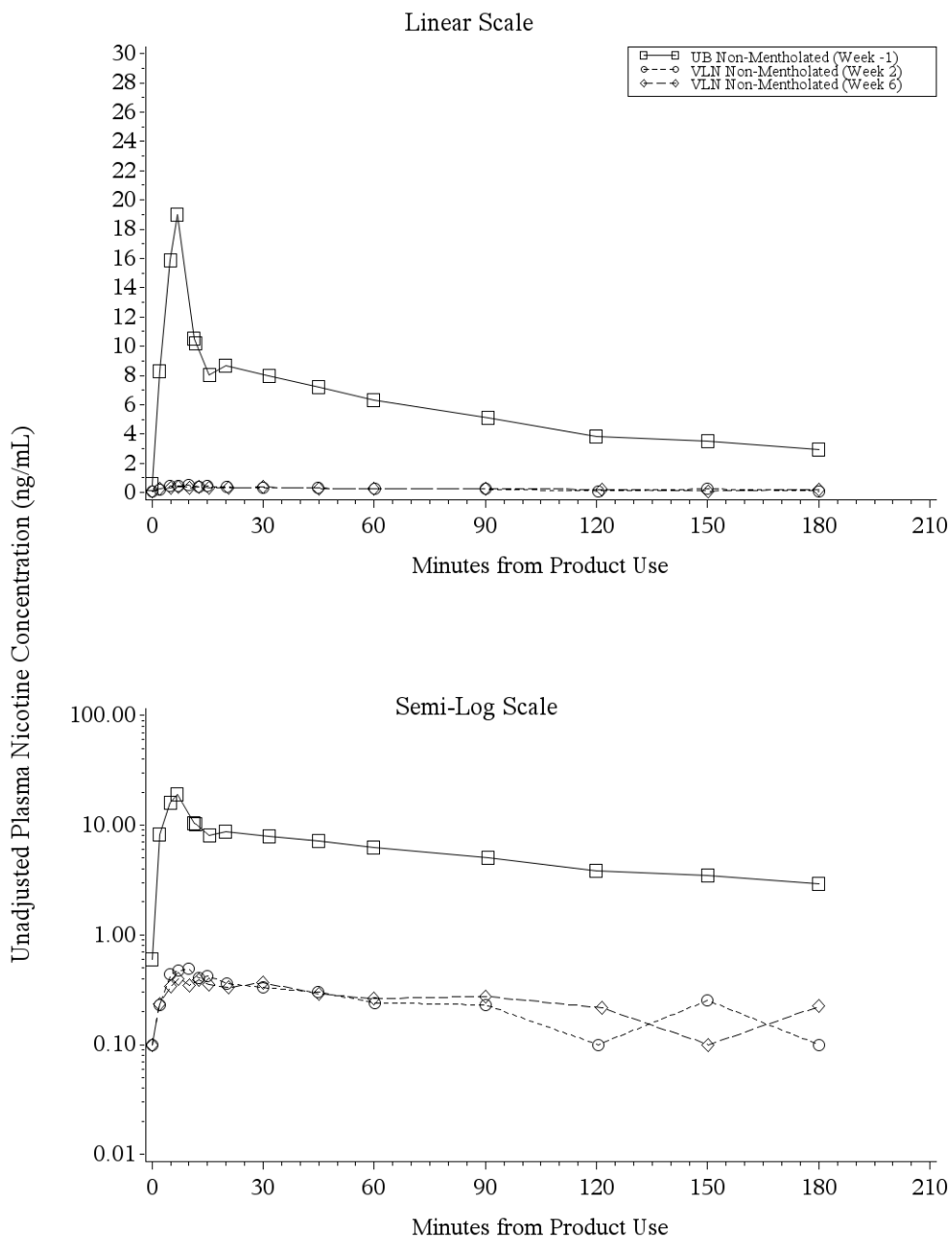
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1008



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.1

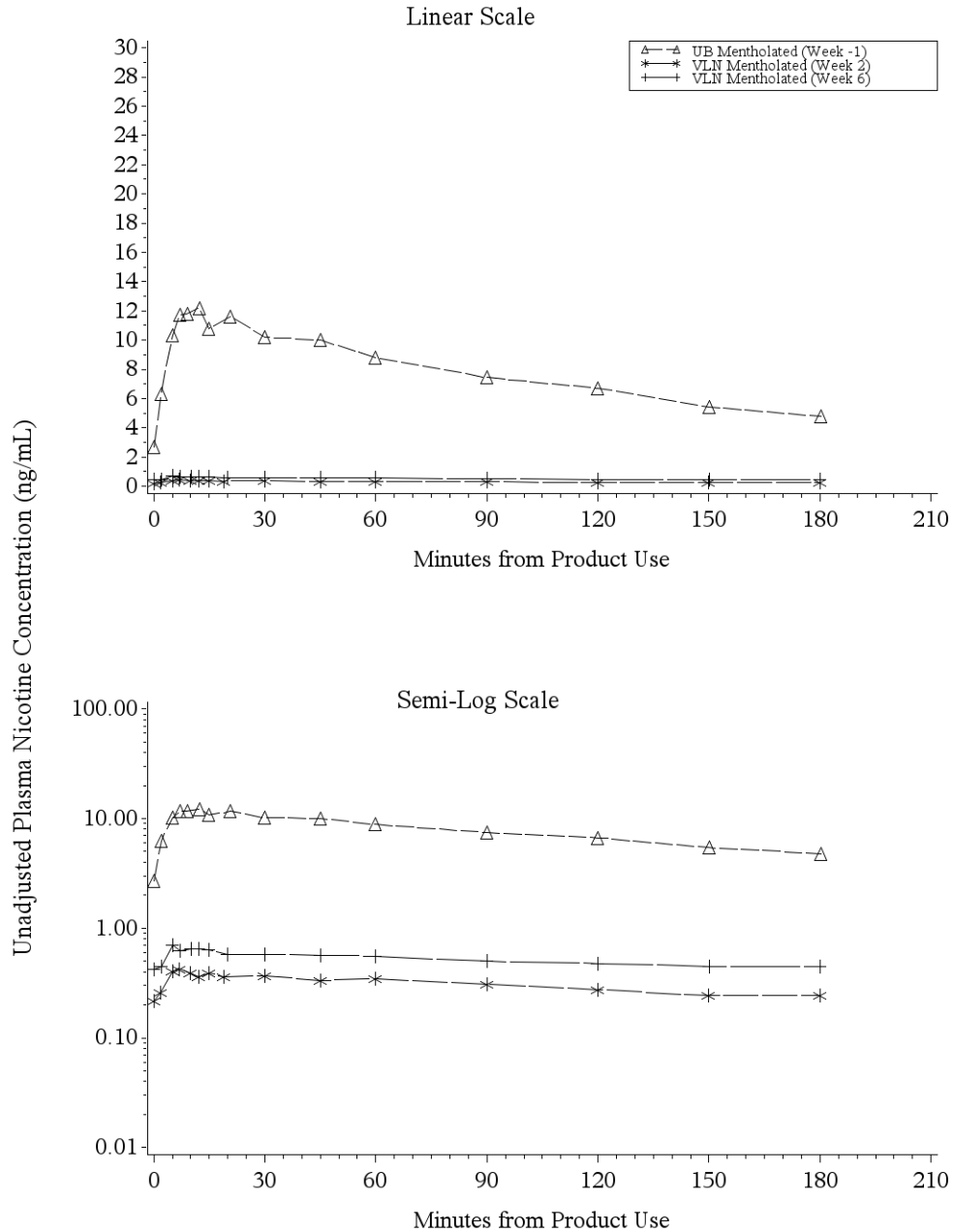
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1013



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.1

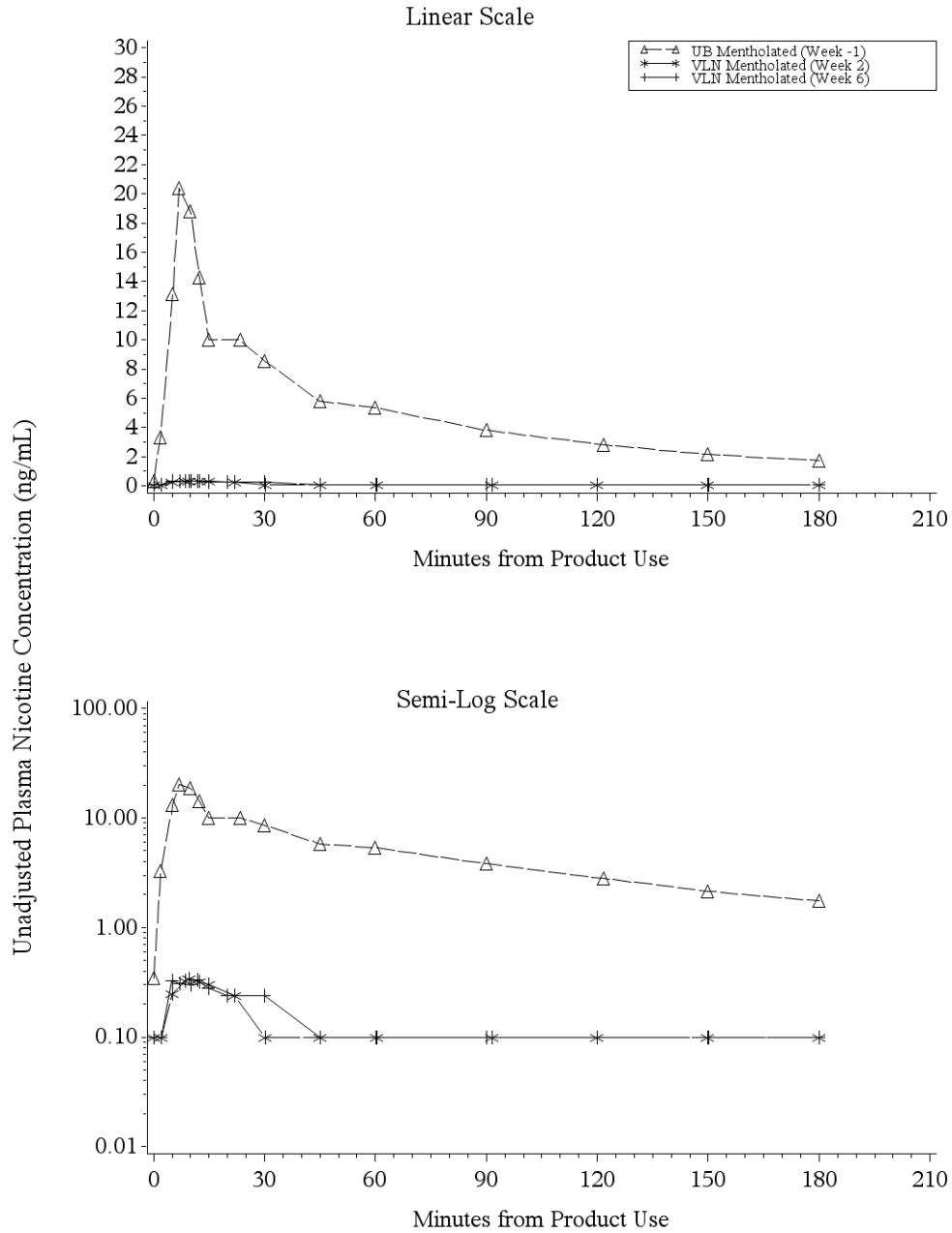
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1014



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.1

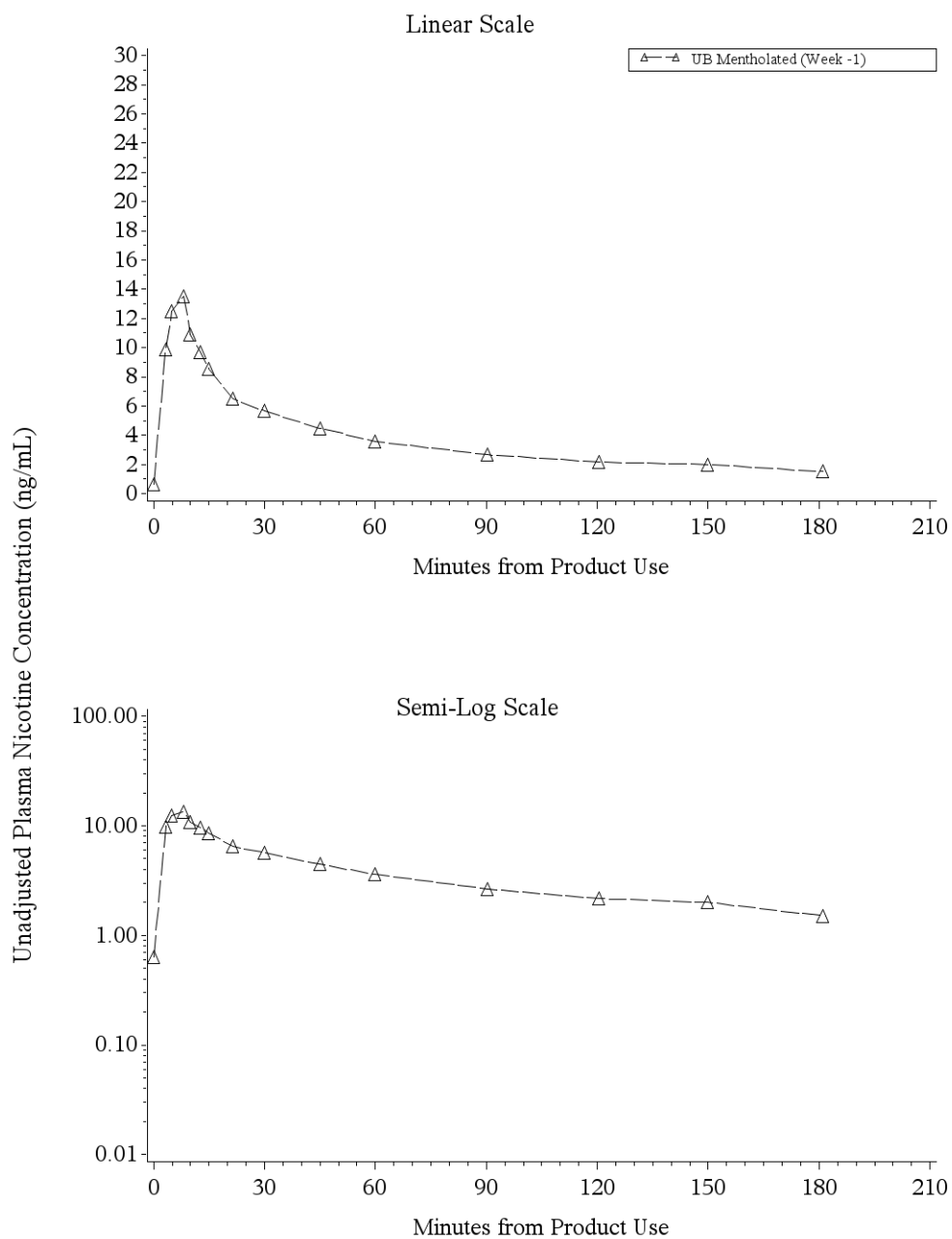
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1015



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.1

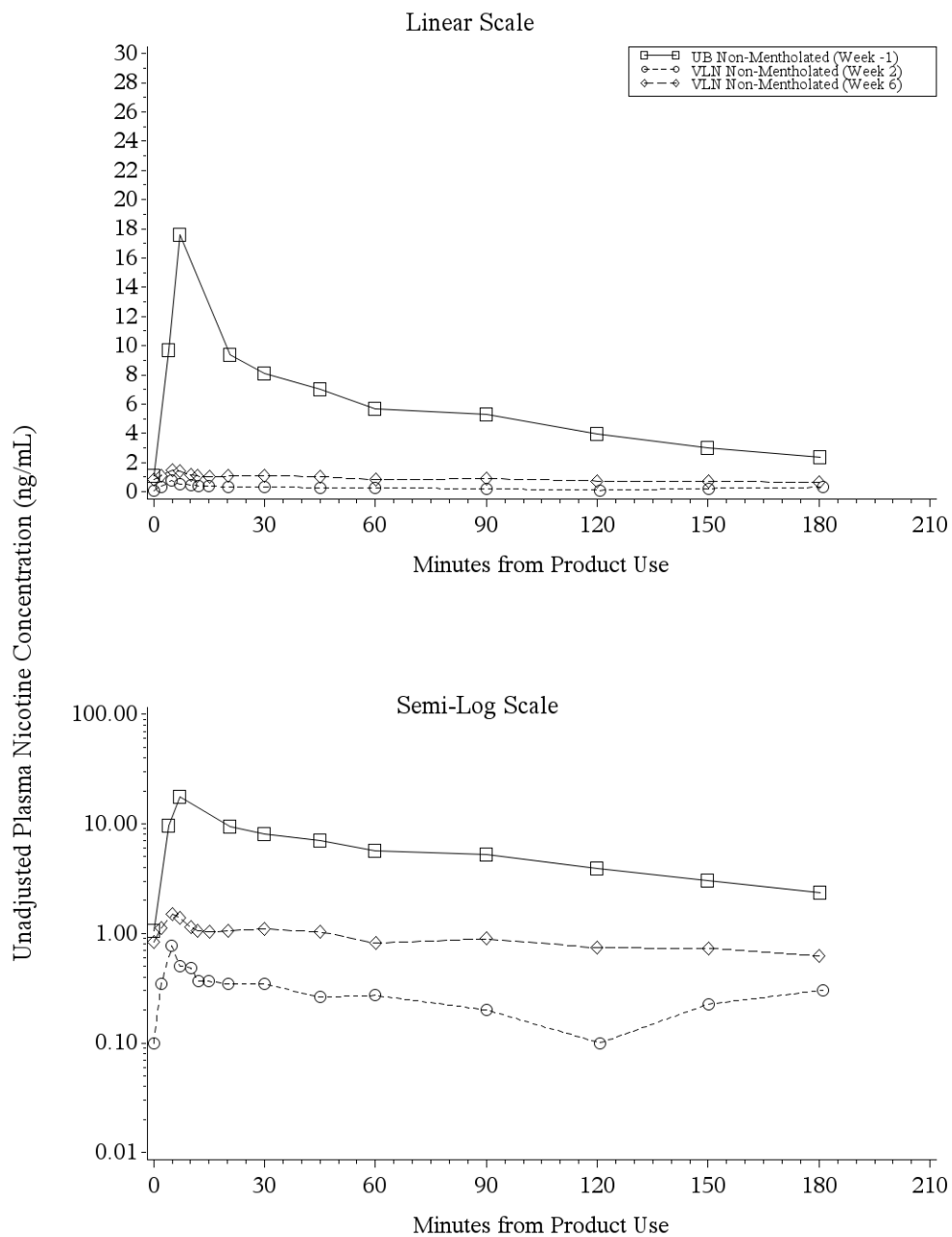
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1018



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.1

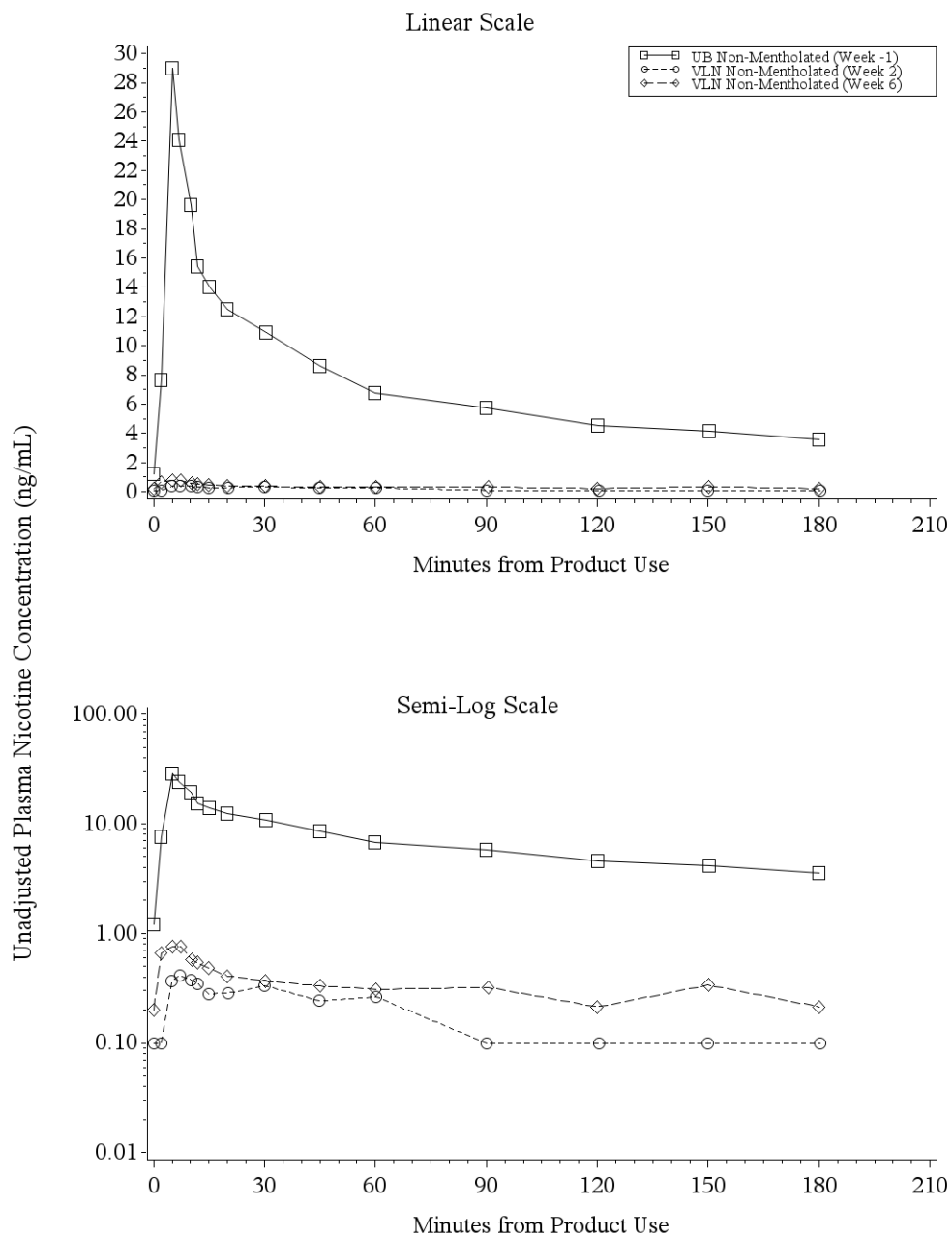
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1019



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.1

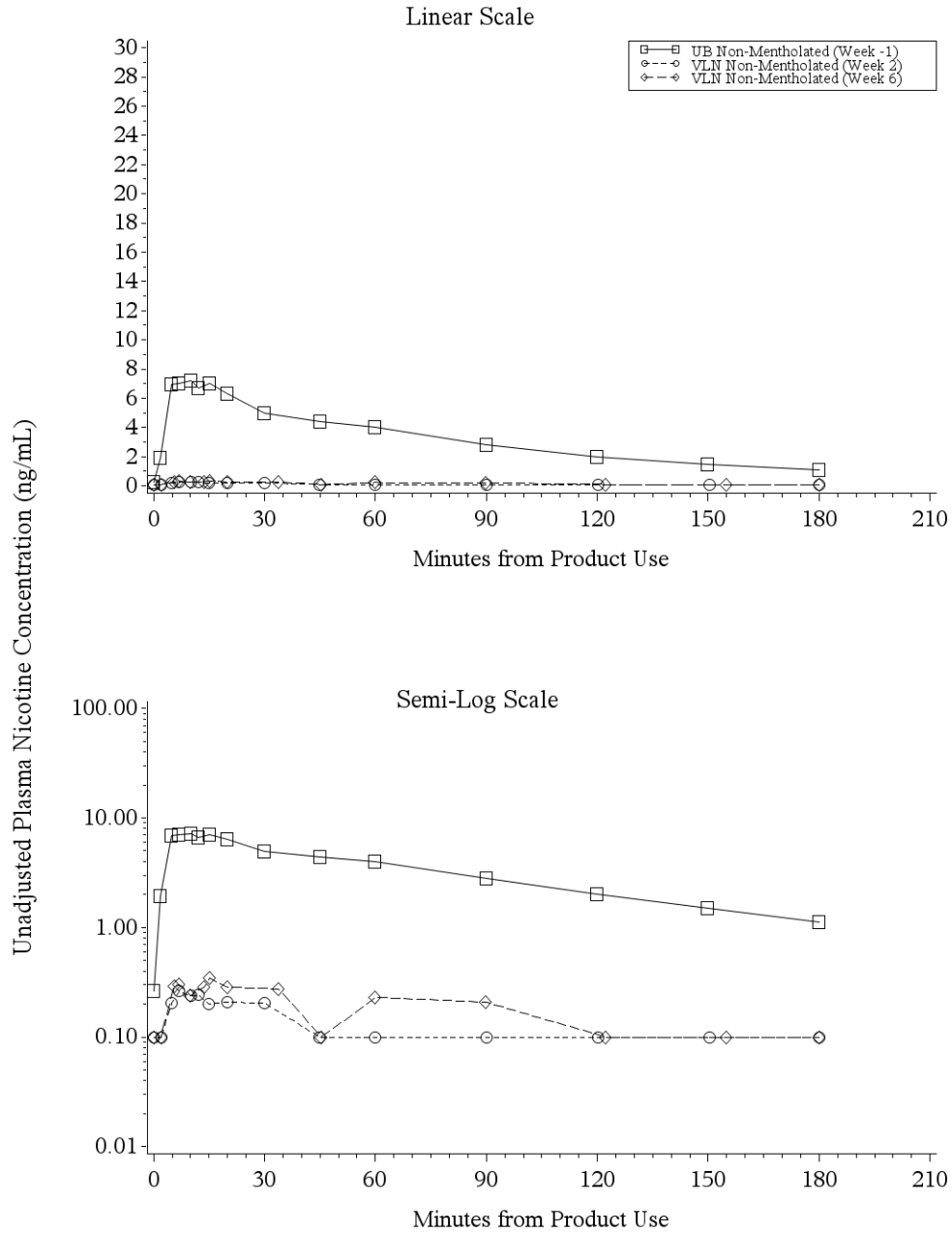
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1020



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.1

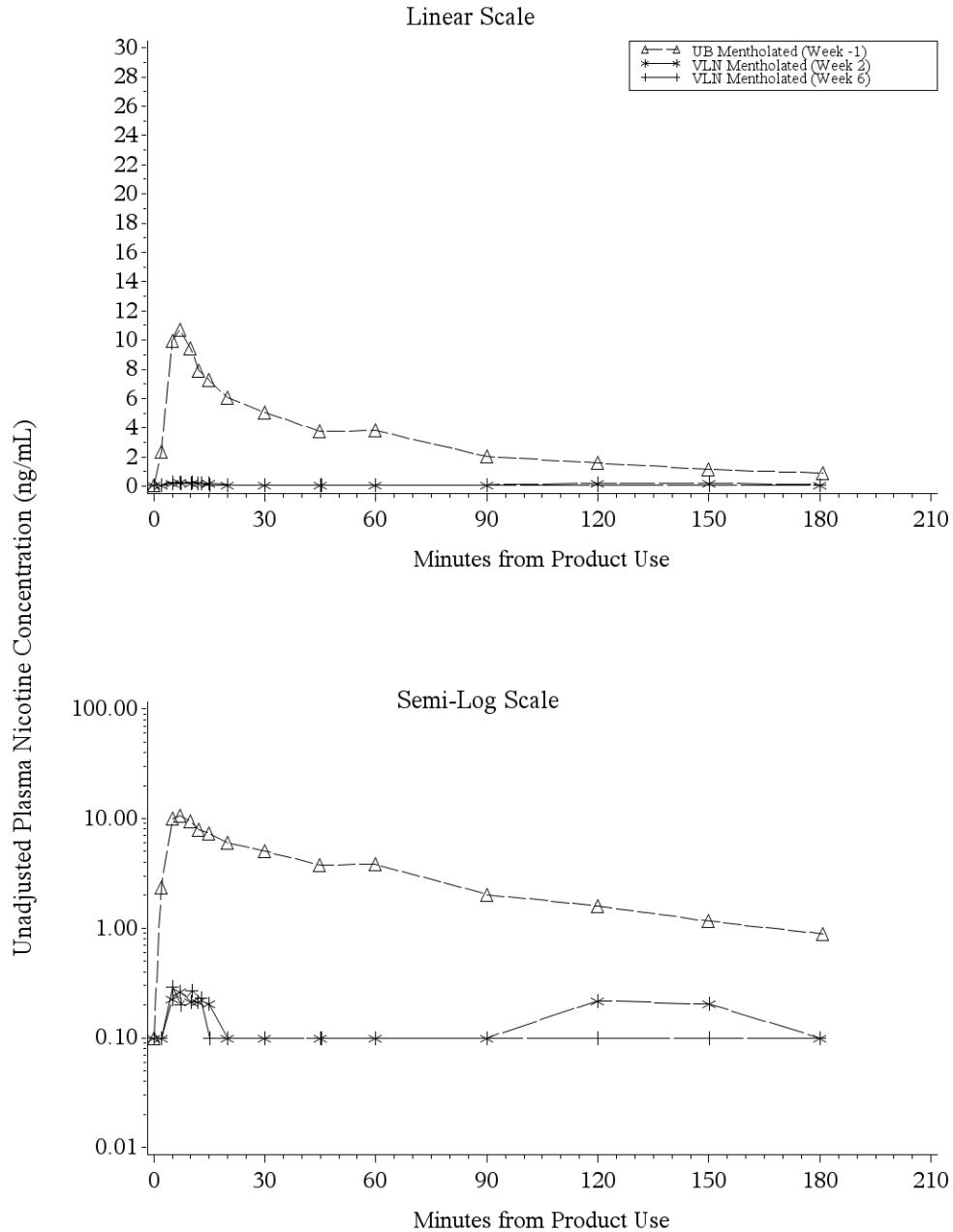
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1023



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.1

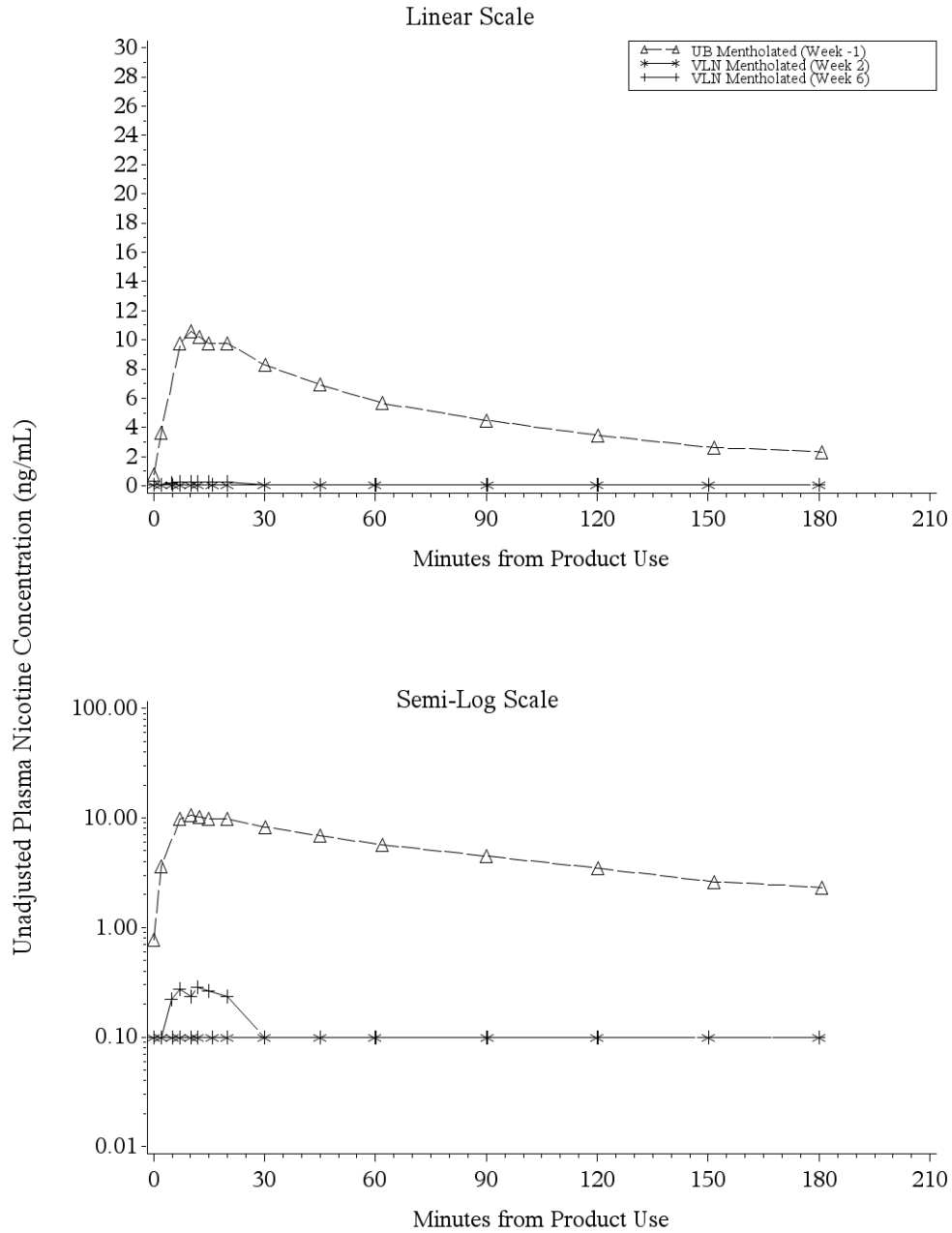
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1029



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.1

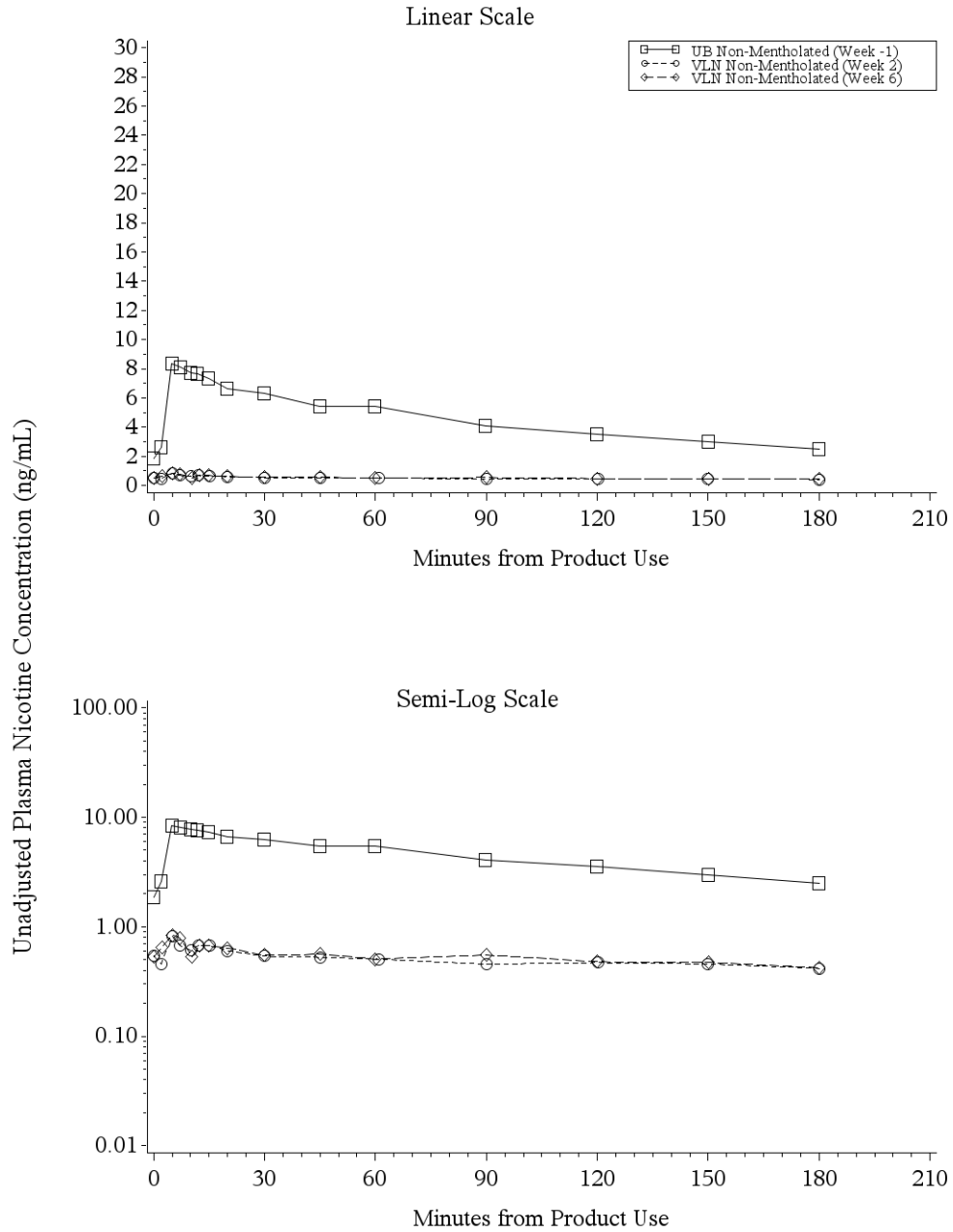
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1032



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.1

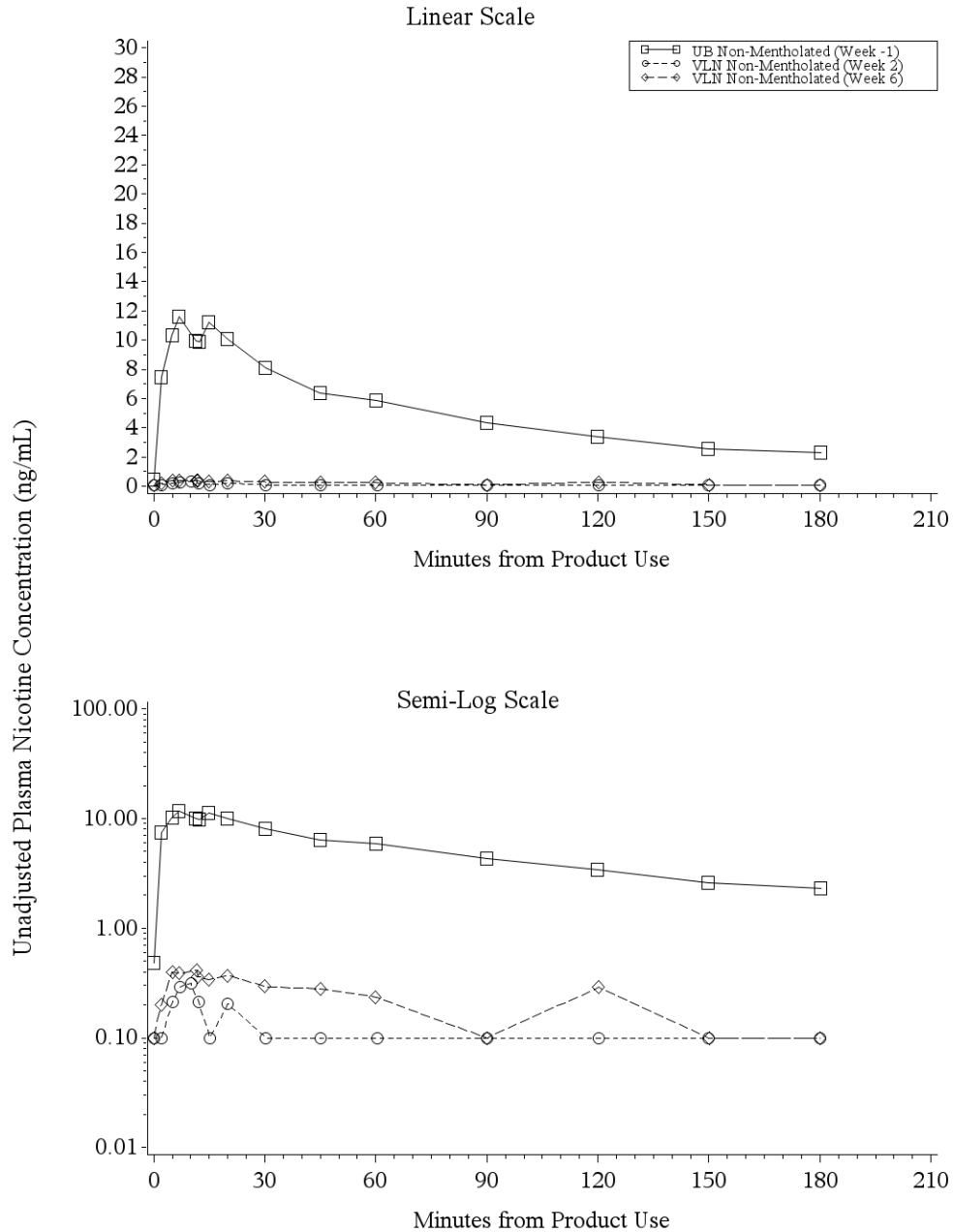
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1035



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.1

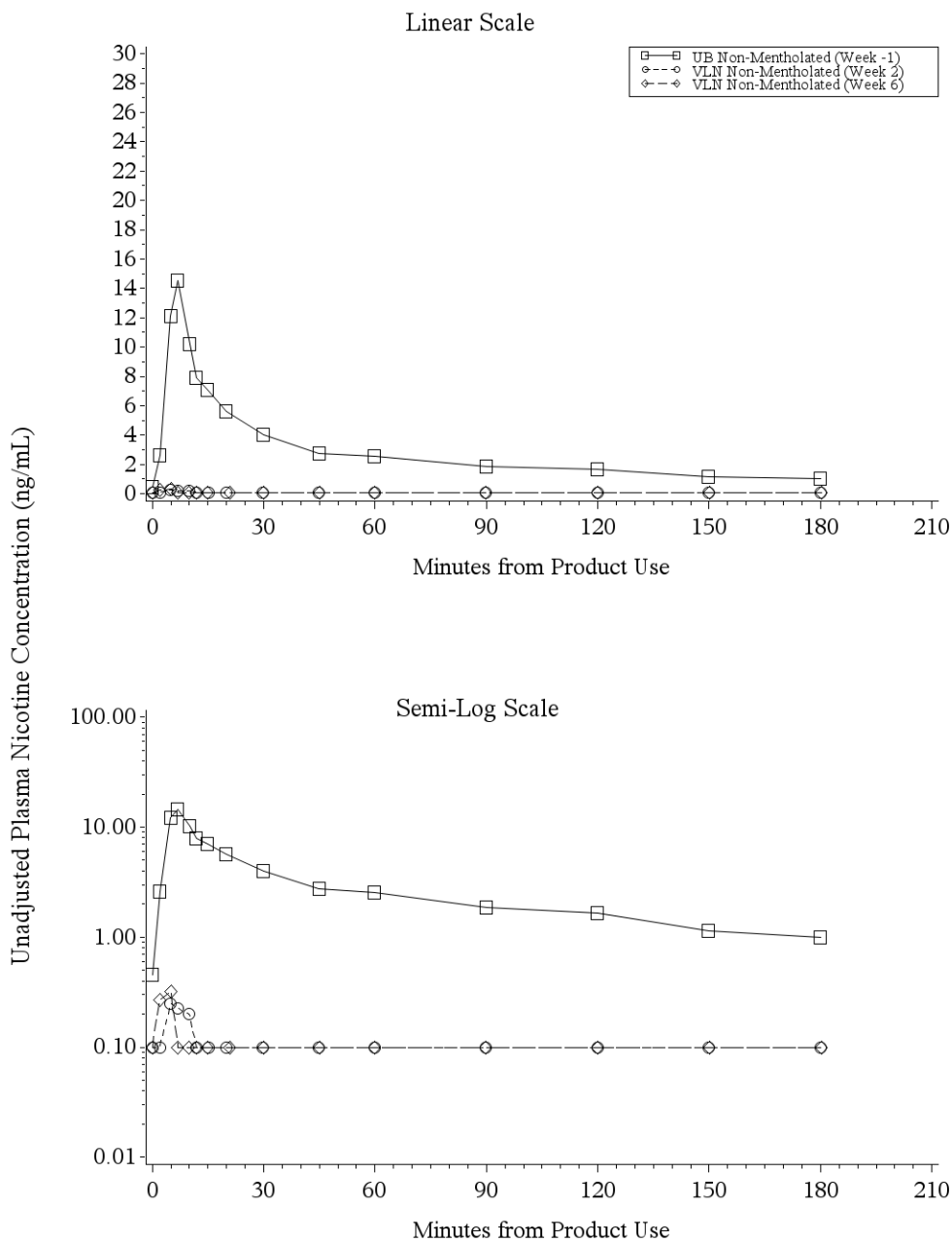
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1038



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Appendix 16.2.6.11.1

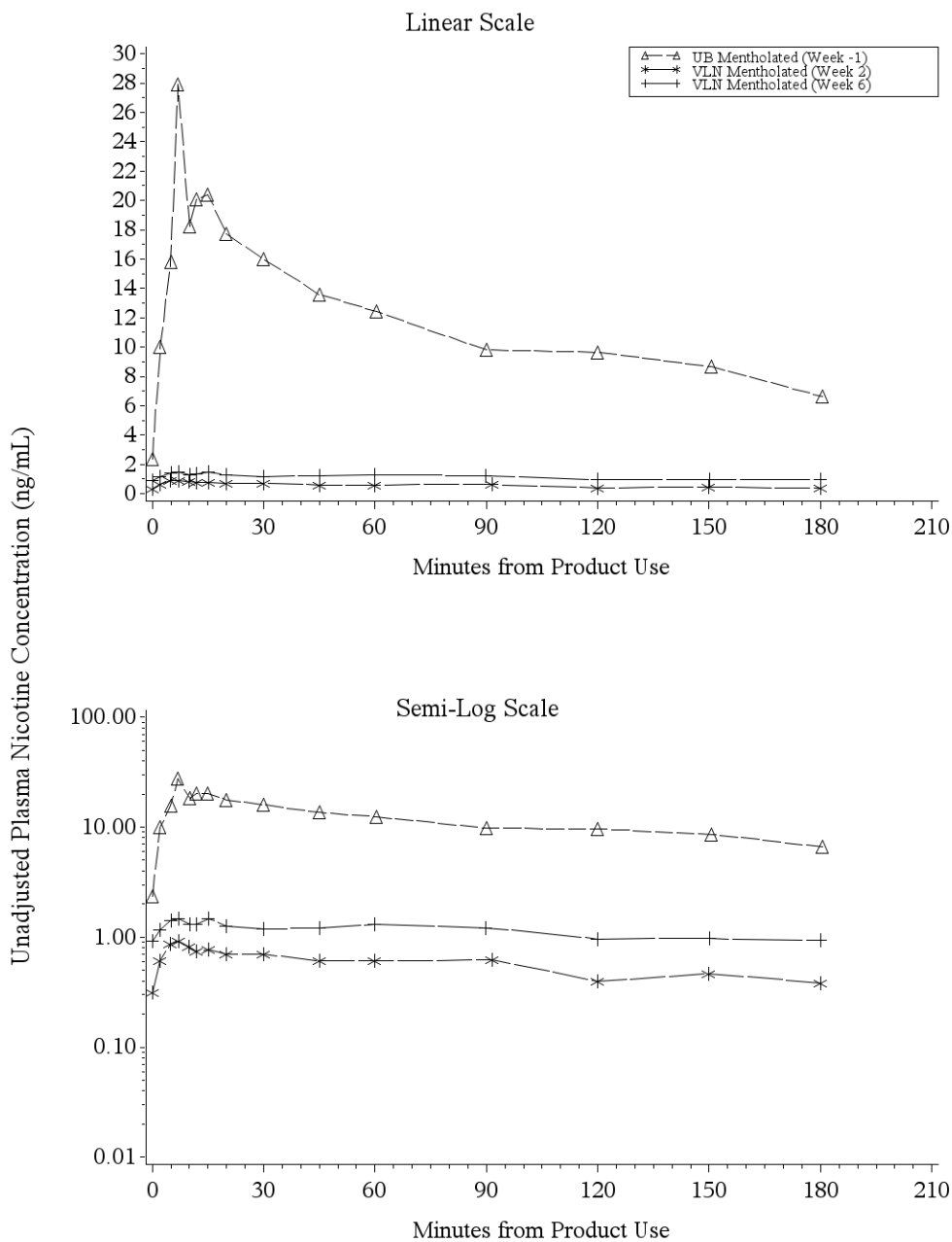
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1042



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.1

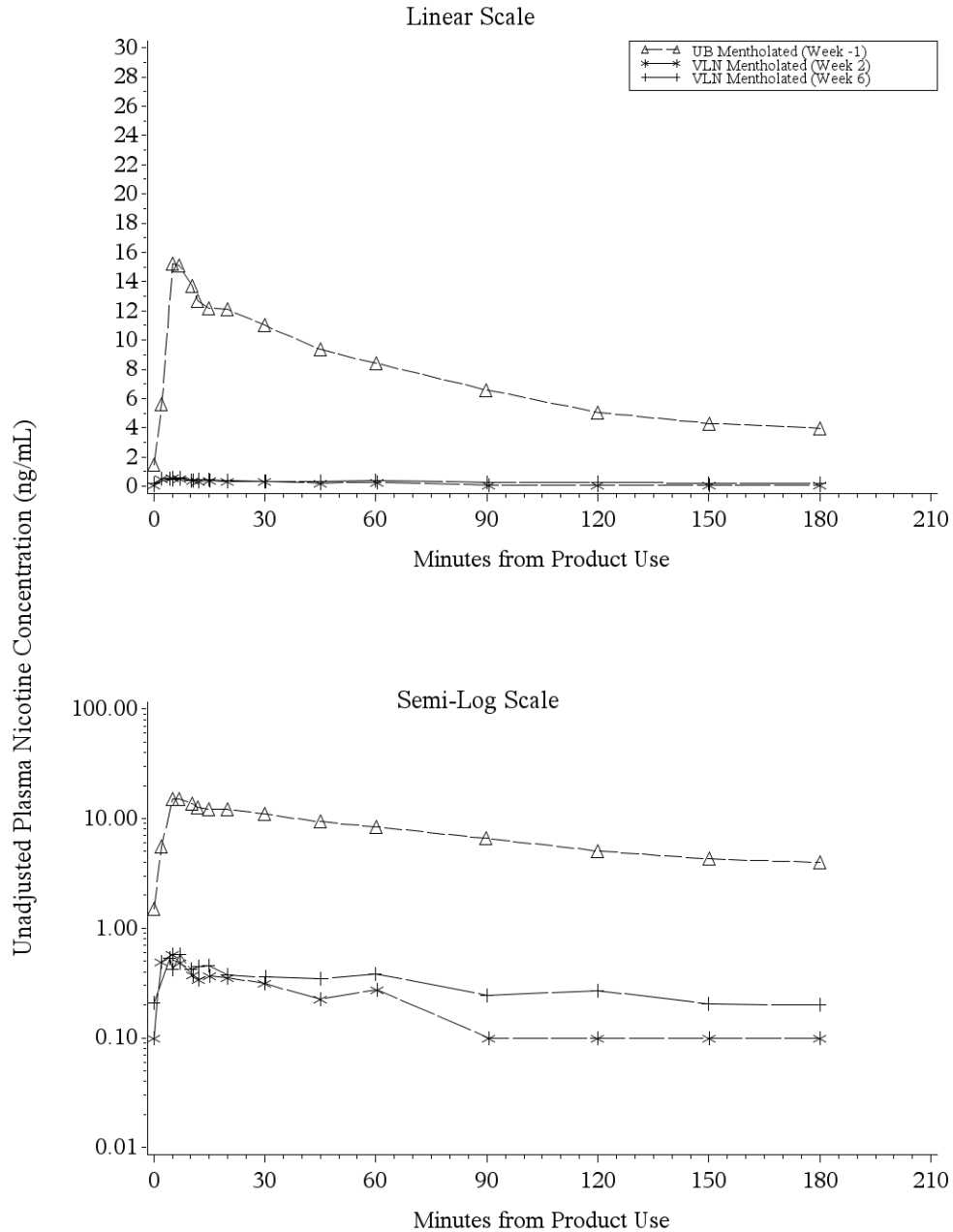
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1052



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.1

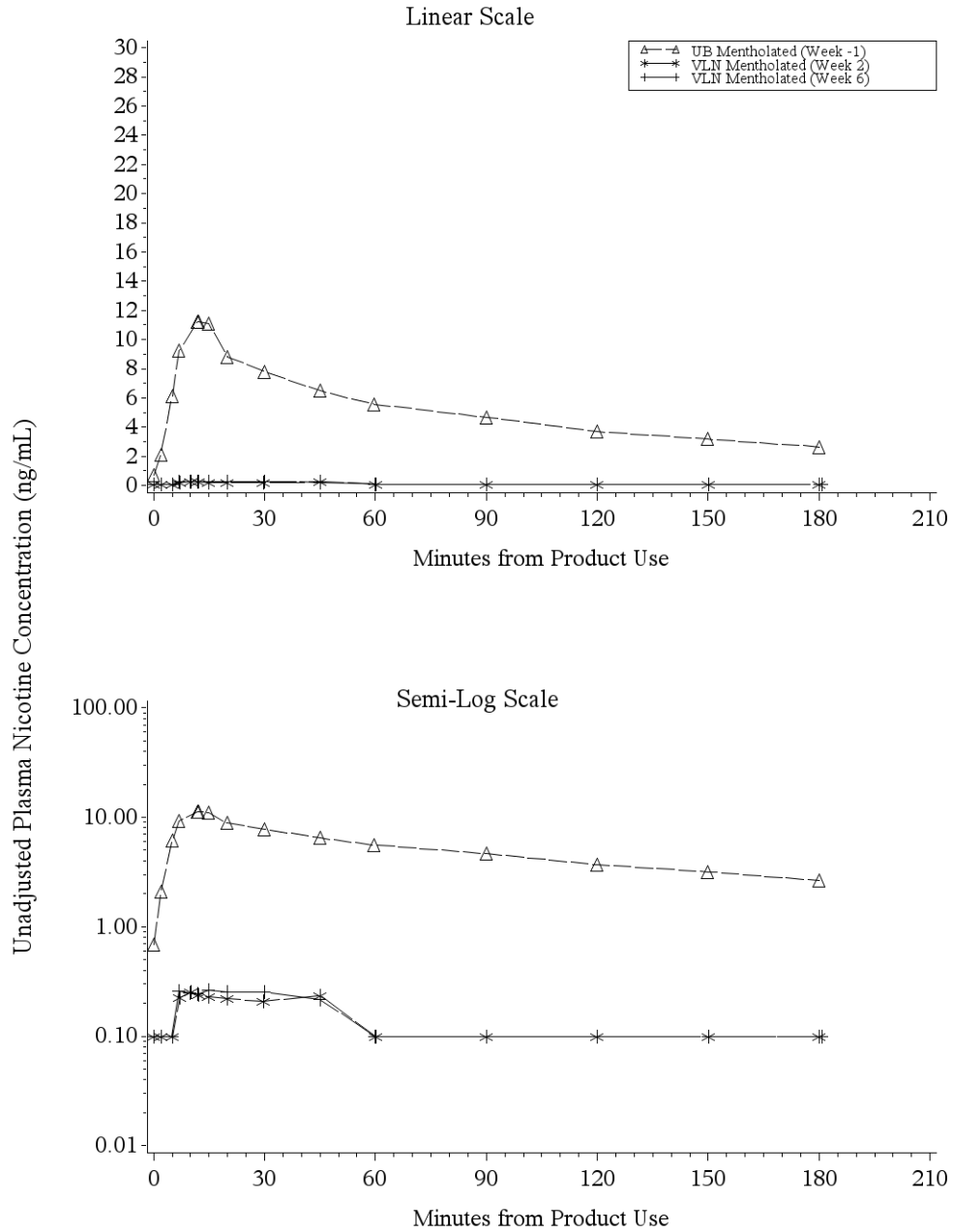
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1053



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Appendix 16.2.6.11.1

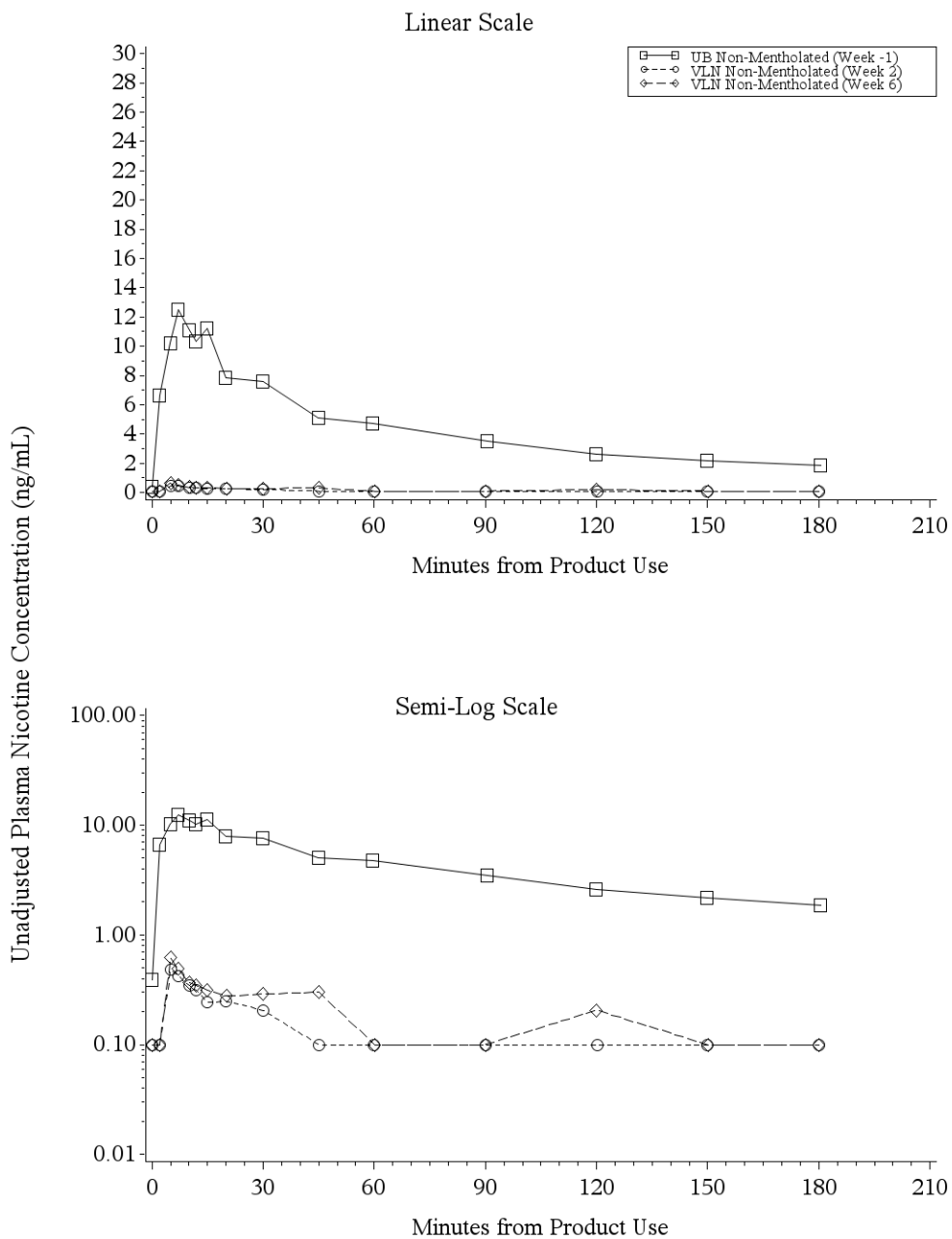
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1055



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.1

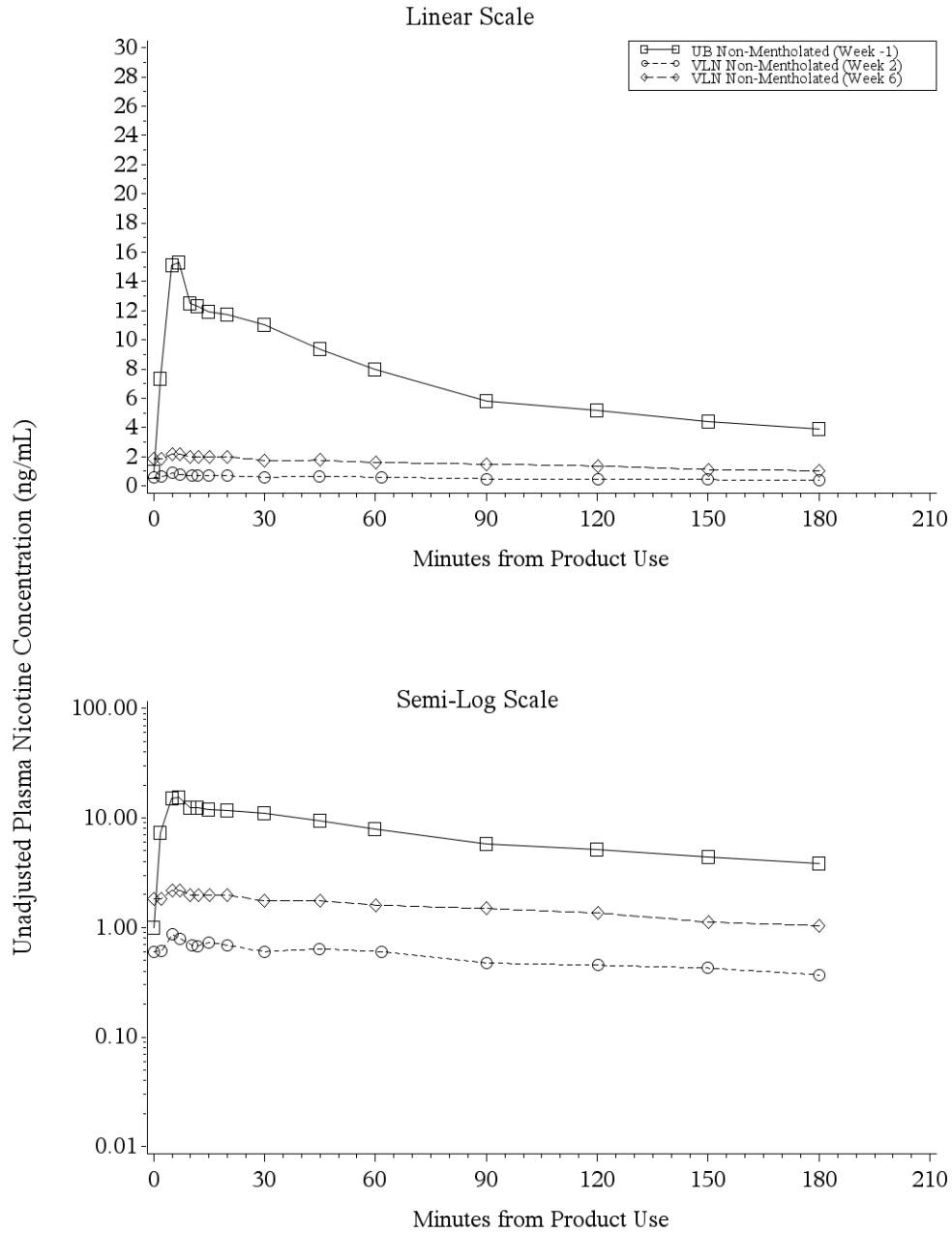
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1056



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.1

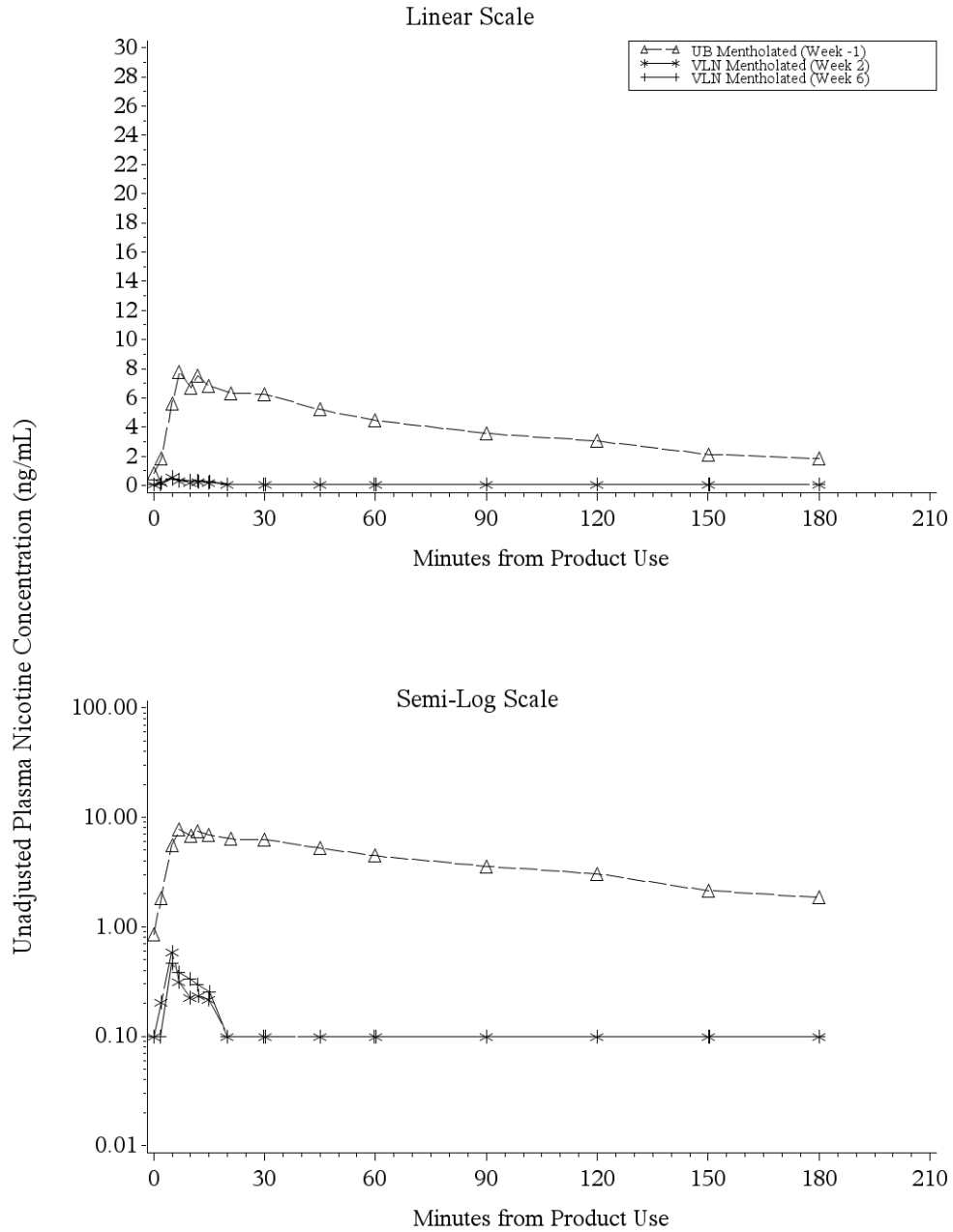
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1058



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.1

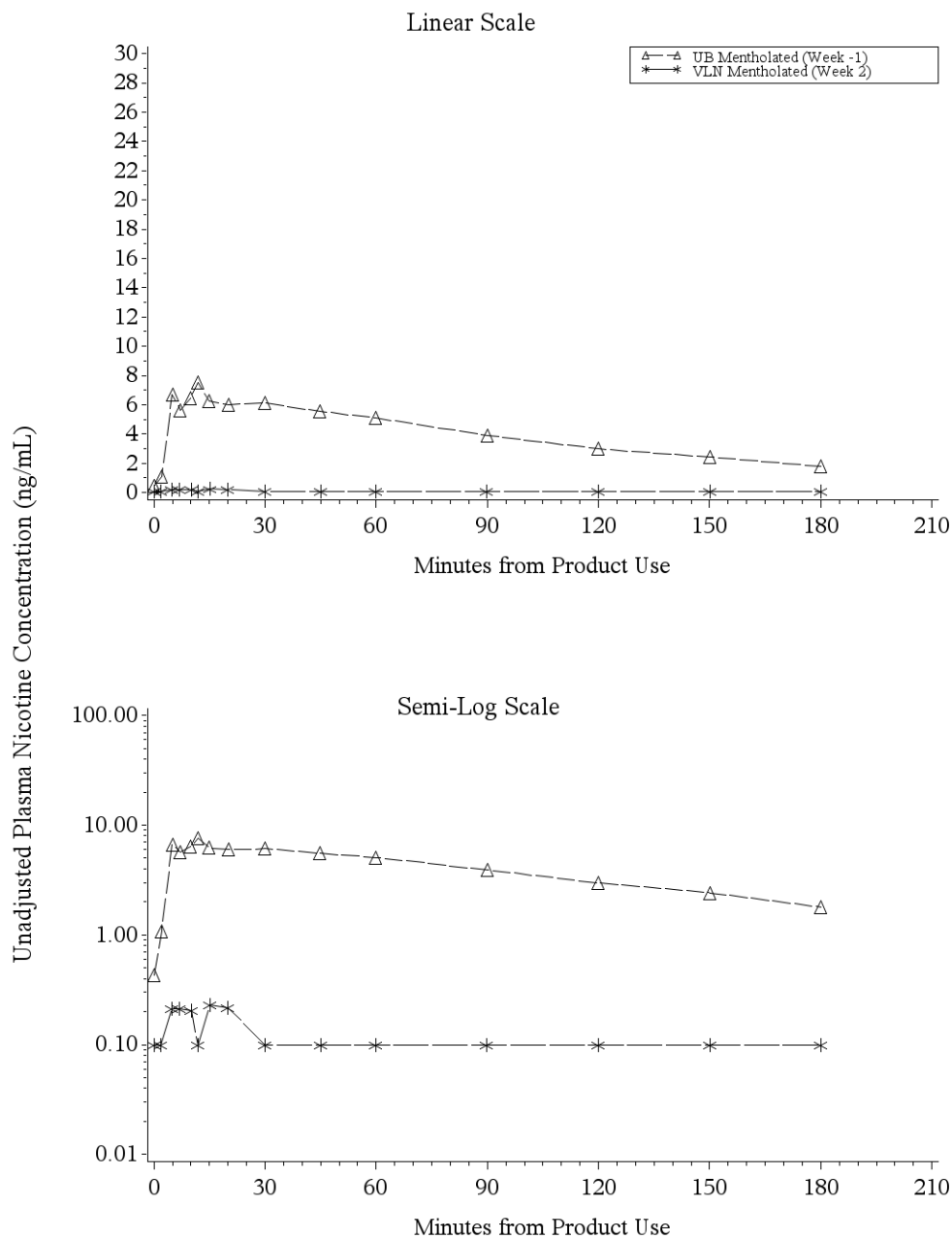
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1063



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Appendix 16.2.6.11.1

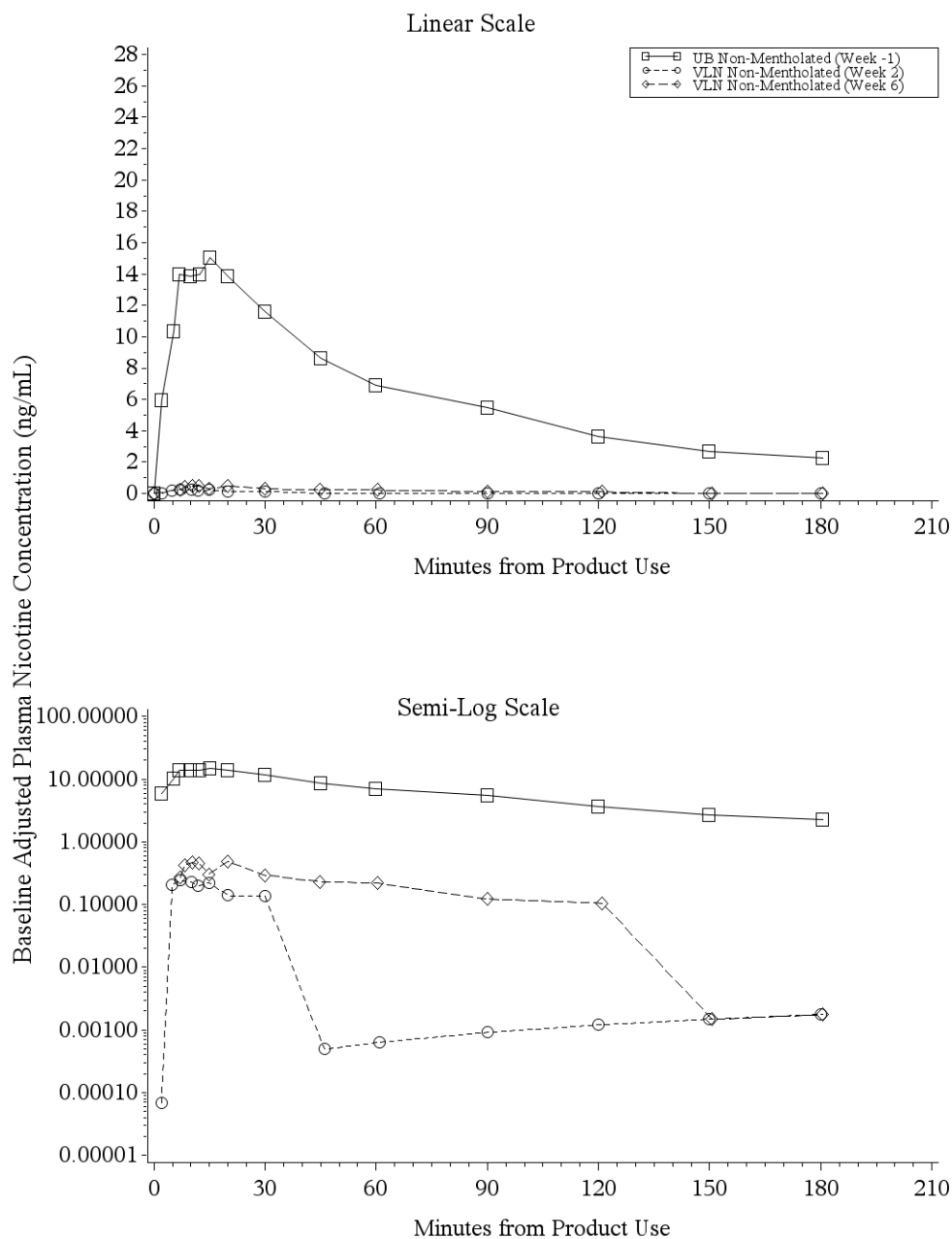
Unadjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1072



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

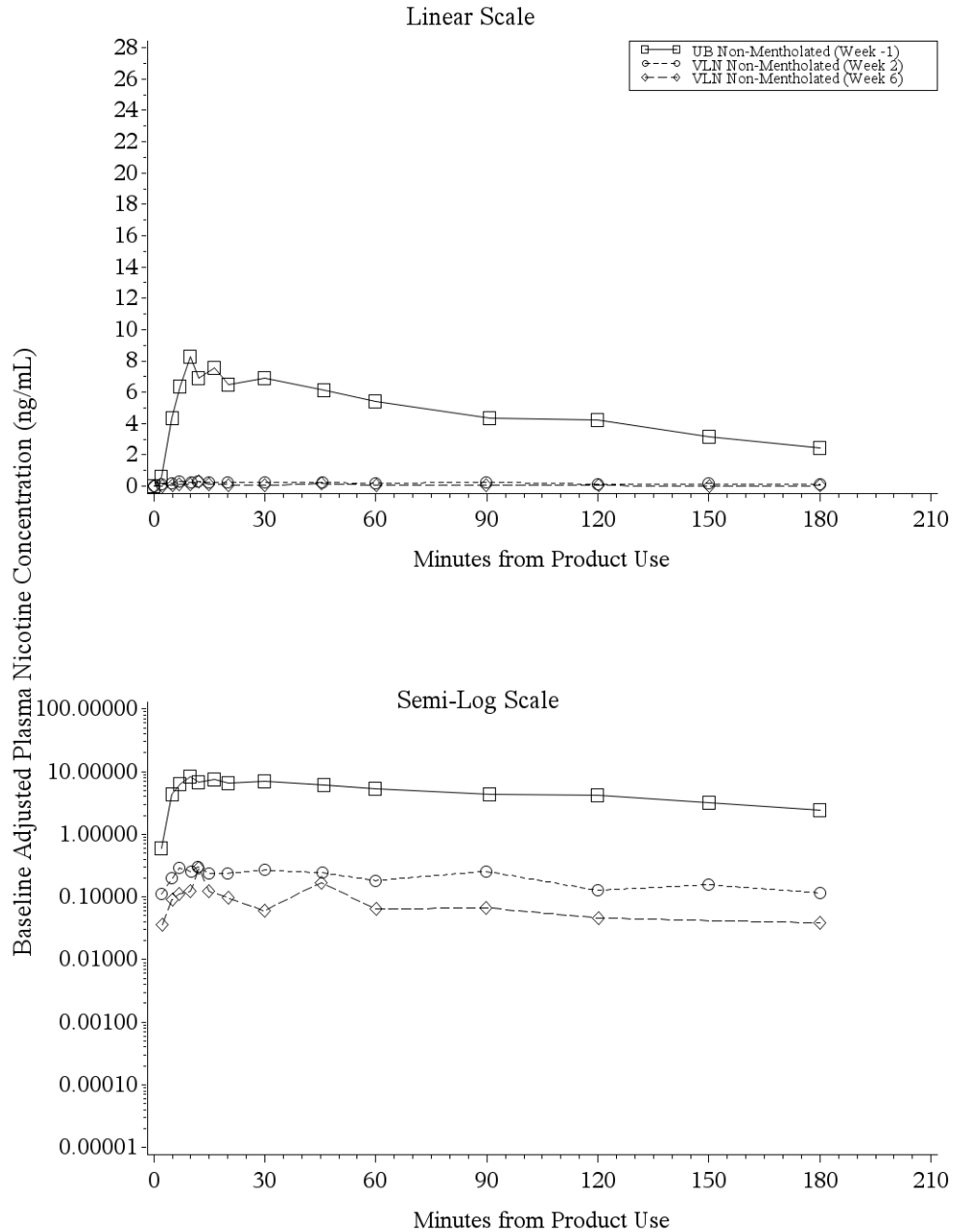
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1001



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

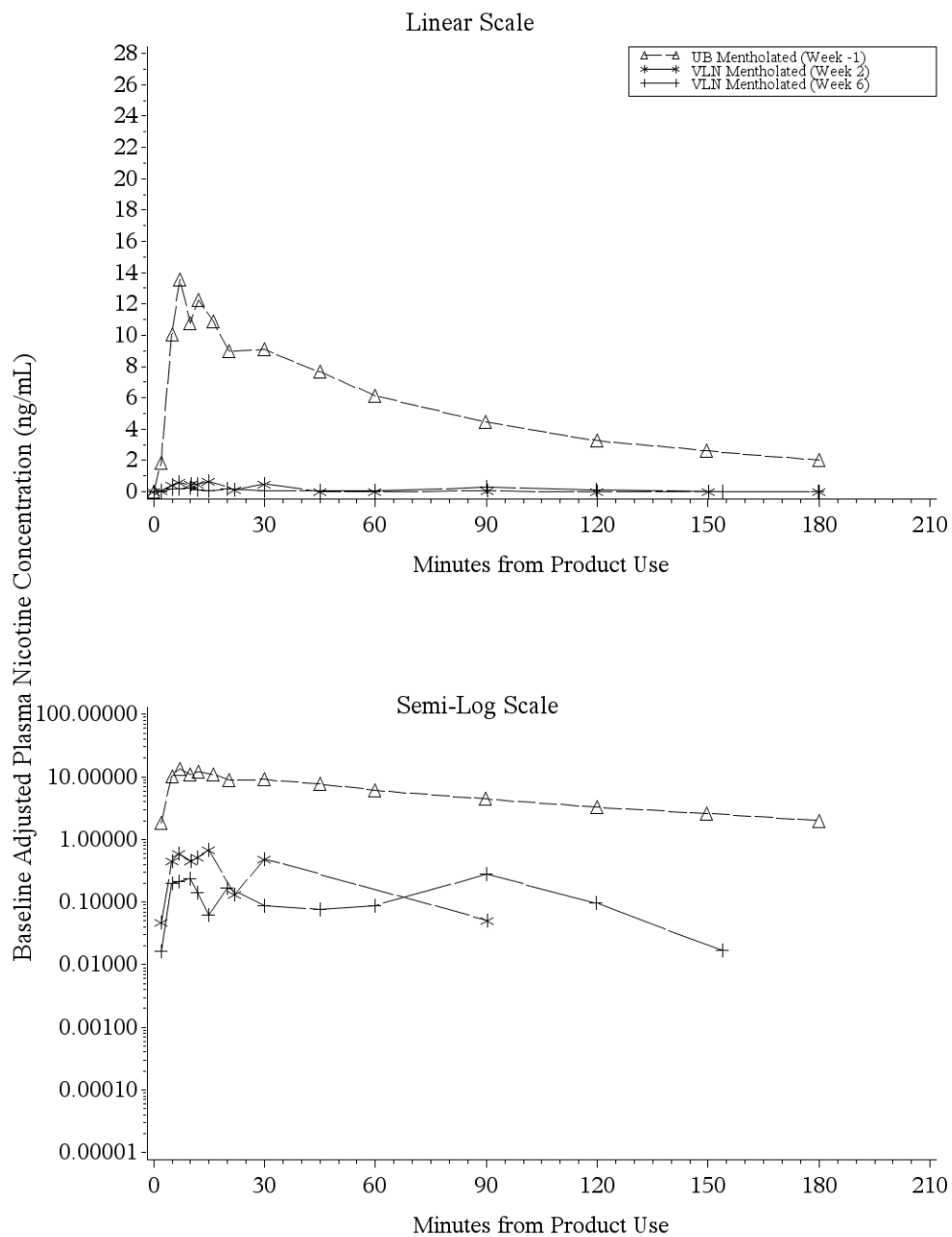
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1002



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

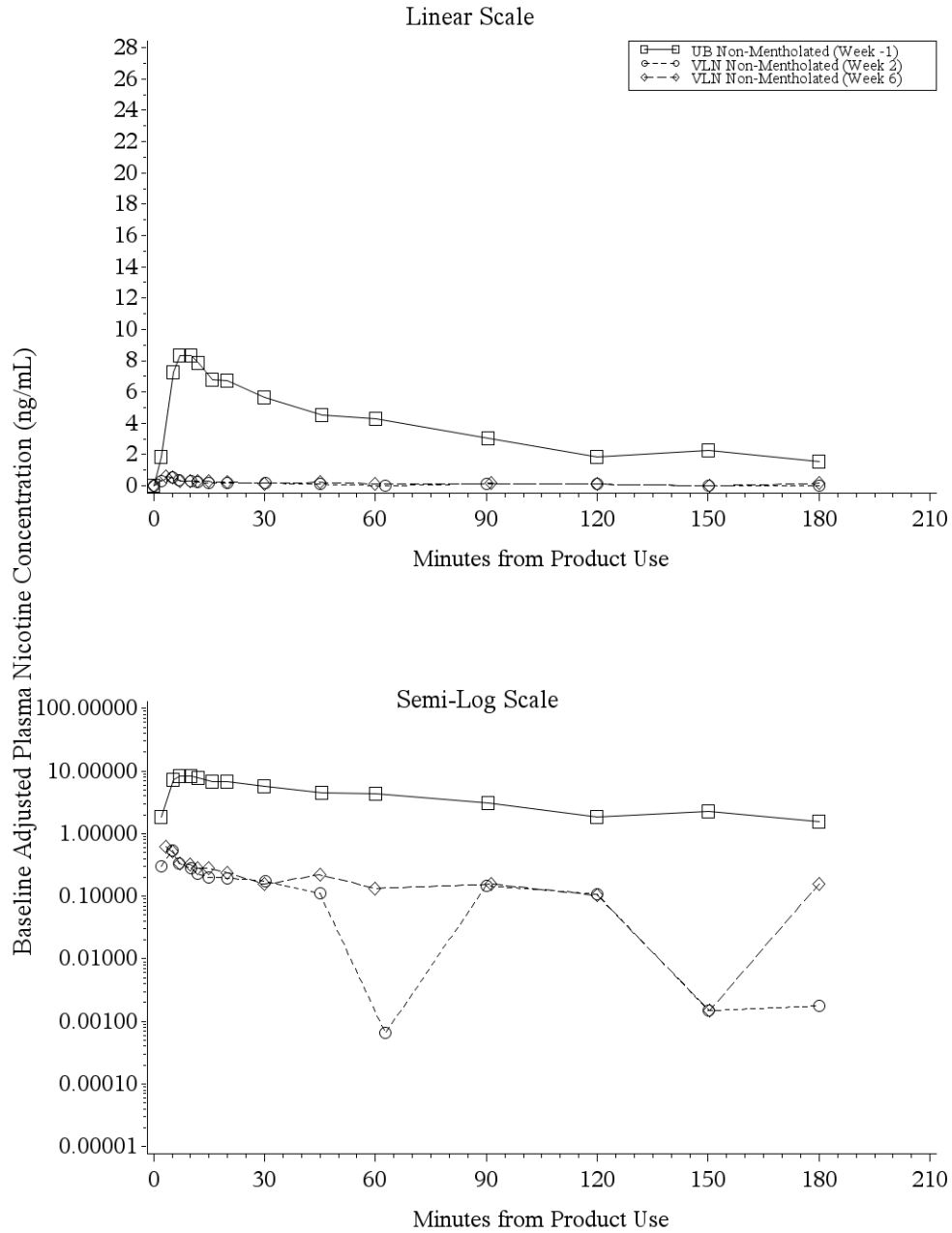
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1003



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

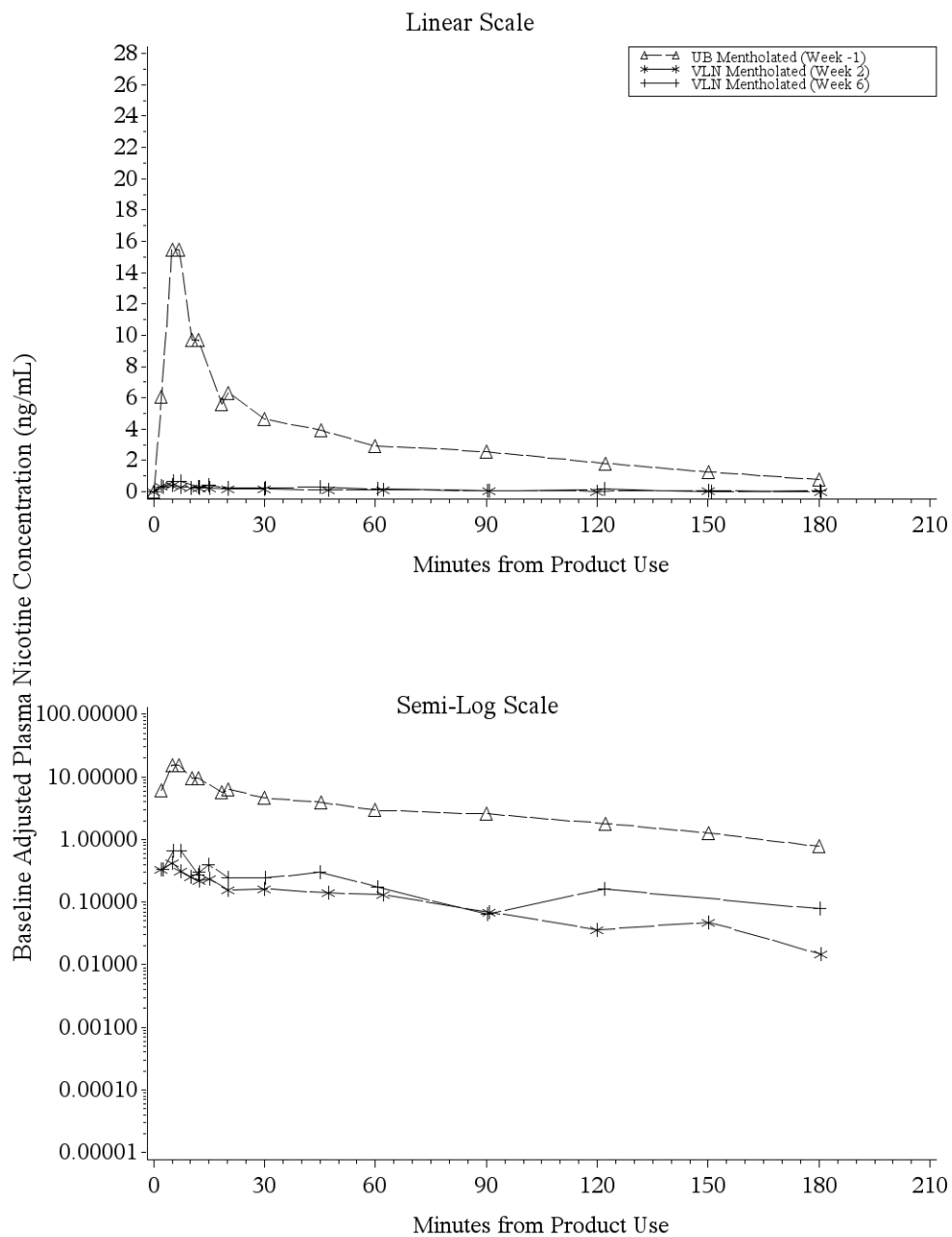
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1007



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

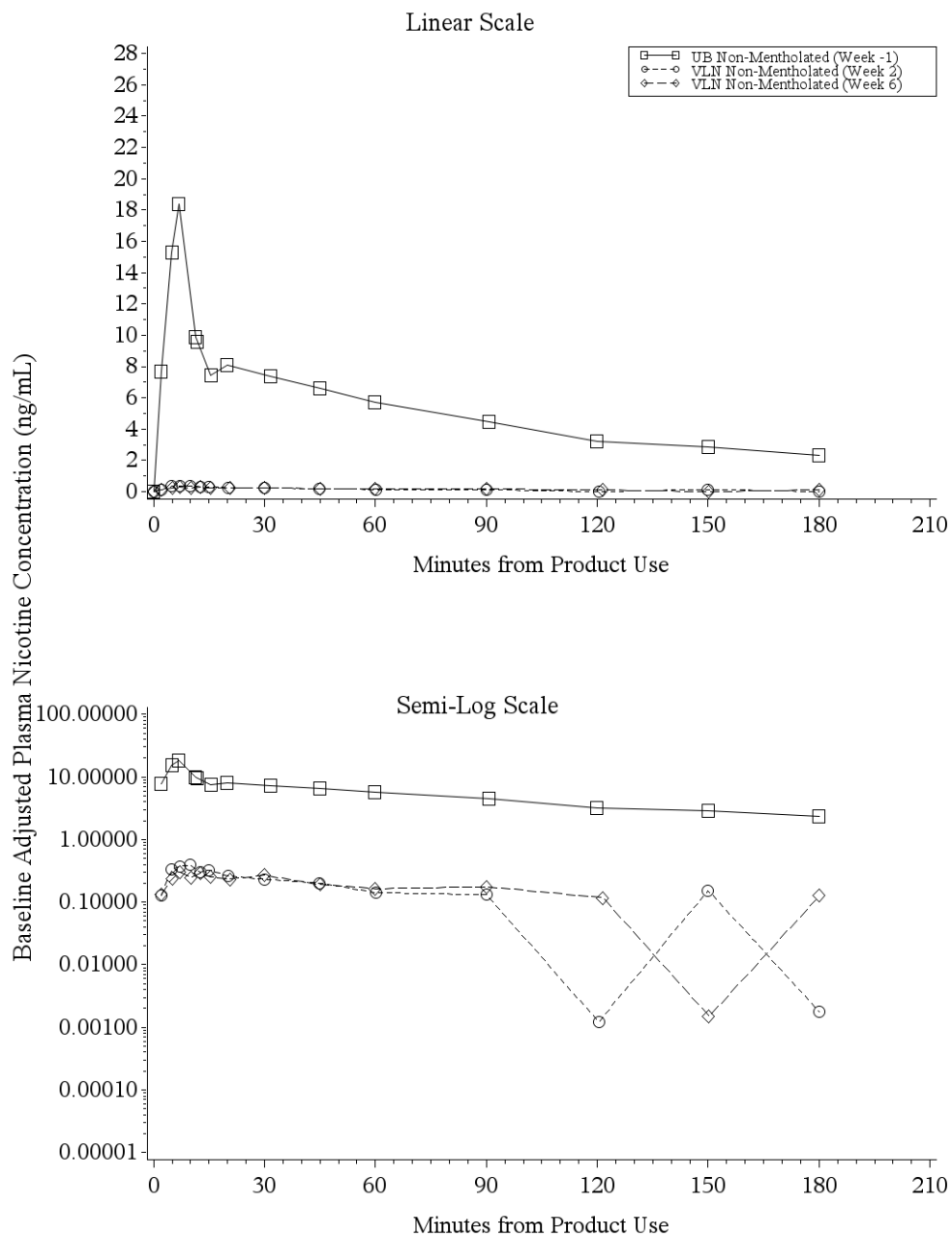
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1008



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

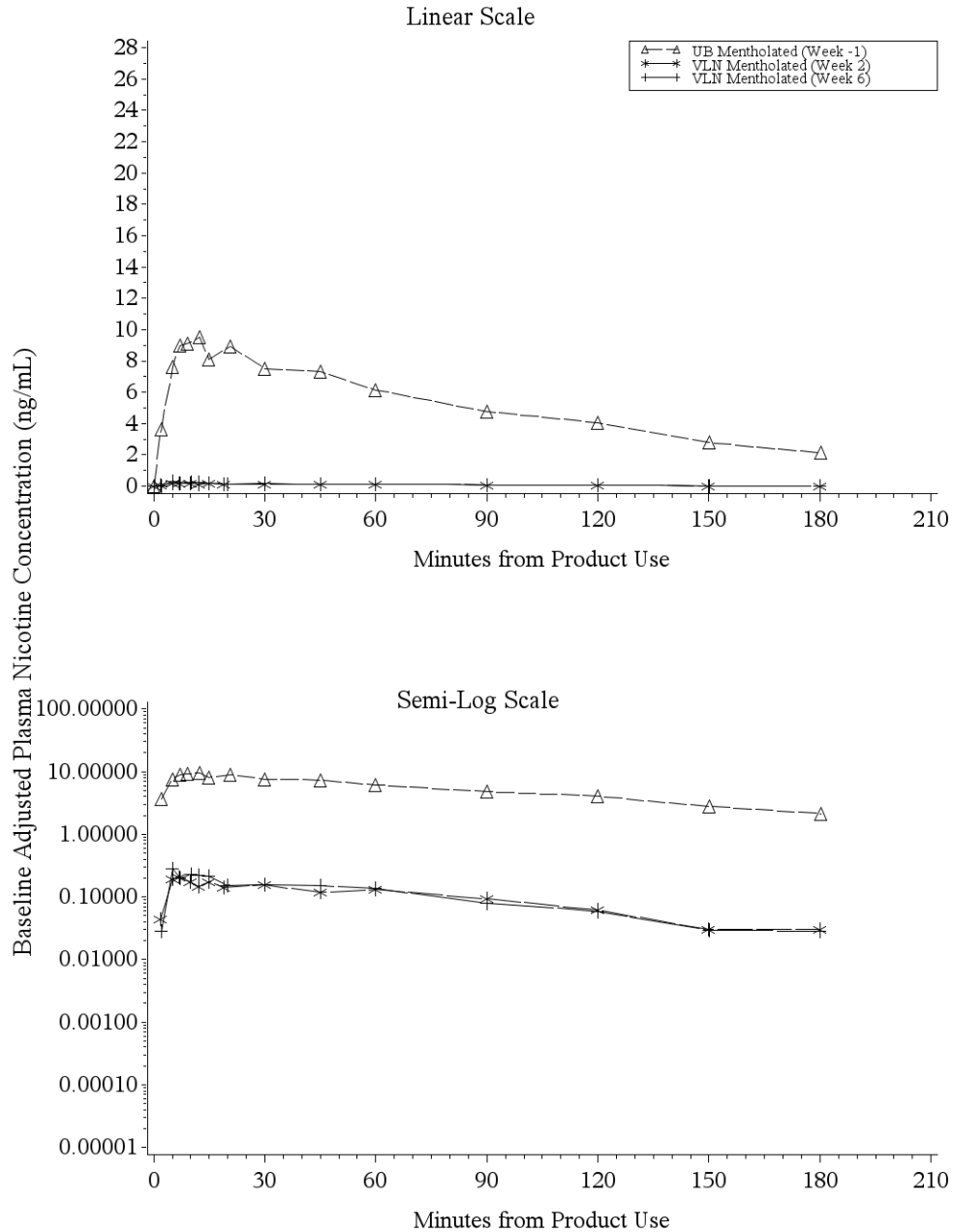
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1013



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

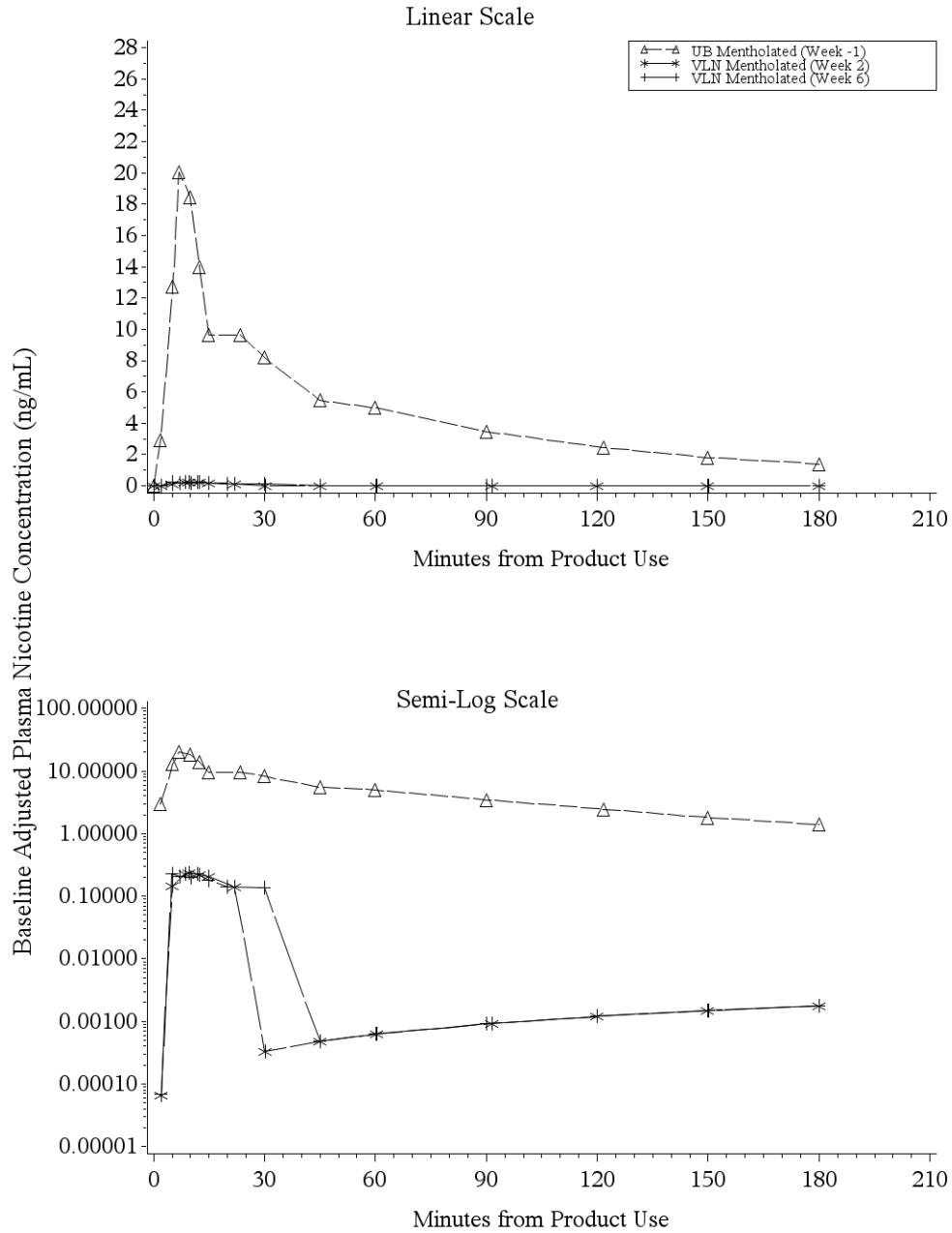
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1014



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

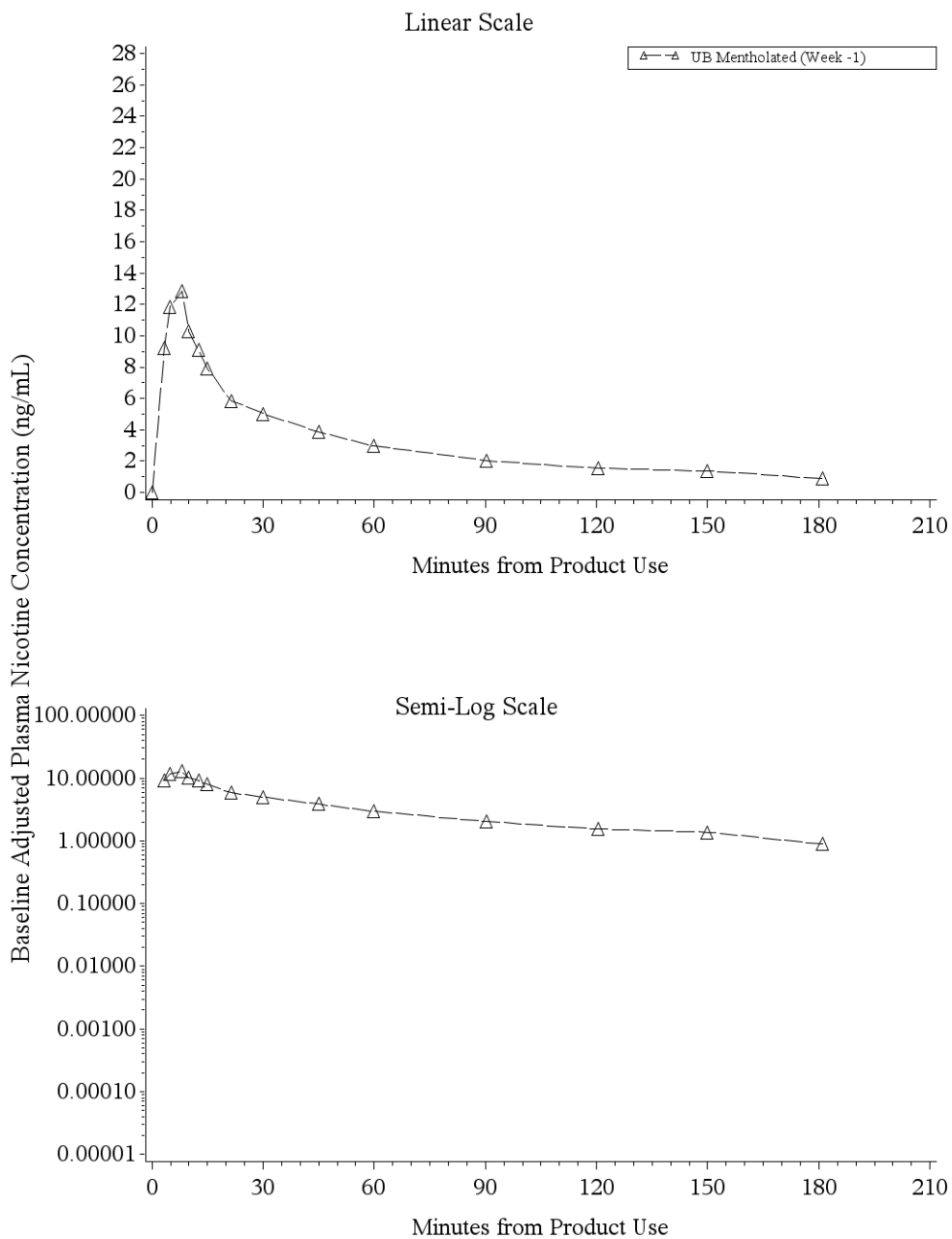
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1015



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

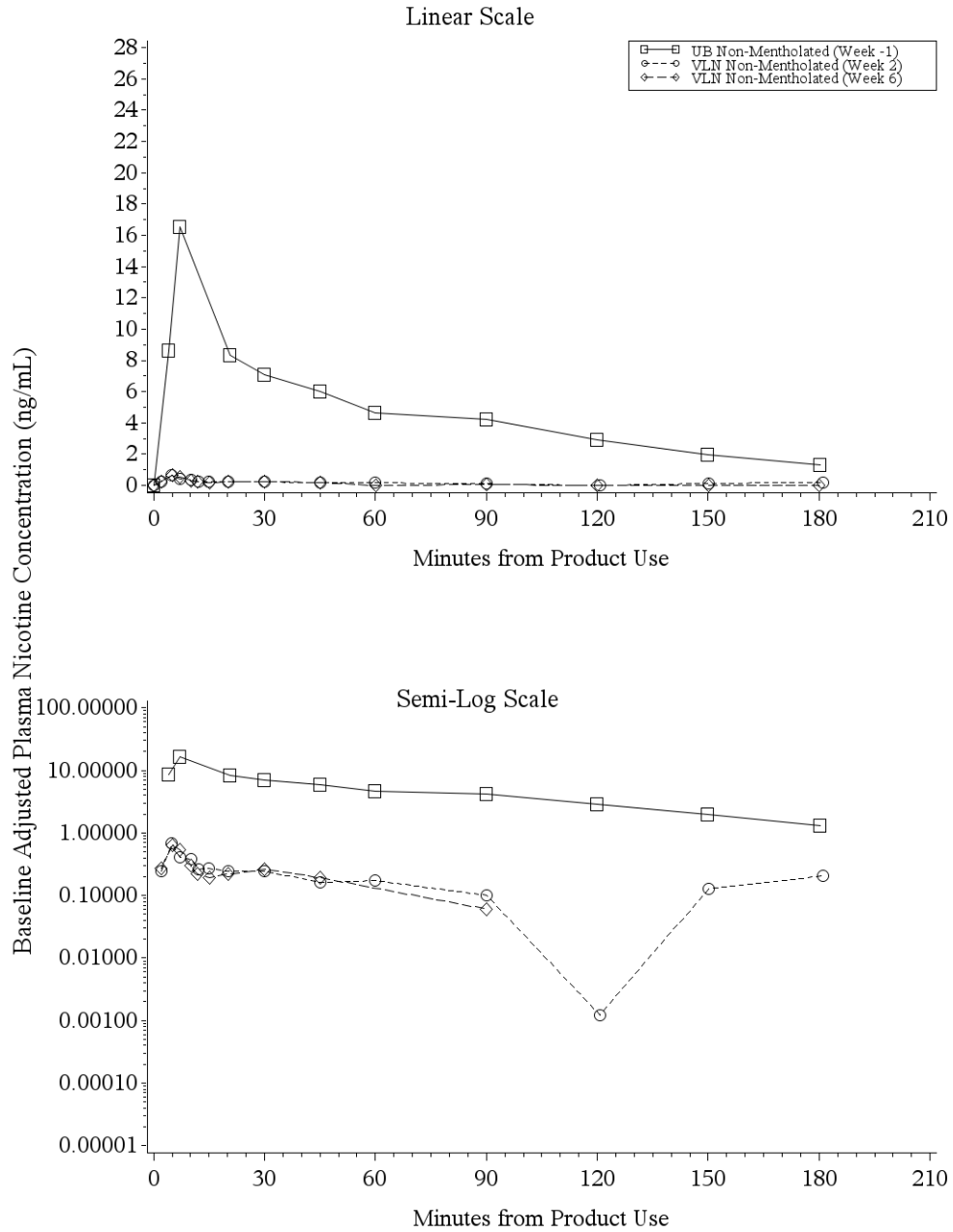
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1018



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

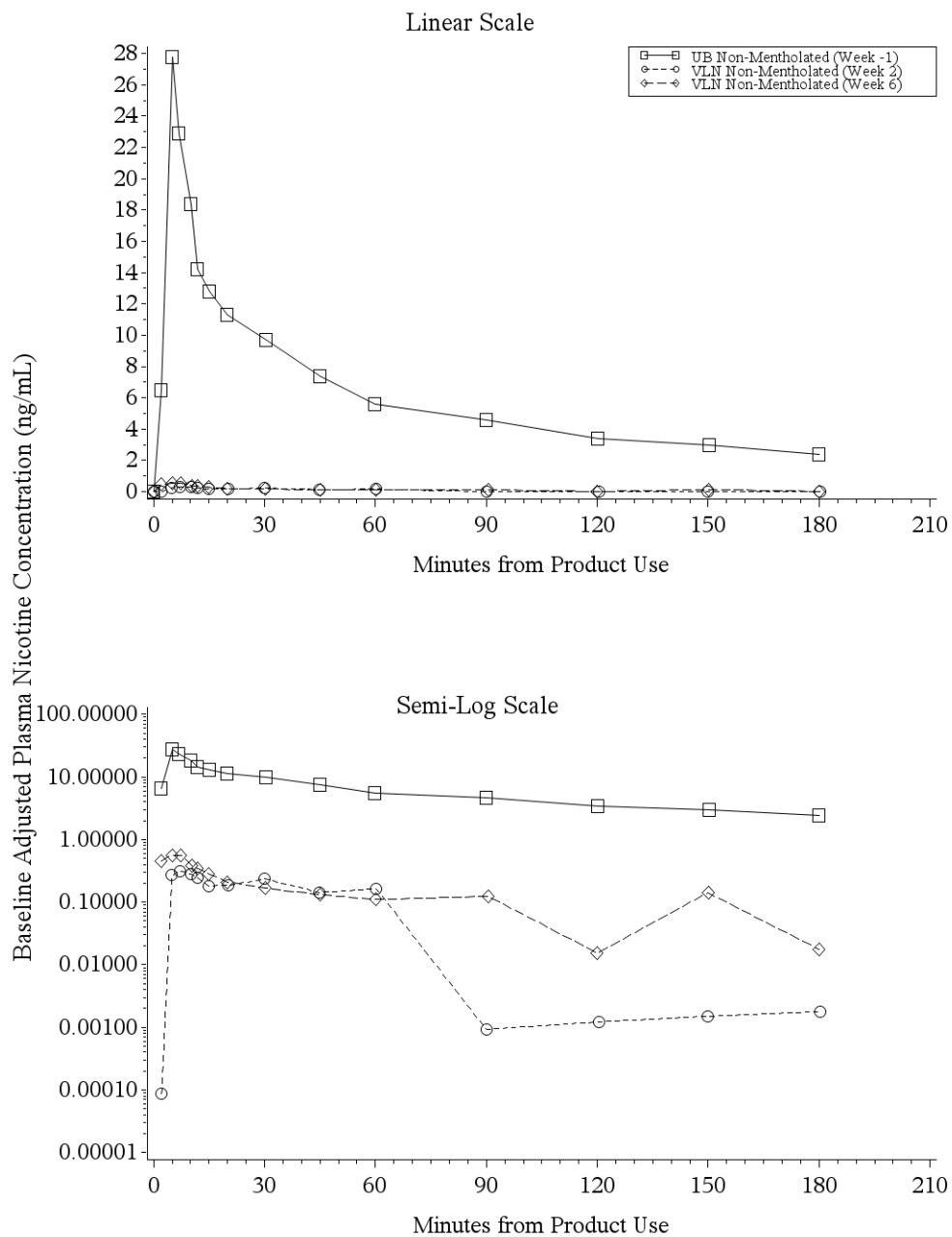
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1019



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

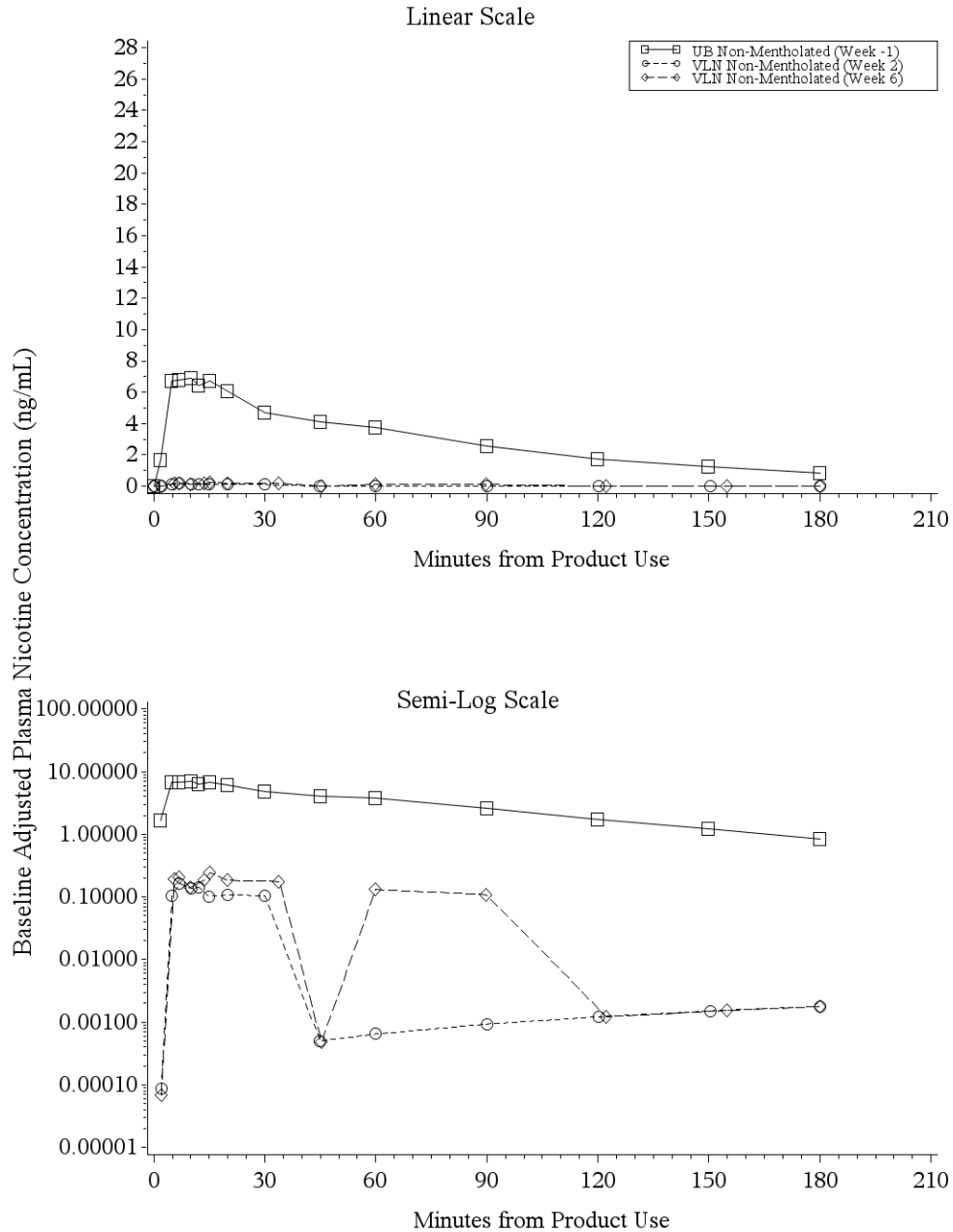
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1020



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

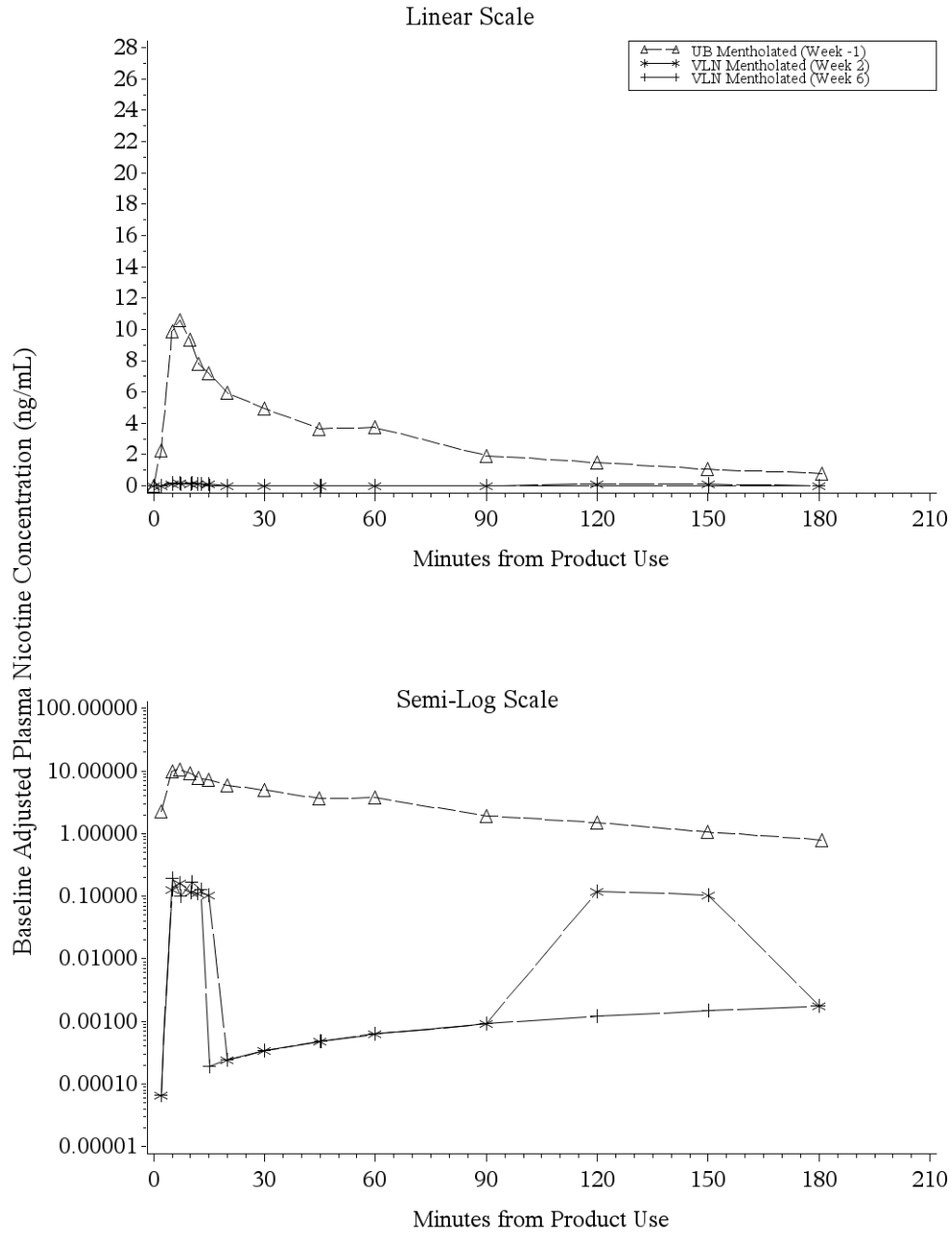
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1023



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

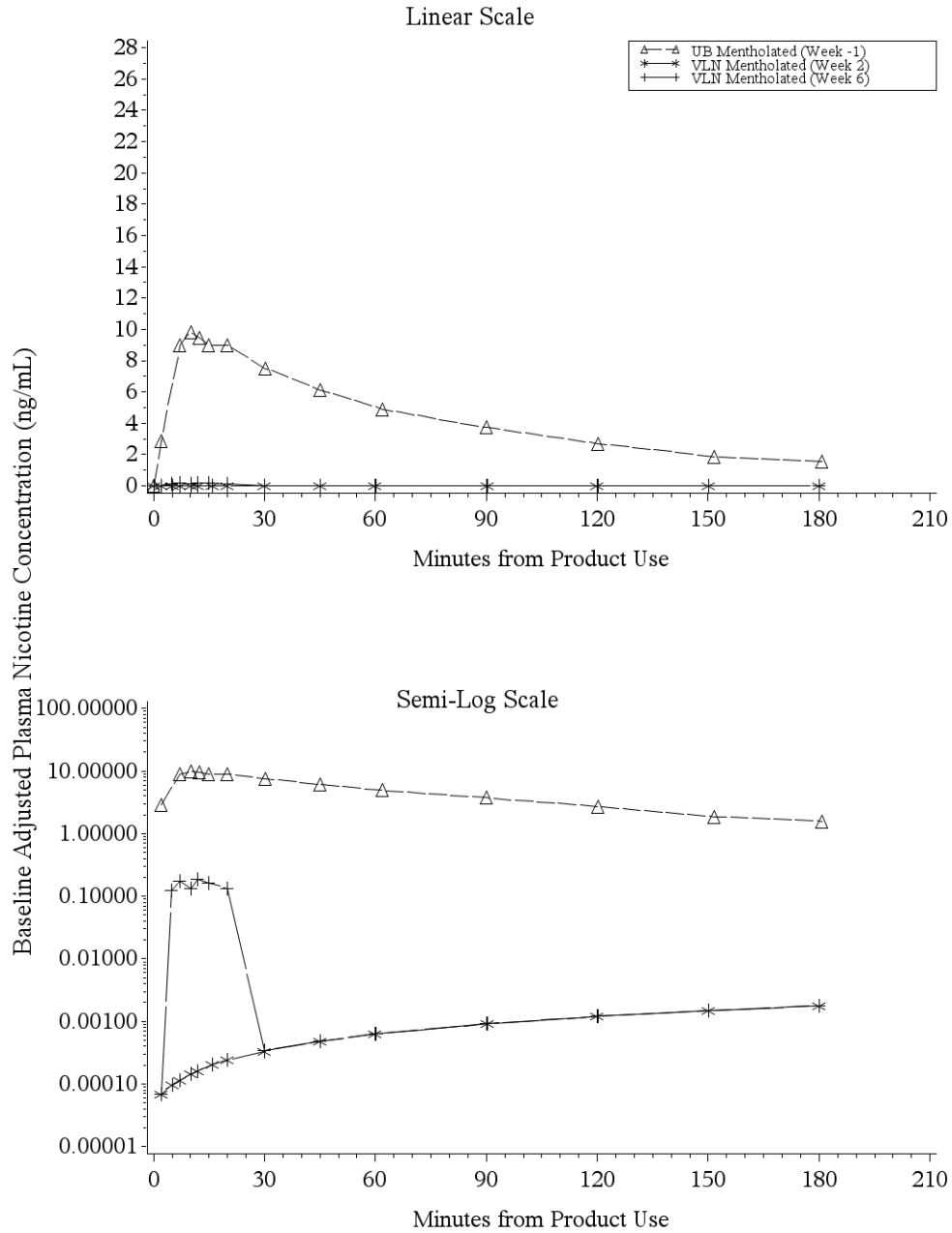
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1029



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

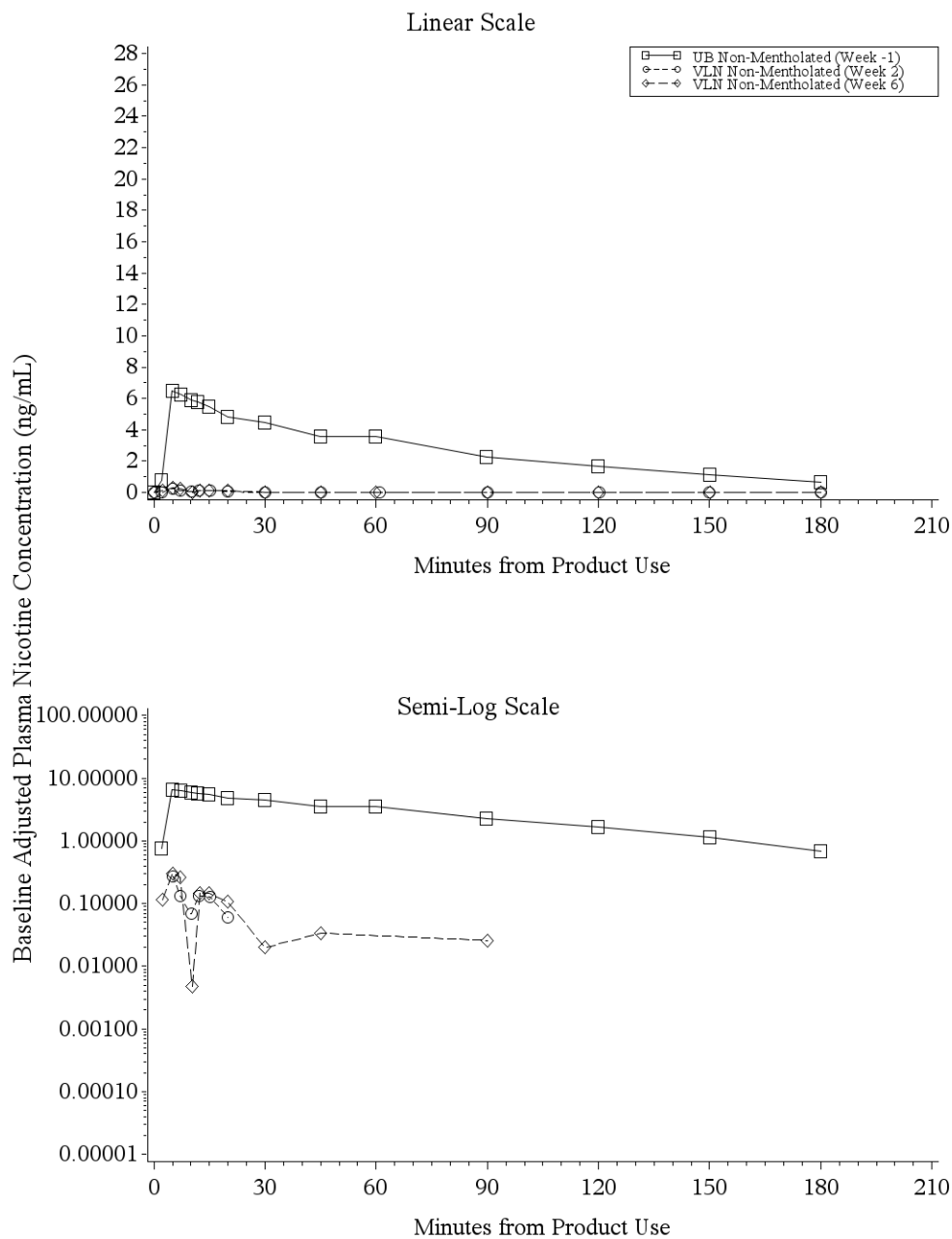
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1032



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

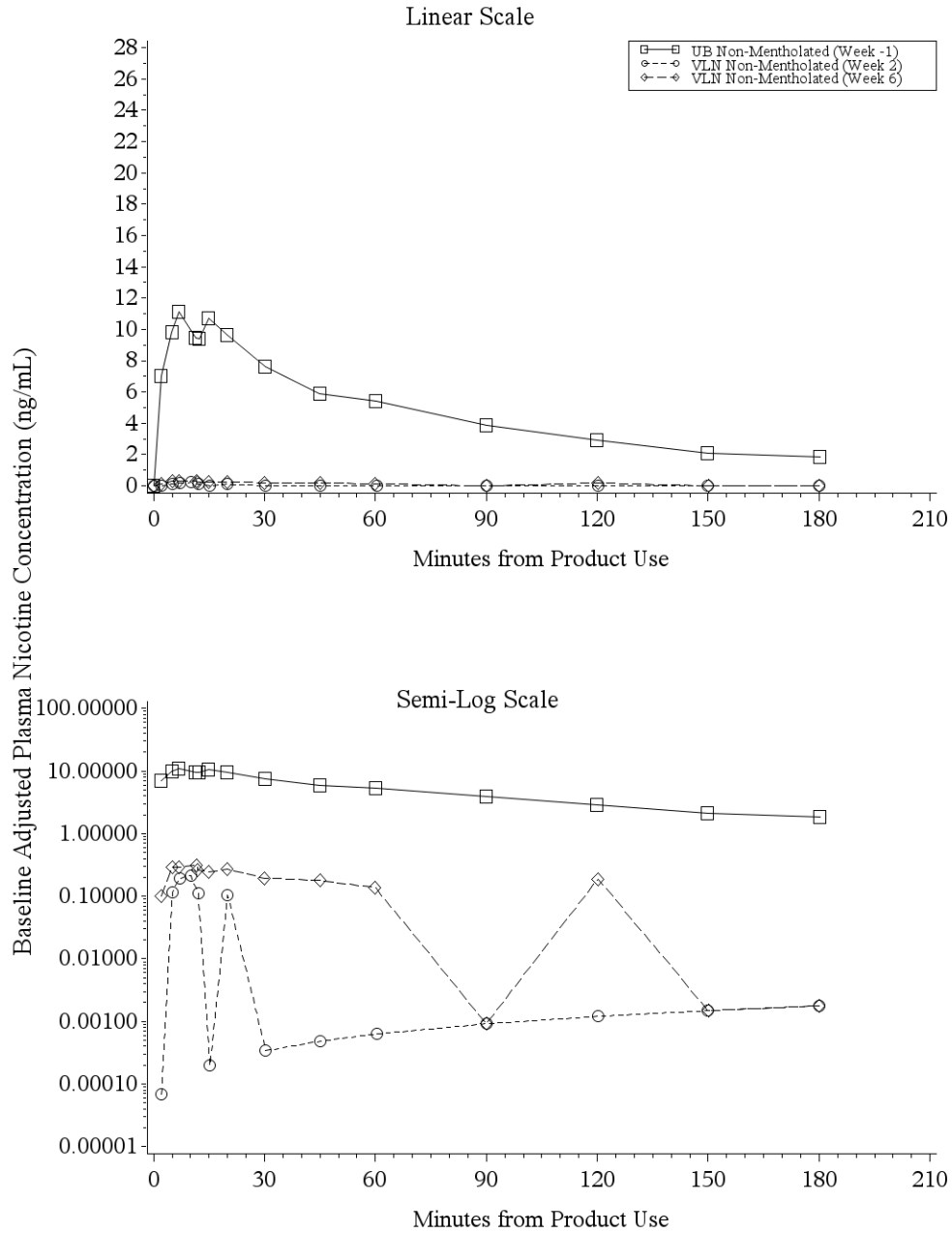
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1035



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

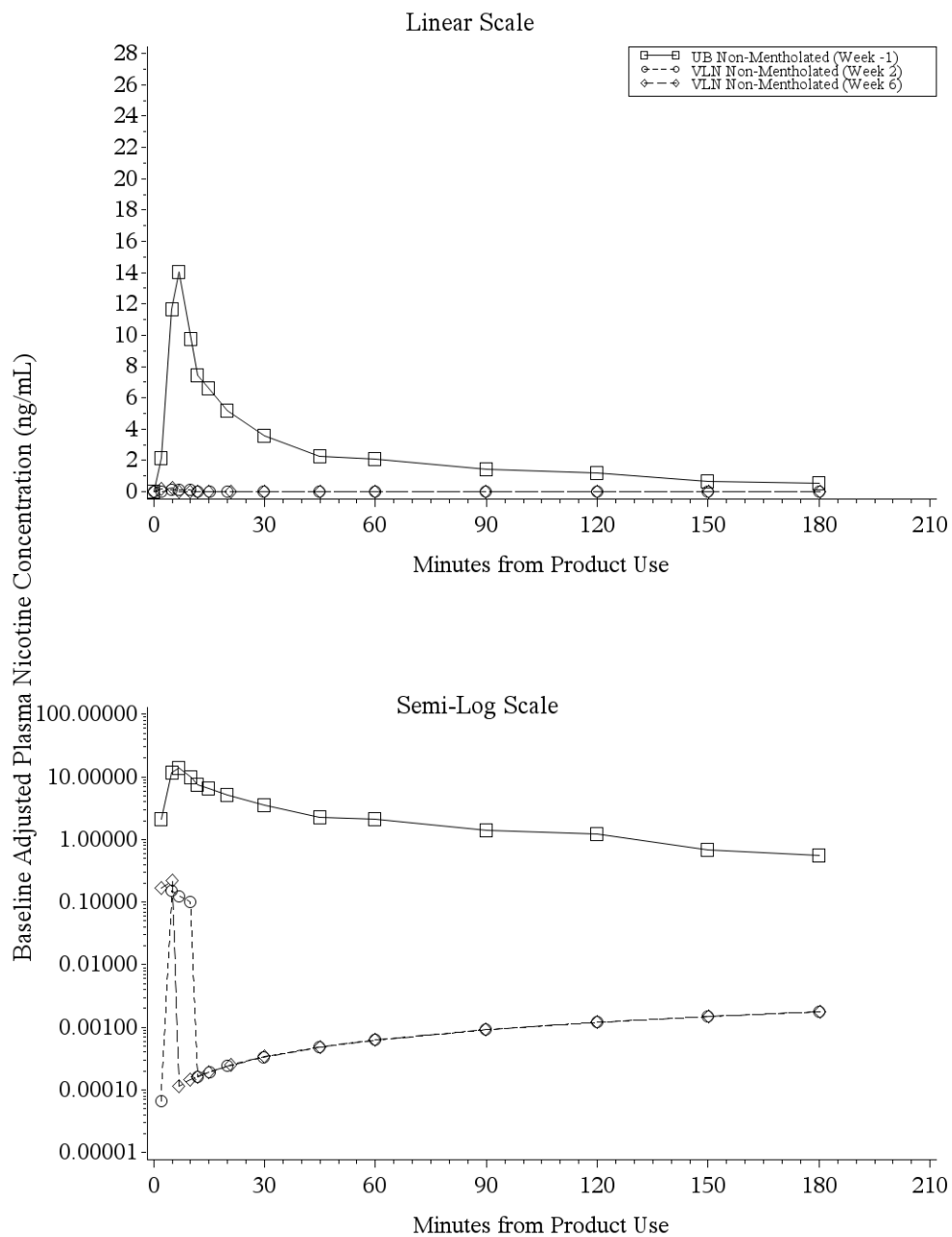
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1038



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

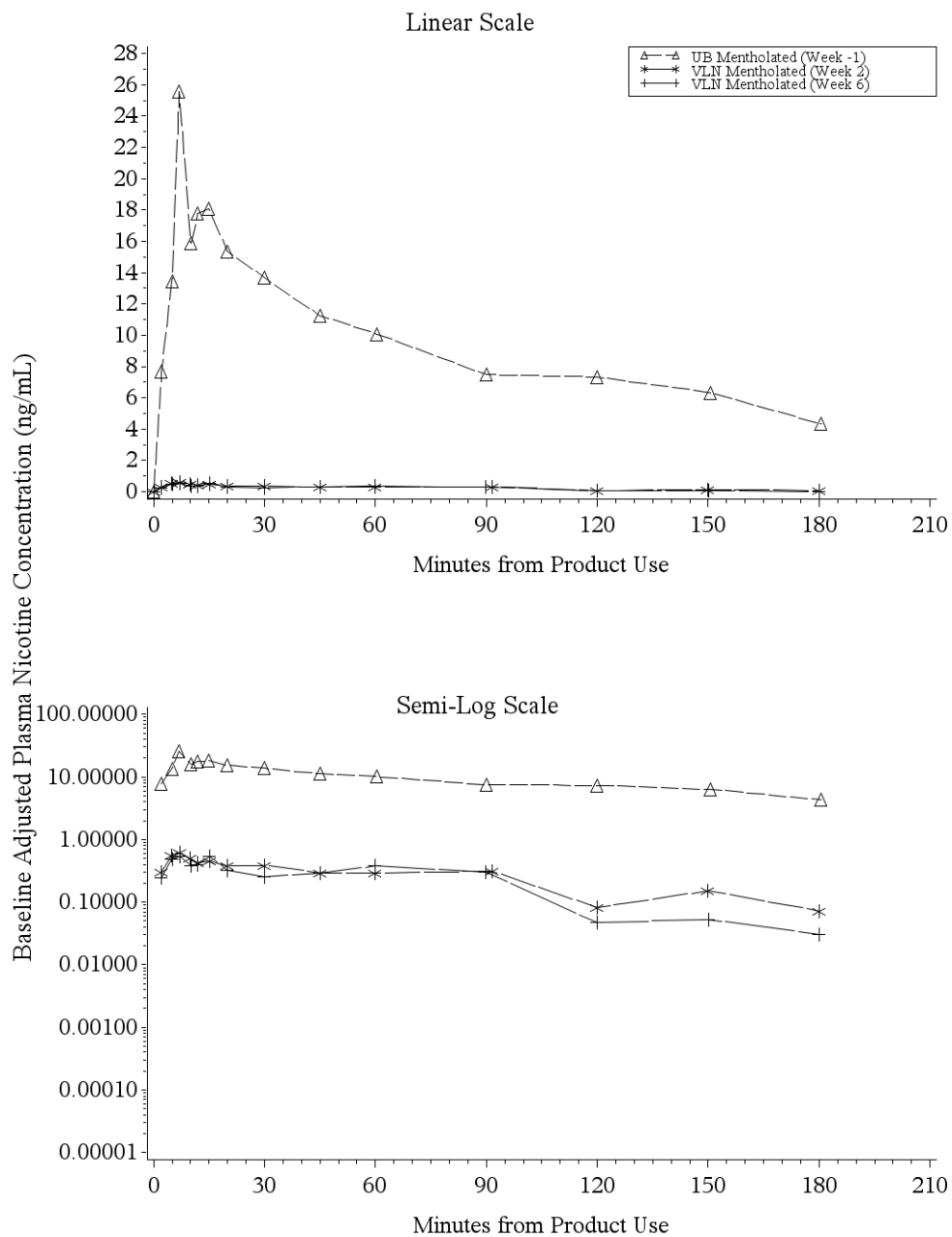
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1042



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

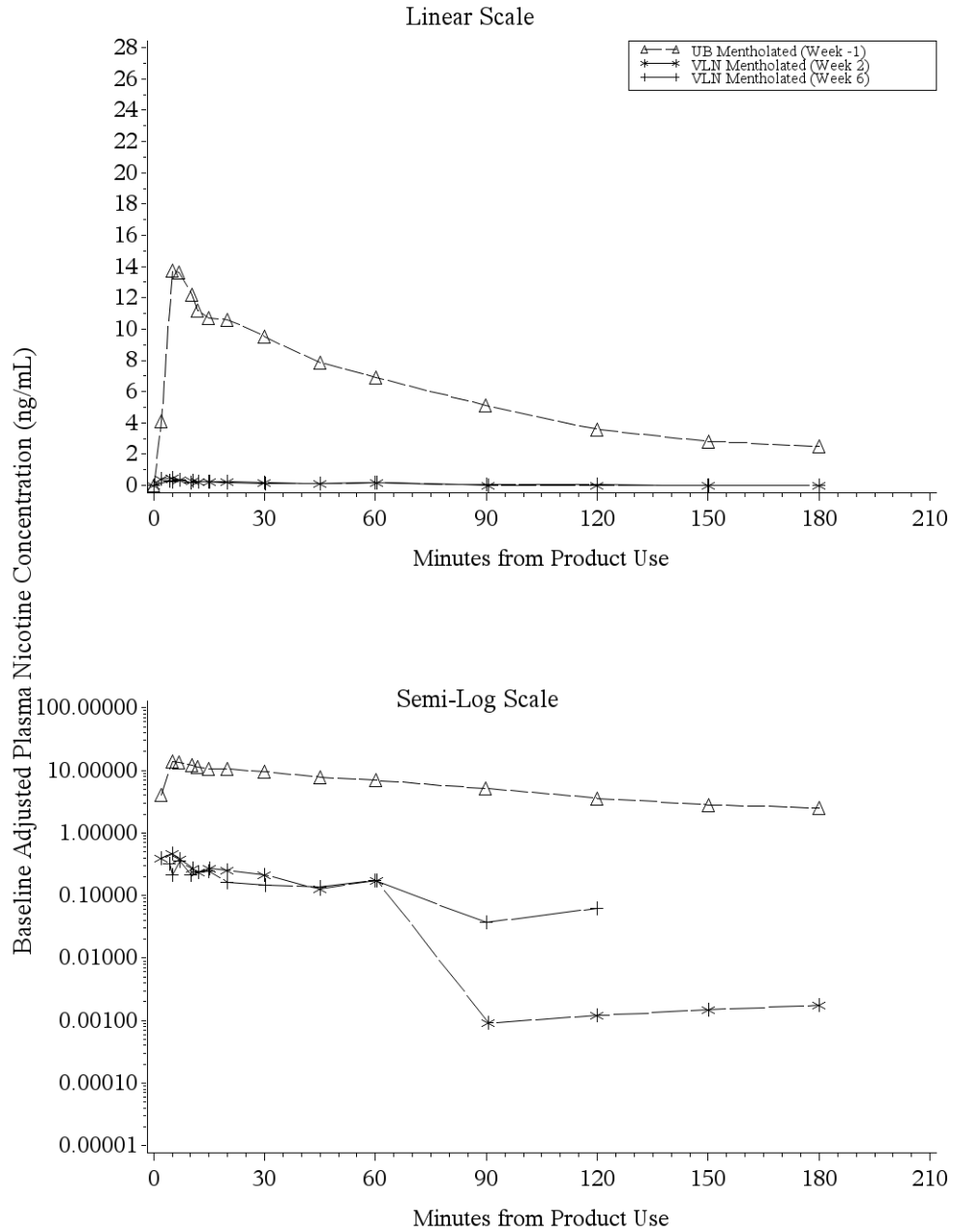
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1052



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

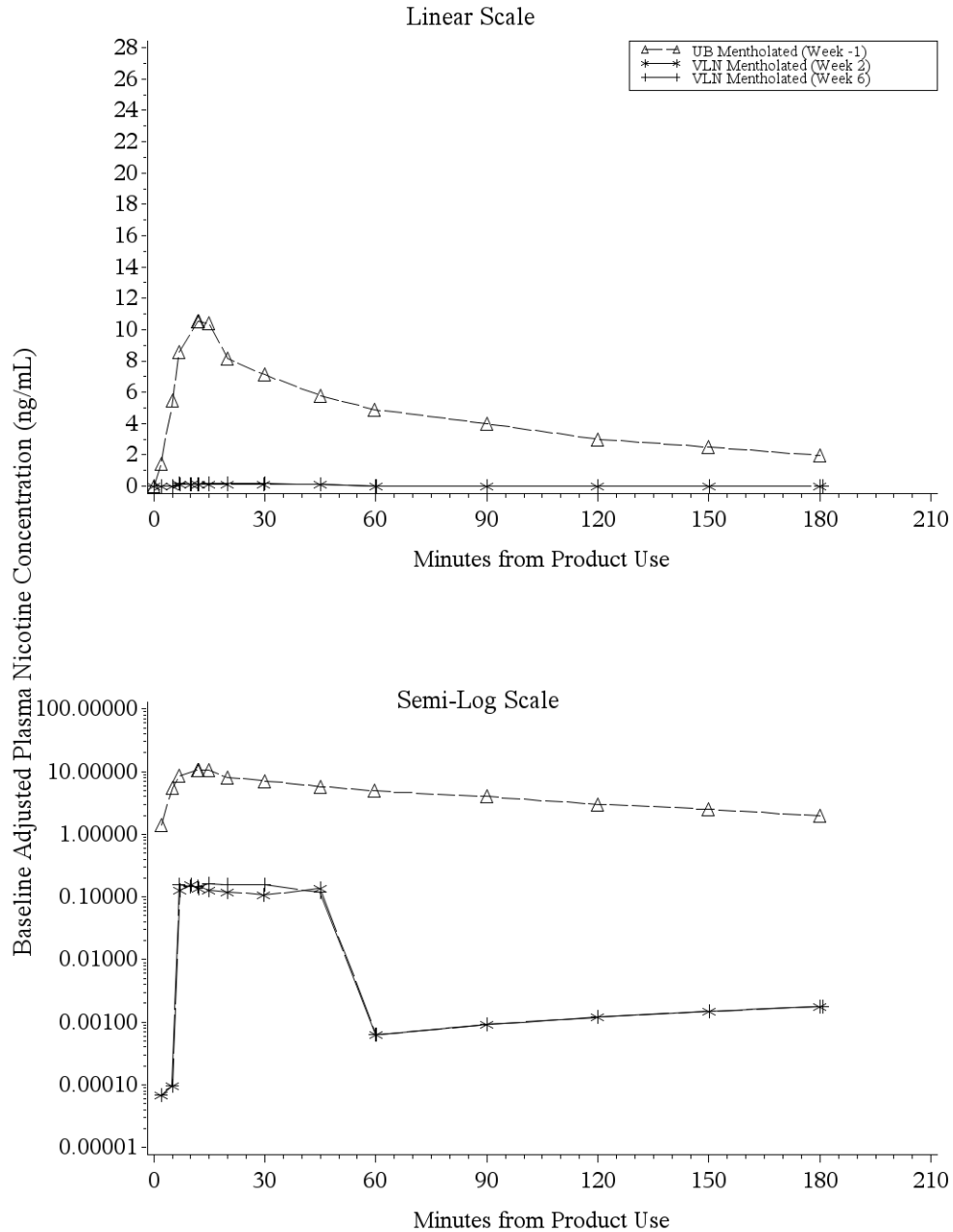
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1053



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

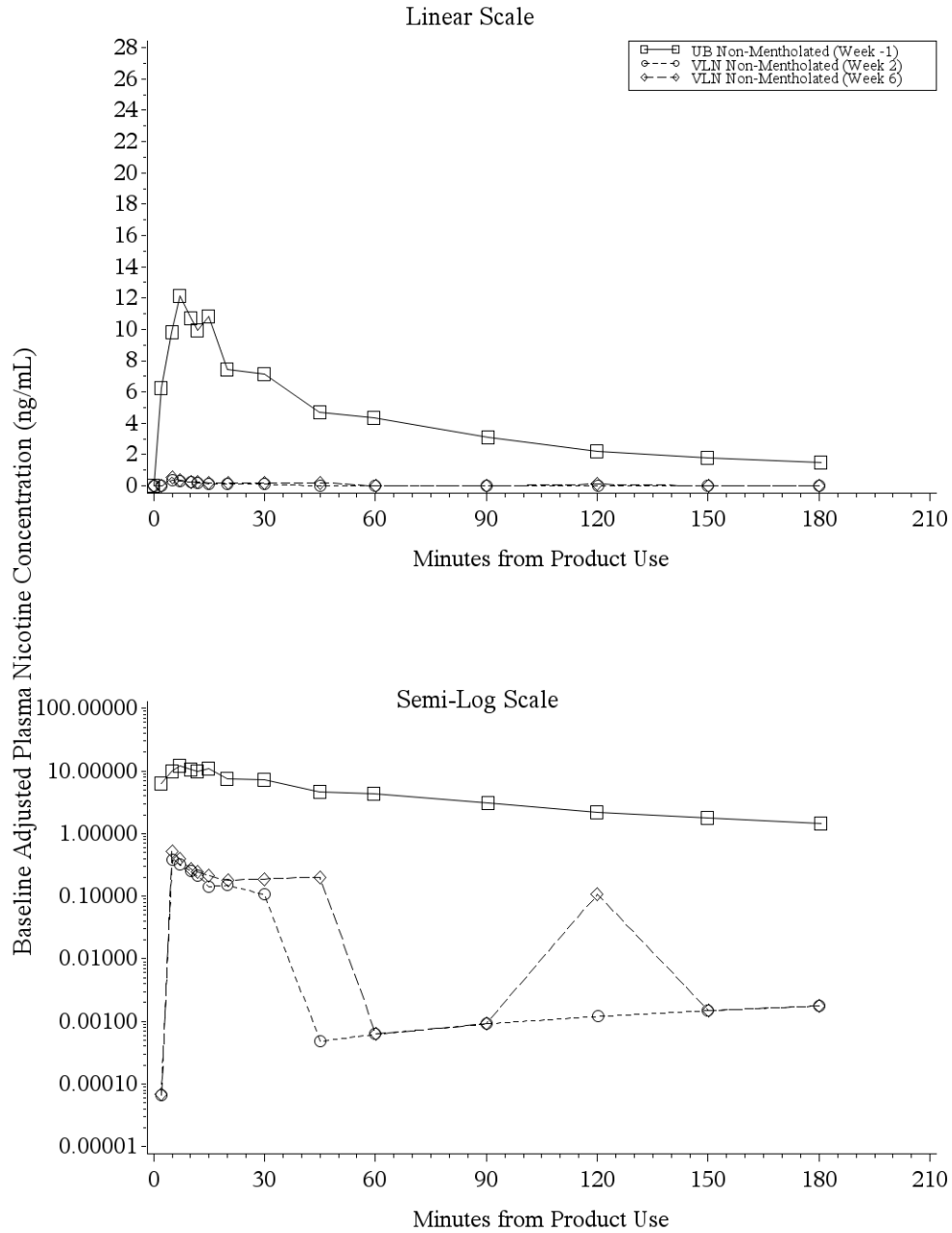
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1055



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

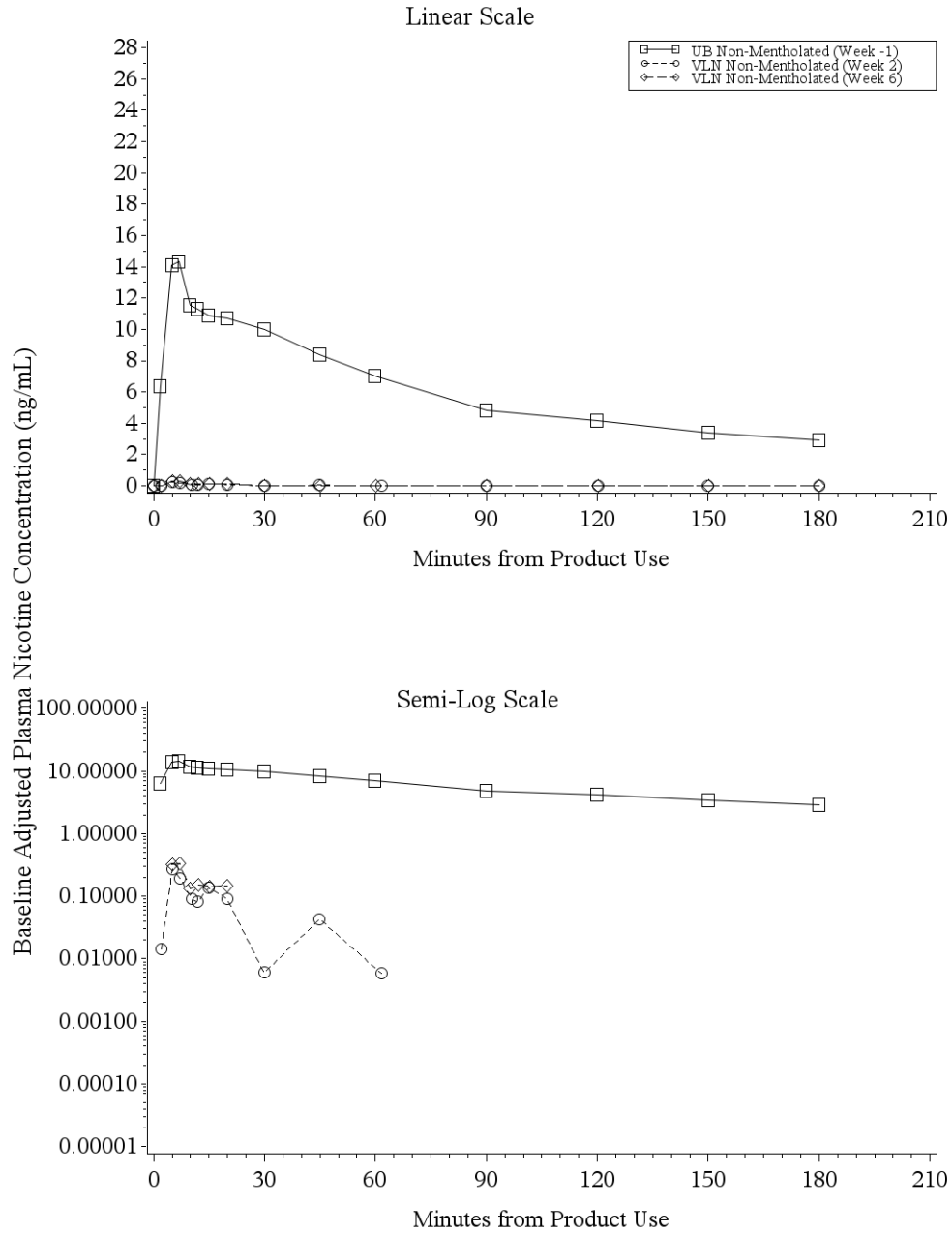
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1056



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

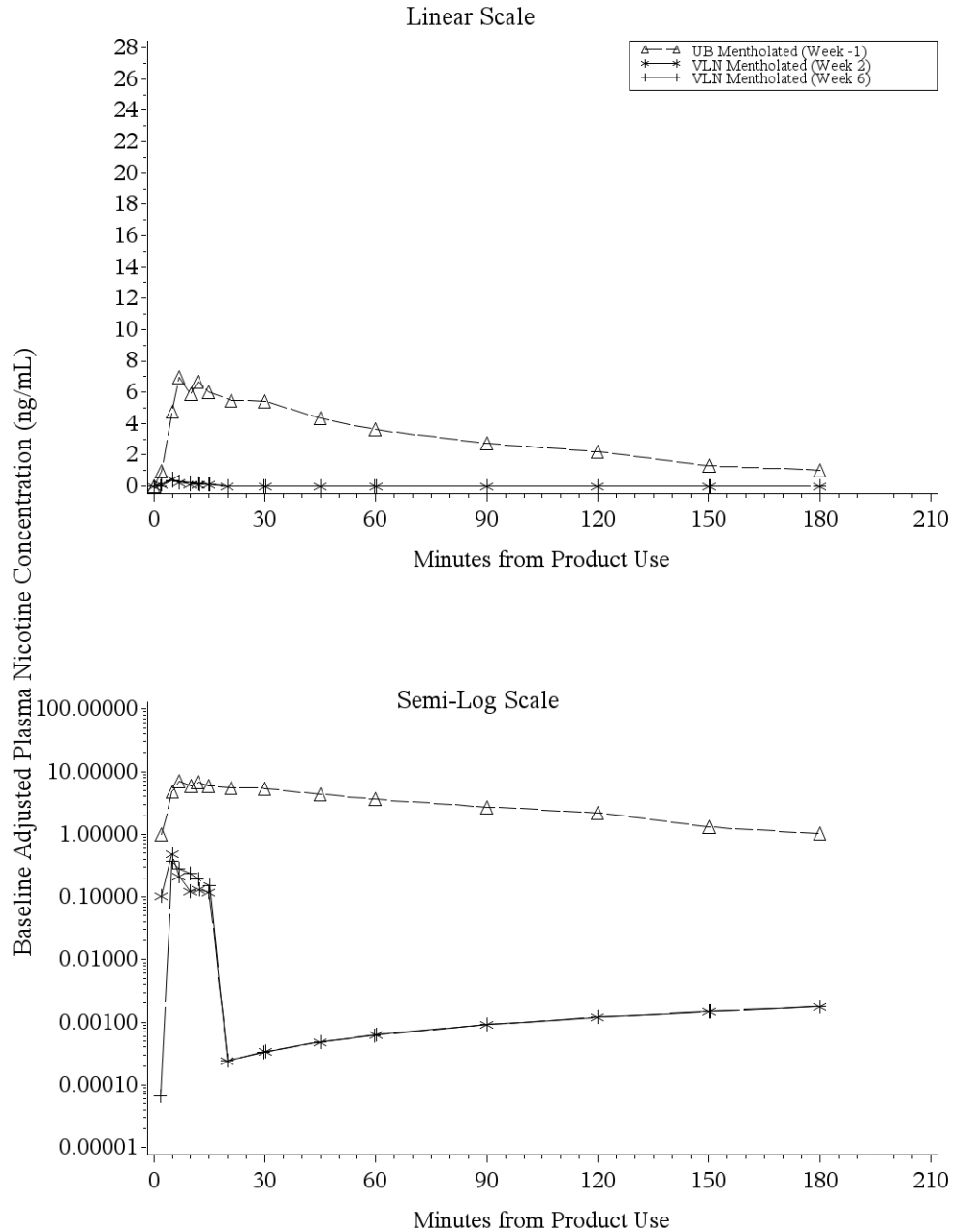
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1058



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

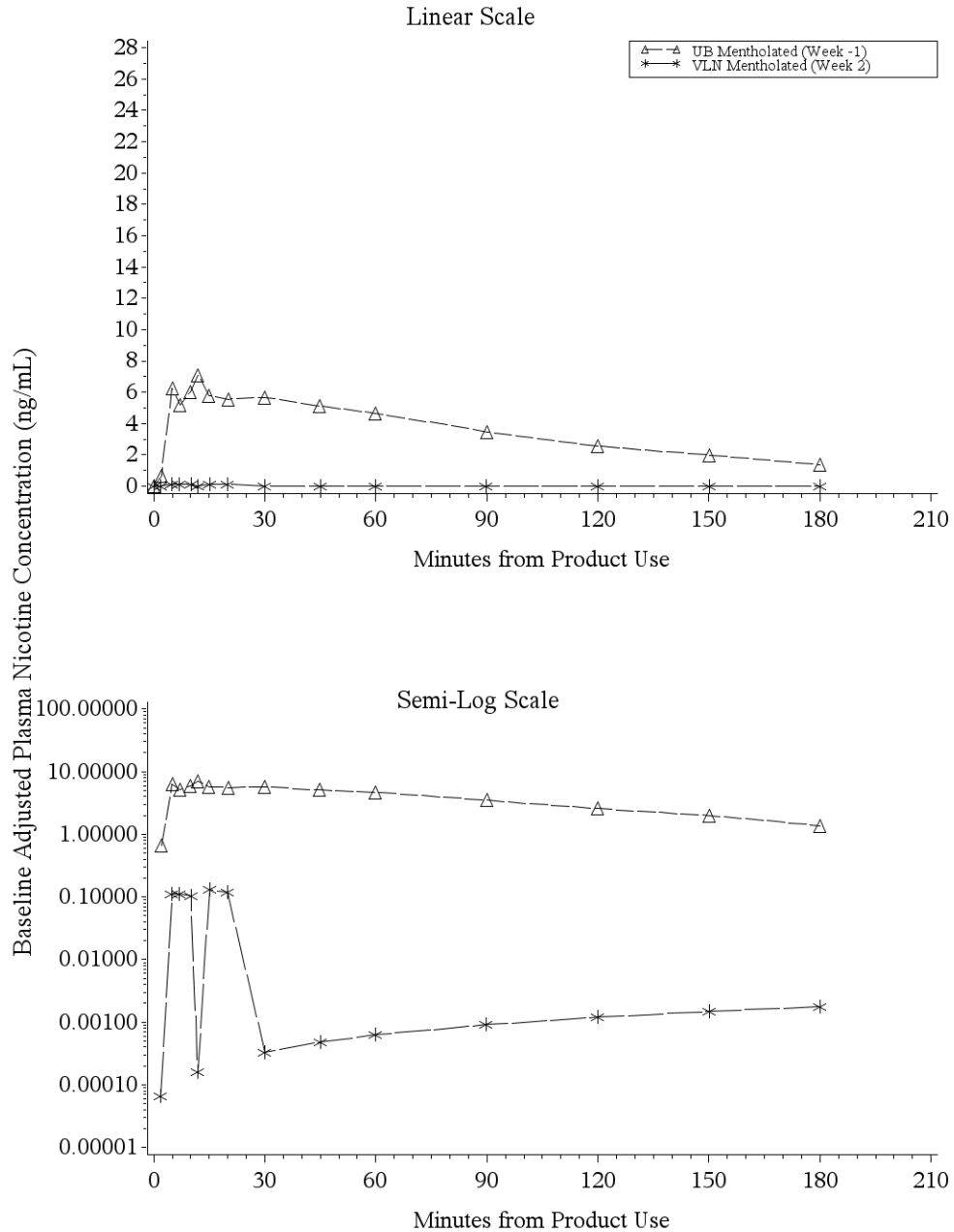
Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1063



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.11.2

Baseline Adjusted Plasma Nicotine Concentrations Versus Time (Linear and Semi-Log Scale) for Subject 1072



Program: /CA24914/sas_prg/pksas/adam_indgraph.sas 12JUN2019 9:29

Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
1001	VLN non-mentholated	-1	24JUL2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	8
		2	09AUG2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	8
		4	22AUG2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	8
		6	06SEP2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	8
1002	VLN non-mentholated	-1	24JUL2018	Within 5 minutes	No	The first one in the morning	21 - 30	Yes	Yes	8
		2	09AUG2018	Within 5 minutes	No	The first one in the morning	21 - 30	Yes	No	7
		6	07SEP2018	Within 5 minutes	No	The first one in the morning	21 - 30	No	No	6
1003	VLN mentholated	-1	24JUL2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
		2	09AUG2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		6	06SEP2018	Within 5 minutes	No	Any other	11 - 20	No	No	4
1007	VLN non-mentholated	-1	24JUL2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	No	No	6
		2	09AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
		4	22AUG2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	No	No	6

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-FTCD.SAS 13JUN2019 4:25

Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
1007	VLN non-mentholated	6	06SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
1008	VLN mentholated	-1	24JUL2018	6 - 30 minutes	No	The first one in the morning	21 - 30	Yes	No	6
		2	09AUG2018	6 - 30 minutes	No	The first one in the morning	21 - 30	Yes	No	6
		4	22AUG2018	6 - 30 minutes	No	The first one in the morning	21 - 30	Yes	No	6
		6	07SEP2018	6 - 30 minutes	No	The first one in the morning	21 - 30	Yes	No	6
1010	UB mentholated	-1	25JUL2018	6 - 30 minutes	No	Any other	21 - 30	Yes	No	5
		2	09AUG2018	6 - 30 minutes	No	The first one in the morning	21 - 30	Yes	No	6
		4	22AUG2018	6 - 30 minutes	No	The first one in the morning	21 - 30	Yes	No	6
		6	06SEP2018	6 - 30 minutes	No	The first one in the morning	21 - 30	Yes	No	6
1011	UB non-mentholated	-1	24JUL2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	Yes	5
		2	09AUG2018	6 - 30 minutes	No	Any other	11 - 20	No	Yes	4
		4	22AUG2018	Within 5 minutes	No	The first one in the morning	21 - 30	No	Yes	7
		6	06SEP2018	Within 5 minutes	No	Any other	11 - 20	No	Yes	5

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-FTCD.SAS 13JUN2019 4:25

Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
1013	VLN non-mentholated	-1	01AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		2	17AUG2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5
		4	30AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		6	13SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
1014	VLN mentholated	-1	01AUG2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5
		2	16AUG2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5
		4	29AUG2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		6	14SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5
1015	VLN mentholated	-1	31JUL2018	31 - 60 minutes	No	Any other	11 - 20	No	Yes	3
		2	17AUG2018	6 - 30 minutes	No	Any other	11 - 20	No	Yes	4
		4	30AUG2018	6 - 30 minutes	No	Any other	11 - 20	No	Yes	4
		6	13SEP2018	6 - 30 minutes	No	Any other	11 - 20	No	Yes	4
1016	UB non-mentholated	-1	31JUL2018	6 - 30 minutes	No	Any other	21 - 30	No	No	4
		2	16AUG2018	6 - 30 minutes	No	Any other	21 - 30	No	No	4
		4	29AUG2018	6 - 30 minutes	No	Any other	21 - 30	No	No	4
		6	13SEP2018	6 - 30 minutes	No	Any other	21 - 30	No	No	4

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-FTCD.SAS 13JUN2019 4:25

Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
1017	UB mentholated	-1	01AUG2018	Within 5 minutes	No	The first one in the morning	21 - 30	No	No	6
		2	16AUG2018	Within 5 minutes	No	The first one in the morning	21 - 30	No	No	6
		4	29AUG2018	Within 5 minutes	No	The first one in the morning	21 - 30	No	Yes	7
		6	13SEP2018	Within 5 minutes	No	The first one in the morning	21 - 30	No	Yes	7
1018	VLN mentholated	-1	01AUG2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
		2	17AUG2018	After 60 minutes	No	Any other	11 - 20	No	No	1
1019	VLN non-mentholated	-1	01AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		2	17AUG2018	Within 5 minutes	Yes	The first one in the morning	21 - 30	Yes	No	8
		4	29AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		6	13SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
1020	VLN non-mentholated	-1	01AUG2018	6 - 30 minutes	Yes	Any other	31 or more	No	Yes	7
		2	17AUG2018	6 - 30 minutes	Yes	Any other	31 or more	No	Yes	7
		4	30AUG2018	31 - 60 minutes	Yes	Any other	11 - 20	No	Yes	4
		6	13SEP2018	6 - 30 minutes	Yes	Any other	21 - 30	No	Yes	6
1021	UB non-mentholated	-1	01AUG2018	After 60 minutes	No	Any other	21 - 30	No	No	2

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-FTCD.SAS 13JUN2019 4:25

Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
1021	UB non-mentholated	2	16AUG2018	After 60 minutes	No	Any other	21 - 30	No	No	2
		4	29AUG2018	After 60 minutes	No	Any other	21 - 30	No	No	2
		6	13SEP2018	After 60 minutes	No	Any other	21 - 30	No	No	2
1023	VLN non-mentholated	-1	01AUG2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	No	No	5
		2	17AUG2018	6 - 30 minutes	Yes	Any other	11 - 20	No	No	4
		4	30AUG2018	6 - 30 minutes	Yes	Any other	11 - 20	No	No	4
		6	13SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
1029	VLN mentholated	-1	28AUG2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	No	No	6
		2	13SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
		4	25SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
		6	11OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
1032	VLN mentholated	-1	27AUG2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	8
		2	13SEP2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
		4	25SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-FTCD.SAS 13JUN2019 4:25

Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
1032	VLN mentholated	6	10OCT2018	6 - 30 minutes	No	The first one in the morning	10 or less	Yes	No	4
1034	VLN non-mentholated	-1	27AUG2018	6 - 30 minutes	No	The first one in the morning	21 - 30	No	No	5
		2	13SEP2018	6 - 30 minutes	No	The first one in the morning	21 - 30	Yes	No	6
		4	25SEP2018	6 - 30 minutes	No	The first one in the morning	21 - 30	Yes	No	6
		6	10OCT2018	Within 5 minutes	No	The first one in the morning	21 - 30	Yes	No	7
1035	VLN non-mentholated	-1	27AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		2	12SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		4	25SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		6	11OCT2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5
1036	UB mentholated	-1	28AUG2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	No	Yes	7
		4	24SEP2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	No	Yes	7
		6	10OCT2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	No	Yes	7

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
1037	UB mentholated	-1	28AUG2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		2	12SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		4	25SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		6	10OCT2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
1038	VLN non-mentholated	-1	28AUG2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	Yes	6
		2	13SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	Yes	6
		4	26SEP2018	6 - 30 minutes	No	Any other	11 - 20	Yes	Yes	5
		6	10OCT2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	Yes	6
1042	VLN non-mentholated	-1	28AUG2018	31 - 60 minutes	No	The first one in the morning	21 - 30	No	No	4
		2	13SEP2018	6 - 30 minutes	Yes	The first one in the morning	10 or less	Yes	No	5
		4	25SEP2018	31 - 60 minutes	No	The first one in the morning	10 or less	Yes	No	3
		6	11OCT2018	6 - 30 minutes	No	The first one in the morning	10 or less	Yes	No	4
1045	UB non-mentholated	-1	28AUG2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
1045	UB non-mentholated	2	11SEP2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	No	No	6
		4	25SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		6	09OCT2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5
1046	UB mentholated	-1	28AUG2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
		2	11SEP2018	31 - 60 minutes	No	Any other	11 - 20	No	No	2
		4	24SEP2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
		6	09OCT2018	31 - 60 minutes	No	Any other	11 - 20	No	No	2
1050	VLN non-mentholated	-1	28AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
		2	13SEP2018	Within 5 minutes	No	The first one in the morning	21 - 30	No	No	6
		4	25SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		6	10OCT2018	Within 5 minutes	No	Any other	11 - 20	Yes	No	5
1051	UB mentholated	-1	28AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
		2	12SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
		4	24SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
1051	UB mentholated	6	10OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
1052	VLN mentholated	-1	28AUG2018	6 - 30 minutes	No	Any other	11 - 20	Yes	No	4
		2	13SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5
		6	11OCT2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	Yes	6
1053	VLN mentholated	-1	28AUG2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5
		2	12SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5
		4	26SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5
		6	11OCT2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
1054	UB non-mentholated	-1	27AUG2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
		2	11SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5
		4	25SEP2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
		6	10OCT2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	Yes	No	7

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
1055	VLN mentholated	-1	28AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
		2	13SEP2018	Within 5 minutes	No	The first one in the morning	21 - 30	Yes	Yes	8
		4	26SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5
		6	10OCT2018	6 - 30 minutes	No	The first one in the morning	10 or less	Yes	No	4
1056	VLN non-mentholated	-1	27AUG2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	Yes	No	7
		2	13SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		4	26SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		6	11OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
1058	VLN non-mentholated	-1	28AUG2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
		2	13SEP2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	8
		4	26SEP2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	8
		6	11OCT2018	Within 5 minutes	Yes	The first one in the morning	21 - 30	Yes	Yes	9

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study		Question*							Total Score
		Week	Date	1	2	3	4	5	6		
1059	UB non-mentholated	-1	10SEP2018	6 - 30 minutes	Yes	Any other	11 - 20	No	Yes	5	
		2	25SEP2018	6 - 30 minutes	Yes	Any other	11 - 20	No	Yes	5	
		4	08OCT2018	6 - 30 minutes	Yes	Any other	11 - 20	No	Yes	5	
		6	24OCT2018	6 - 30 minutes	Yes	Any other	11 - 20	No	Yes	5	
1060	VLN mentholated	-1	10SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7	
		2	26SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7	
		4	09OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6	
		6	24OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6	
1063	VLN mentholated	-1	10SEP2018	6 - 30 minutes	No	Any other	31 or more	No	No	5	
		2	27SEP2018	6 - 30 minutes	No	Any other	21 - 30	No	No	4	
		4	09OCT2018	6 - 30 minutes	No	Any other	21 - 30	No	No	4	
		6	24OCT2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3	
1064	UB non-mentholated	-1	10SEP2018	Within 5 minutes	Yes	Any other	21 - 30	Yes	Yes	8	
		2	25SEP2018	Within 5 minutes	Yes	Any other	11 - 20	No	Yes	6	
1066	VLN non-mentholated	-1	11SEP2018	6 - 30 minutes	No	Any other	11 - 20	Yes	Yes	5	
		2	26SEP2018	6 - 30 minutes	No	Any other	11 - 20	No	Yes	4	
		4	09OCT2018	6 - 30 minutes	No	Any other	11 - 20	Yes	Yes	5	
		6	23OCT2018	31 - 60 minutes	No	Any other	11 - 20	Yes	Yes	4	

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
1069	UB non-mentholated	-1	11SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
		2	26SEP2018	Within 5 minutes	No	The first one in the morning	21 - 30	Yes	Yes	8
		4	09OCT2018	Within 5 minutes	No	The first one in the morning	21 - 30	Yes	Yes	8
		6	24OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
1070	VLN non-mentholated	-1	10SEP2018	6 - 30 minutes	No	Any other	11 - 20	No	Yes	4
		2	26SEP2018	6 - 30 minutes	No	Any other	11 - 20	No	Yes	4
		4	08OCT2018	6 - 30 minutes	No	Any other	11 - 20	No	Yes	4
		6	24OCT2018	6 - 30 minutes	No	Any other	11 - 20	No	Yes	4
1071	VLN non-mentholated	-1	10SEP2018	Within 5 minutes	No	The first one in the morning	21 - 30	Yes	No	7
		2	25SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		4	08OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
1072	VLN mentholated	-1	10SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		2	27SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		4	09OCT2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
1074	VLN non-mentholated	-1	10SEP2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
		2	26SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		4	09OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		6	23OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
1075	UB non-mentholated	-1	10SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
		2	26SEP2018	Within 5 minutes	No	Any other	11 - 20	No	No	4
		4	09OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
		6	24OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
1077	VLN non-mentholated	-1	10SEP2018	6 - 30 minutes	No	The first one in the morning	21 - 30	No	No	5
		2	26SEP2018	6 - 30 minutes	No	The first one in the morning	31 or more	Yes	No	7
		4	09OCT2018	6 - 30 minutes	No	The first one in the morning	31 or more	Yes	No	7
		6	24OCT2018	6 - 30 minutes	No	The first one in the morning	21 - 30	Yes	No	6
1078	VLN non-mentholated	-1	11SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	Yes	6

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
1078	VLN non-mentholated	2	25SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	Yes	6
		4	09OCT2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	Yes	6
		6	24OCT2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	Yes	6
1079	VLN mentholated	-1	11SEP2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
		2	26SEP2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
		4	09OCT2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
		6	24OCT2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
1082	VLN non-mentholated	-1	10SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		2	26SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		4	09OCT2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
		6	24OCT2018	6 - 30 minutes	No	Any other	11 - 20	Yes	No	4
1083	VLN non-mentholated	-1	17SEP2018	6 - 30 minutes	No	Any other	21 - 30	No	Yes	5
		2	03OCT2018	6 - 30 minutes	No	Any other	21 - 30	No	Yes	5
		4	16OCT2018	6 - 30 minutes	No	The first one in the morning	21 - 30	Yes	Yes	7
		6	31OCT2018	6 - 30 minutes	No	Any other	11 - 20	No	Yes	4
1084	VLN non-mentholated	-1	17SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
1084	VLN non-mentholated	2	03OCT2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		4	16OCT2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
1086	VLN non-mentholated	-1	18SEP2018	Within 5 minutes	No	Any other	31 or more	Yes	Yes	8
		2	02OCT2018	Within 5 minutes	No	The first one in the morning	31 or more	Yes	Yes	9
		4	15OCT2018	Within 5 minutes	No	The first one in the morning	31 or more	Yes	Yes	9
		6	30OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
1088	VLN mentholated	-1	18SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		2	03OCT2018	6 - 30 minutes	No	The first one in the morning	10 or less	No	No	3
		4	16OCT2018	6 - 30 minutes	No	Any other	10 or less	No	No	2
		6	31OCT2018	6 - 30 minutes	No	Any other	10 or less	No	No	2
1089	UB non-mentholated	-1	17SEP2018	After 60 minutes	No	Any other	11 - 20	No	No	1
		2	02OCT2018	After 60 minutes	No	Any other	11 - 20	No	No	1
		4	15OCT2018	After 60 minutes	No	Any other	11 - 20	No	No	1
		6	30OCT2018	After 60 minutes	No	Any other	11 - 20	No	No	1
1092	VLN mentholated	-1	18SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
1092	VLN mentholated	2	03OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
		4	16OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
		6	31OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
1094	VLN mentholated	-1	18SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
		2	02OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		4	15OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		6	31OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
1095	VLN mentholated	-1	17SEP2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	8
		2	02OCT2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	8
		4	15OCT2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
		6	30OCT2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	8
1096	VLN non-mentholated	-1	18SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	Yes	6

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
1096	VLN non-mentholated	2	27SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	Yes	6
		4	16OCT2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	Yes	6
		6	31OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
1097	VLN mentholated	-1	18SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
		2	03OCT2018	31 - 60 minutes	No	The first one in the morning	11 - 20	No	No	3
		4	16OCT2018	Within 5 minutes	No	The first one in the morning	10 or less	No	No	4
		6	31OCT2018	Within 5 minutes	No	The first one in the morning	10 or less	No	No	4
1098	VLN non-mentholated	-1	04OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		6	16NOV2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
1099	VLN non-mentholated	-1	04OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
		2	19OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
		4	01NOV2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
1099	VLN non-mentholated	6	16NOV2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
1100	VLN non-mentholated	-1	04OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
		2	19OCT2018	Within 5 minutes	No	The first one in the morning	21 - 30	Yes	Yes	8
		4	01NOV2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
		6	16NOV2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
1101	VLN non-mentholated	-1	03OCT2018	Within 5 minutes	Yes	Any other	11 - 20	Yes	Yes	7
		6	16NOV2018	Within 5 minutes	Yes	The first one in the morning	21 - 30	Yes	Yes	9
1103	VLN non-mentholated	-1	03OCT2018	Within 5 minutes	No	The first one in the morning	21 - 30	No	No	6
		2	19OCT2018	Within 5 minutes	Yes	The first one in the morning	21 - 30	No	No	7
		4	01NOV2018	Within 5 minutes	No	The first one in the morning	21 - 30	No	Yes	7
		6	16NOV2018	Within 5 minutes	No	The first one in the morning	21 - 30	No	No	6
1105	VLN non-mentholated	-1	03OCT2018	Within 5 minutes	Yes	Any other	11 - 20	No	Yes	6
		2	19OCT2018	Within 5 minutes	Yes	Any other	21 - 30	No	Yes	7

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
1105	VLN non-mentholated	4	02NOV2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	8
		6	16NOV2018	Within 5 minutes	No	The first one in the morning	21 - 30	Yes	Yes	8
1106	UB non-mentholated	-1	04OCT2018	Within 5 minutes	No	The first one in the morning	21 - 30	Yes	No	7
		2	19OCT2018	Within 5 minutes	Yes	The first one in the morning	21 - 30	Yes	No	8
		4	31OCT2018	Within 5 minutes	No	Any other	21 - 30	Yes	No	6
		6	16NOV2018	Within 5 minutes	Yes	The first one in the morning	21 - 30	Yes	No	8
1107	VLN non-mentholated	-1	04OCT2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
		2	19OCT2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
		4	02NOV2018	6 - 30 minutes	No	Any other	11 - 20	Yes	No	4
		6	16NOV2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
1108	UB non-mentholated	-1	03OCT2018	6 - 30 minutes	No	Any other	11 - 20	No	Yes	4
		2	18OCT2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
		4	31OCT2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
		6	15NOV2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
1109	UB non-mentholated	-1	04OCT2018	31 - 60 minutes	No	The first one in the morning	11 - 20	Yes	Yes	5
		2	19OCT2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
1109	UB non-mentholated	4	01NOV2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	Yes	6
		6	16NOV2018	6 - 30 minutes	No	Any other	11 - 20	Yes	Yes	5
1111		-1		Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	
1112	VLN non-mentholated	-1	03OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
		2	19OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
		4	02NOV2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
		6	16NOV2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
1114	UB non-mentholated	-1	03OCT2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
		2	18OCT2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
		4	01NOV2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
		6	15NOV2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
1115	VLN non-mentholated	-1	03OCT2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	Yes	5

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
1115	VLN non-mentholated	2	19OCT2018	6 - 30 minutes	No	The first one in the morning	21 - 30	Yes	Yes	7
		4	02NOV2018	6 - 30 minutes	No	The first one in the morning	21 - 30	Yes	Yes	7
2001		-1		Within 5 minutes	No	The first one in the morning	21 - 30	Yes	Yes	
2002	UB mentholated	-1	23JUL2018	6 - 30 minutes	No	The first one in the morning	21 - 30	Yes	Yes	7
		2	08AUG2018	6 - 30 minutes	Yes	The first one in the morning	21 - 30	Yes	Yes	8
		4	21AUG2018	6 - 30 minutes	Yes	The first one in the morning	21 - 30	Yes	Yes	8
		6	05SEP2018	6 - 30 minutes	Yes	The first one in the morning	21 - 30	Yes	Yes	8
2003	VLN mentholated	-1	16JUL2018	6 - 30 minutes	No	Any other	11 - 20	Yes	No	4
		2	31JUL2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		4	14AUG2018	6 - 30 minutes	No	Any other	11 - 20	Yes	Yes	5
		6	28AUG2018	6 - 30 minutes	No	Any other	11 - 20	Yes	Yes	5
2007	VLN non-mentholated	-1	16JUL2018	Within 5 minutes	Yes	Any other	11 - 20	No	Yes	6
		2	01AUG2018	6 - 30 minutes	Yes	Any other	21 - 30	No	Yes	6
		4	14AUG2018	Within 5 minutes	Yes	Any other	11 - 20	No	Yes	6
		6	29AUG2018	Within 5 minutes	Yes	Any other	11 - 20	No	Yes	6

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
2008	VLN mentholated	-1	16JUL2018	6 - 30 minutes	No	The first one in the morning	10 or less	No	No	3
		2	01AUG2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		4	14AUG2018	31 - 60 minutes	No	The first one in the morning	11 - 20	No	No	3
		6	28AUG2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	Yes	5
2009	VLN non-mentholated	-1	16JUL2018	6 - 30 minutes	No	Any other	10 or less	Yes	No	3
		2	31JUL2018	31 - 60 minutes	Yes	The first one in the morning	10 or less	No	No	3
		4	14AUG2018	6 - 30 minutes	Yes	The first one in the morning	10 or less	Yes	No	5
2010	UB mentholated	-1	17JUL2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
		2	01AUG2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		4	14AUG2018	Within 5 minutes	No	Any other	11 - 20	No	No	4
		6	29AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
2011	VLN mentholated	-1	16JUL2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		2	31JUL2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	No	Yes	6

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
2011	VLN mentholated	4	13AUG2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	No	Yes	6
		6	28AUG2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	No	Yes	6
2014	VLN mentholated	-1	17JUL2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	Yes	5
		2	01AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
		4	14AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
		6	29AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
2015	UB mentholated	-1	17JUL2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	No	Yes	6
		2	31JUL2018	6 - 30 minutes	Yes	The first one in the morning	10 or less	Yes	Yes	6
		4	13AUG2018	6 - 30 minutes	Yes	The first one in the morning	10 or less	No	Yes	5
		6	28AUG2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
2016	VLN mentholated	-1	16JUL2018	6 - 30 minutes	No	The first one in the morning	10 or less	Yes	No	4
		2	01AUG2018	6 - 30 minutes	No	Any other	10 or less	No	No	2

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
2017	VLN mentholated	-1	16JUL2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
		2	01AUG2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
		4	13AUG2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
		6	28AUG2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	No	6
2018	UB mentholated	-1	16JUL2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	Yes	5
		2	01AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
		4	14AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
		6	29AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
2020	VLN mentholated	-1	16JUL2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	No	6
		2	31JUL2018	Within 5 minutes	No	Any other	11 - 20	Yes	No	5
		4	13AUG2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5
		6	28AUG2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5
2021	VLN mentholated	-1	17JUL2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
2021	VLN mentholated	2	01AUG2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
		4	14AUG2018	6 - 30 minutes	No	Any other	11 - 20	Yes	No	4
		6	28AUG2018	6 - 30 minutes	No	Any other	10 or less	No	No	2
2023	VLN mentholated	-1	17JUL2018	31 - 60 minutes	No	The first one in the morning	10 or less	No	No	2
		2	01AUG2018	6 - 30 minutes	Yes	Any other	11 - 20	No	No	4
		4	14AUG2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
		6	28AUG2018	31 - 60 minutes	No	The first one in the morning	11 - 20	No	No	3
2024	UB non-mentholated	-1	17JUL2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	No	No	6
2025	UB non-mentholated	-1	16JUL2018	Within 5 minutes	No	The first one in the morning	21 - 30	Yes	No	7
		2	01AUG2018	Within 5 minutes	No	The first one in the morning	21 - 30	Yes	No	7
		4	13AUG2018	Within 5 minutes	No	The first one in the morning	21 - 30	Yes	No	7
		6	28AUG2018	Within 5 minutes	No	The first one in the morning	21 - 30	Yes	Yes	8
2027		-1		Within 5 minutes	Yes	The first one in the morning	21 - 30	No	Yes	
2028	VLN non-mentholated	-1	17JUL2018	6 - 30 minutes	No	Any other	11 - 20	No	Yes	4

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
2028	VLN non-mentholated	2	01AUG2018	6 - 30 minutes	No	Any other	31 or more	No	Yes	6
		4	13AUG2018	6 - 30 minutes	No	Any other	21 - 30	No	Yes	5
		6	29AUG2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
2029	UB mentholated	-1	24JUL2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		2	08AUG2018	Within 5 minutes	No	The first one in the morning	21 - 30	Yes	No	7
		4	21AUG2018	6 - 30 minutes	No	The first one in the morning	21 - 30	Yes	No	6
		6	05SEP2018	Within 5 minutes	Yes	The first one in the morning	21 - 30	Yes	No	8
2035		-1		6 - 30 minutes	Yes	Any other	11 - 20	No	Yes	
2039	VLN mentholated	2	08AUG2018	Within 5 minutes	No	The first one in the morning	10 or less	No	No	4
		4	21AUG2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		6	04SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
2050	UB mentholated	-1	08AUG2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	No	Yes	7
		2	23AUG2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	No	Yes	7

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
2050	UB mentholated	4	04SEP2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	No	Yes	7
		6	20SEP2018	Within 5 minutes	Yes	Any other	11 - 20	No	Yes	6
2052	VLN mentholated	-1	08AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
		2	23AUG2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		4	05SEP2018	6 - 30 minutes	No	The first one in the morning	21 - 30	No	No	5
		6	20SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
2057	VLN mentholated	-1	08AUG2018	31 - 60 minutes	Yes	The first one in the morning	10 or less	No	No	3
		2	23AUG2018	31 - 60 minutes	Yes	The first one in the morning	10 or less	No	No	3
		4	05SEP2018	31 - 60 minutes	Yes	The first one in the morning	10 or less	No	No	3
		6	20SEP2018	31 - 60 minutes	No	The first one in the morning	10 or less	No	No	2
2058	VLN mentholated	-1	08AUG2018	6 - 30 minutes	No	Any other	11 - 20	Yes	No	4
		2	23AUG2018	6 - 30 minutes	No	Any other	10 or less	No	No	2
		4	05SEP2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
		6	19SEP2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
2059	UB mentholated	-1	07AUG2018	6 - 30 minutes	No	Any other	10 or less	No	Yes	3
		2	23AUG2018	6 - 30 minutes	No	Any other	11 - 20	No	Yes	4
		4	04SEP2018	6 - 30 minutes	No	Any other	11 - 20	No	Yes	4
		6	19SEP2018	6 - 30 minutes	No	Any other	11 - 20	No	Yes	4
2060	VLN mentholated	-1	07AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	Yes	6
		2	23AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
		4	05SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
		6	19SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
2064	VLN mentholated	-1	08AUG2018	6 - 30 minutes	No	The first one in the morning	21 - 30	Yes	No	6
		2	23AUG2018	Within 5 minutes	No	The first one in the morning	21 - 30	Yes	No	7
		4	05SEP2018	Within 5 minutes	No	The first one in the morning	21 - 30	Yes	No	7
		6	20SEP2018	6 - 30 minutes	No	The first one in the morning	21 - 30	Yes	No	6
2066	VLN mentholated	-1	08AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		2	23AUG2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
2066	VLN mentholated	4	05SEP2018	Within 5 minutes	No	The first one in the morning	10 or less	Yes	No	5
		6	19SEP2018	Within 5 minutes	No	The first one in the morning	10 or less	Yes	No	5
2067	VLN non-mentholated	-1	08AUG2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
		2	23AUG2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	Yes	6
		4	05SEP2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	No	6
		6	20SEP2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	No	No	5
2075	VLN mentholated	-1	08AUG2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	Yes	6
2076	VLN mentholated	-1	01SEP2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
		2	15SEP2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
		4	29SEP2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
		6	13OCT2018	6 - 30 minutes	No	Any other	10 or less	No	No	2
2086	VLN non-mentholated	-1	01SEP2018	6 - 30 minutes	Yes	Any other	21 - 30	No	No	5
		2	15SEP2018	Within 5 minutes	No	Any other	31 or more	Yes	No	7
		4	29SEP2018	After 60 minutes	No	Any other	21 - 30	No	No	2

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
2088	VLN mentholated	-1	01SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		2	15SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		4	29SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5
		6	13OCT2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5
2092	VLN mentholated	-1	01SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		2	15SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5
		4	29SEP2018	6 - 30 minutes	No	The first one in the morning	10 or less	No	No	3
		6	13OCT2018	6 - 30 minutes	No	The first one in the morning	10 or less	Yes	No	4
2099	VLN non-mentholated	-1	01SEP2018	After 60 minutes	No	Any other	21 - 30	No	Yes	3
		2	16SEP2018	31 - 60 minutes	No	Any other	21 - 30	No	Yes	4
		4	29SEP2018	31 - 60 minutes	No	Any other	21 - 30	No	Yes	4
		6	13OCT2018	31 - 60 minutes	No	Any other	21 - 30	No	Yes	4
2100	UB mentholated	-1	01SEP2018	31 - 60 minutes	No	The first one in the morning	11 - 20	Yes	No	4
		2	16SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	No	5

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
2100	UB mentholated	4	29SEP2018	6 - 30 minutes	No	Any other	11 - 20	Yes	No	4
		6	13OCT2018	6 - 30 minutes	No	Any other	11 - 20	Yes	No	4
2108	VLN non-mentholated	-1	31AUG2018	Within 5 minutes	No	Any other	31 or more	Yes	Yes	8
		2	15SEP2018	Within 5 minutes	No	Any other	31 or more	Yes	Yes	8
		4	29SEP2018	Within 5 minutes	No	Any other	31 or more	Yes	Yes	8
		6	13OCT2018	Within 5 minutes	No	Any other	31 or more	Yes	Yes	8
2110	UB mentholated	-1	06SEP2018	31 - 60 minutes	No	Any other	11 - 20	No	No	2
		2	21SEP2018	After 60 minutes	No	Any other	11 - 20	No	No	1
		4	05OCT2018	After 60 minutes	No	Any other	10 or less	No	No	0
		6	20OCT2018	31 - 60 minutes	No	Any other	10 or less	No	No	1
2113	VLN mentholated	-1	06SEP2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	8
		2	21SEP2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	8
2115	VLN mentholated	-1	06SEP2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
		2	21SEP2018	Within 5 minutes	No	The first one in the morning	10 or less	Yes	Yes	6
2119	VLN mentholated	-1	06SEP2018	6 - 30 minutes	No	The first one in the morning	21 - 30	No	No	5
		2	21SEP2018	Within 5 minutes	No	The first one in the morning	21 - 30	Yes	No	7

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
2119	VLN mentholated	4	04OCT2018	6 - 30 minutes	No	The first one in the morning	21 - 30	Yes	No	6
		6	19OCT2018	6 - 30 minutes	No	The first one in the morning	21 - 30	Yes	No	6
2120	VLN non-mentholated	-1	07SEP2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
		2	21SEP2018	6 - 30 minutes	Yes	The first one in the morning	21 - 30	Yes	Yes	8
		4	04OCT2018	6 - 30 minutes	Yes	The first one in the morning	21 - 30	Yes	Yes	8
		6	20OCT2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
2122	UB non-mentholated	-1	06SEP2018	31 - 60 minutes	Yes	The first one in the morning	11 - 20	Yes	No	5
		2	22SEP2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		4	05OCT2018	31 - 60 minutes	Yes	The first one in the morning	11 - 20	Yes	No	5
		6	19OCT2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	No	6
2125	UB mentholated	-1	06SEP2018	6 - 30 minutes	Yes	The first one in the morning	10 or less	Yes	No	5
		2	21SEP2018	6 - 30 minutes	No	The first one in the morning	10 or less	Yes	No	4

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
2125	UB mentholated	4	05OCT2018	Within 5 minutes	No	The first one in the morning	10 or less	Yes	No	5
		6	19OCT2018	6 - 30 minutes	No	The first one in the morning	10 or less	Yes	No	4
2126	VLN mentholated	-1	06SEP2018	6 - 30 minutes	Yes	Any other	21 - 30	No	Yes	6
		2	21SEP2018	6 - 30 minutes	Yes	Any other	11 - 20	No	Yes	5
		4	04OCT2018	31 - 60 minutes	No	Any other	11 - 20	No	Yes	3
		6	19OCT2018	6 - 30 minutes	No	Any other	11 - 20	No	Yes	4
2136	VLN non-mentholated	-1	07SEP2018	Within 5 minutes	Yes	The first one in the morning	21 - 30	No	Yes	8
		2	22SEP2018	Within 5 minutes	Yes	The first one in the morning	21 - 30	Yes	Yes	9
		4	05OCT2018	Within 5 minutes	Yes	The first one in the morning	21 - 30	Yes	Yes	9
2140	UB non-mentholated	-1	23SEP2018	6 - 30 minutes	Yes	Any other	11 - 20	No	Yes	5
		2	08OCT2018	After 60 minutes	Yes	Any other	11 - 20	No	Yes	3
		4	21OCT2018	6 - 30 minutes	Yes	Any other	11 - 20	No	Yes	5
		6	05NOV2018	After 60 minutes	Yes	Any other	11 - 20	No	Yes	3
2142	VLN non-mentholated	-1	24SEP2018	Within 5 minutes	No	Any other	21 - 30	Yes	Yes	7
2143	VLN non-mentholated	-1	23SEP2018	Within 5 minutes	Yes	The first one in the morning	31 or more	Yes	Yes	10

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
2143	VLN non-mentholated	2	08OCT2018	Within 5 minutes	Yes	The first one in the morning	31 or more	Yes	Yes	10
		4	22OCT2018	Within 5 minutes	Yes	The first one in the morning	31 or more	Yes	Yes	10
		6	05NOV2018	Within 5 minutes	Yes	The first one in the morning	31 or more	Yes	Yes	10
2158	UB non-mentholated	-1	19OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
		2	03NOV2018	6 - 30 minutes	No	Any other	11 - 20	No	No	3
2159	VLN non-mentholated	-1	20OCT2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
		2	03NOV2018	6 - 30 minutes	Yes	The first one in the morning	21 - 30	Yes	Yes	8
		4	16NOV2018	Within 5 minutes	Yes	The first one in the morning	21 - 30	Yes	Yes	9
		6	01DEC2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	8
2164	VLN non-mentholated	-1	19OCT2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	Yes	6
		2	03NOV2018	Within 5 minutes	No	The first one in the morning	21 - 30	Yes	Yes	8
		4	17NOV2018	Within 5 minutes	No	The first one in the morning	31 or more	Yes	Yes	9
		6	01DEC2018	Within 5 minutes	No	Any other	31 or more	Yes	Yes	8

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
2168	VLN non-mentholated	-1	19OCT2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	No	Yes	7
		2	04NOV2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	Yes	No	7
		4	17NOV2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	No	Yes	6
		6	01DEC2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	No	Yes	7
2169		-1		Within 5 minutes	Yes	The first one in the morning	21 - 30	Yes	Yes	
2170	UB non-mentholated	-1	19OCT2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
		2	03NOV2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
		4	17NOV2018	6 - 30 minutes	Yes	Any other	11 - 20	Yes	Yes	6
		6	02DEC2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	8
2175	UB mentholated	-1	19OCT2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	Yes	6
		2	04NOV2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	Yes	6
		4	17NOV2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	Yes	6
		6	01DEC2018	6 - 30 minutes	No	Any other	11 - 20	Yes	Yes	5

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
2189	VLN mentholated	-1	19OCT2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
2210		-1		6 - 30 minutes	No	The first one in the morning	21 - 30	No	Yes	
2211	VLN mentholated	-1	19OCT2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	8
		2	03NOV2018	Within 5 minutes	Yes	The first one in the morning	21 - 30	No	Yes	8
		4	16NOV2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	No	Yes	7
		6	01DEC2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	No	Yes	7
2212	UB mentholated	-1	19OCT2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	No	Yes	6
		2	03NOV2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	No	Yes	6
		4	18NOV2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	No	Yes	7
		6	02DEC2018	6 - 30 minutes	Yes	Any other	11 - 20	No	Yes	5
2213	VLN mentholated	-1	19OCT2018	6 - 30 minutes	Yes	Any other	31 or more	Yes	Yes	8
		2	03NOV2018	6 - 30 minutes	Yes	Any other	31 or more	Yes	Yes	8
		4	17NOV2018	6 - 30 minutes	Yes	Any other	31 or more	Yes	No	7

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
2213	VLN mentholated	6	02DEC2018	Within 5 minutes	No	The first one in the morning	31 or more	Yes	Yes	9
2214		-1		6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	No	
2215	UB mentholated	-1	19OCT2018	Within 5 minutes	No	Any other	10 or less	No	Yes	4
		2	03NOV2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	Yes	6
		4	16NOV2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	Yes	6
		6	01DEC2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
2220	VLN non-mentholated	-1	20OCT2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	Yes	6
		2	04NOV2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
		4	16NOV2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		6	02DEC2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
2224		-1		31 - 60 minutes	No	The first one in the morning	11 - 20	No	No	

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
2235	VLN mentholated	-1	03NOV2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
		2	18NOV2018	6 - 30 minutes	No	The first one in the morning	11 - 20	Yes	Yes	6
		4	01DEC2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
		6	15DEC2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
2244	VLN non-mentholated	-1	03NOV2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	No	Yes	7
		2	18NOV2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	No	Yes	7
		4	01DEC2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	8
		6	15DEC2018	Within 5 minutes	Yes	The first one in the morning	11 - 20	No	Yes	7
2247	VLN mentholated	-1	06DEC2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	No	No	5
2251	UB non-mentholated	-1	07DEC2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	No	4
		2	22DEC2018	6 - 30 minutes	No	The first one in the morning	11 - 20	No	Yes	5
		4	04JAN2019	6 - 30 minutes	No	The first one in the morning	11 - 20	No	Yes	5

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
2251	UB non-mentholated	6	18JAN2019	6 - 30 minutes	No	Any other	11 - 20	No	Yes	4
2257	UB non-mentholated	-1	06DEC2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
		2	22DEC2018	6 - 30 minutes	Yes	The first one in the morning	11 - 20	No	Yes	6
		4	04JAN2019	6 - 30 minutes	Yes	The first one in the morning	11 - 20	Yes	Yes	7
		6	19JAN2019	6 - 30 minutes	Yes	The first one in the morning	11 - 20	No	Yes	6
2259	UB mentholated	-1	06DEC2018	6 - 30 minutes	Yes	Any other	11 - 20	No	Yes	5
		2	22DEC2018	After 60 minutes	Yes	Any other	11 - 20	No	Yes	3
		4	03JAN2019	After 60 minutes	No	The first one in the morning	10 or less	No	Yes	2
		6	18JAN2019	After 60 minutes	Yes	The first one in the morning	10 or less	Yes	Yes	4
2263		-1		6 - 30 minutes	No	Any other	11 - 20	No	No	
2269	VLN mentholated	-1	06DEC2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	No	5
		2	22DEC2018	6 - 30 minutes	No	Any other	11 - 20	No	Yes	4
		4	03JAN2019	6 - 30 minutes	No	Any other	11 - 20	No	No	3
		6	18JAN2019	6 - 30 minutes	No	Any other	10 or less	No	No	2

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?

3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

6. Do you smoke if you are so ill that you are in bed most of the day?

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.12 FTCD Response and Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*						Total Score
				1	2	3	4	5	6	
2272	VLN mentholated	-1	06DEC2018	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	No	6
		2	21DEC2018	Within 5 minutes	No	The first one in the morning	11 - 20	No	Yes	6
		4	04JAN2019	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7
		6	18JAN2019	Within 5 minutes	No	The first one in the morning	11 - 20	Yes	Yes	7

Note: * 1. How soon after you wake up do you smoke your first cigarette? 2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema, etc.)?
 3. Which cigarette would you hate most to give up?; 4. How many cigarettes per day do you smoke?
 5. Do you smoke more frequently during the first hours after waking than during the rest of the day?
 6. Do you smoke if you are so ill that you are in bed most of the day?
 Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
1001	VLN non-mentholated	-1	24JUL2018	3	3	2	3	3	3	3	1	1	1	2.4	2.2
		2	09AUG2018	4	4	4	4	5	5	5	2	2	6	4.8	3.4
		4	22AUG2018	4	2	2	1	2	2	4	1	1	2	2.8	1.4
		6	06SEP2018	6	5	6	6	6	6	6	6	2	6	6.0	5.0
1002	VLN non-mentholated	-1	24JUL2018	7	7	7	7	7	7	7	5	7	7	7.0	6.6
		2	09AUG2018	7	7	7	7	7	7	7	7	7	7	7.0	7.0
		6	07SEP2018	7	7	7	7	7	7	7	7	7	7	7.0	7.0
1003	VLN mentholated	-1	24JUL2018	4	2	3	3	3	3	2	3	3	3	3.0	2.8
		2	09AUG2018	4	2	3	2	4	4	4	1	2	3	3.6	2.2
		6	06SEP2018	5	4	5	3	3	4	4	2	2	4	4.4	2.8
1007	VLN non-mentholated	-1	24JUL2018	3	2	4	3	2	3	2		1	3	3.0	1.8
		2	09AUG2018	4	5	7	3	7	7	1	1	1	7	5.2	3.4
		4	22AUG2018	3	7	7	7	7	7	7	4	7	7	6.2	6.4
		6	06SEP2018	3	3	3	5	4	4	3	3	4	3	3.2	3.8
1008	VLN mentholated	-1	24JUL2018	5	1	6	3	1	6	5	1	2	5	5.4	1.6
		2	09AUG2018	4	2	5	3	3	4	5	2	1	3	4.2	2.2
		4	22AUG2018	5	2	6	1	1	5	7	1	1	4	5.4	1.2
		6	07SEP2018	6	2	6	2	2	7	7	1	1	6	6.4	1.6
1010	UB mentholated	-1	25JUL2018	3	3	3	3	2	2	2	2	2	4	2.8	2.4
		2	09AUG2018	3	2	2	2	2	2	2	2	2	4	2.6	2.0
		4	22AUG2018	3	3	3	3	3	3	3	3	3	3	3.0	3.0
		6	06SEP2018	3	3	4	3	3	3	1	1	2	3	2.8	2.4

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
1011	UB non-mentholated	-1	24JUL2018	4	2	4	4	4	4	4	4	4	4	4.0	3.6
		2	09AUG2018	3	2	4	3	2	2	2	2	2	2	2.6	2.2
		4	22AUG2018	4	4	4	4	4	4	4	4	4	4	4.0	4.0
		6	06SEP2018	4	4	4	4	4	4	4	4	4	4	4.0	4.0
1013	VLN non-mentholated	-1	01AUG2018	5	4	4	3	4	6	6	4	4	5	5.2	3.8
		2	17AUG2018	5	5	5	3	3	5	5	3	2	5	5.0	3.2
		4	30AUG2018	4	4	4	2	4	4	4	2	2	3	3.8	2.8
		6	13SEP2018	4	3	5	3	2	4	4	1	2	3	4.0	2.2
1014	VLN mentholated	-1	01AUG2018	3	2	5	2	1	4	4	1	1	5	4.2	1.4
		2	16AUG2018	4	2	3	1	1	3	3	1	1	3	3.2	1.2
		4	29AUG2018	1	1	1	1	1	1	1	1	1	1	1.0	1.0
		6	14SEP2018	2	2	2	1	1	5	5	1	1	3	3.4	1.2
1015	VLN mentholated	-1	31JUL2018	3	3	5	2	2	4	5	2	1	5	4.4	2.0
		2	17AUG2018	4	4	2	2	2	4	2	2	2	5	3.4	2.4
		4	30AUG2018	6	3	4	2	3	5	5	2	4	2	4.4	2.8
		6	13SEP2018	1	1	2	1	1	1	1	1	1	4	1.8	1.0
1016	UB non-mentholated	-1	31JUL2018	3	3	5	2	2	4	4	3	2	5	4.2	2.4
		2	16AUG2018	4	3	4	2	2	3	2	1	1	5	3.6	1.8
		4	29AUG2018	2	2	2	2	2	2	2	2	2	4	2.4	2.0
		6	13SEP2018	4	3	3	3	3	3	3	1	2	3	3.2	2.4
1017	UB mentholated	-1	01AUG2018	4	4	5	3	3	5	6	3	4	7	5.4	3.4
		2	16AUG2018	4	3	5	4	3	5	5	4	3	6	5.0	3.4

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
1017	UB mentholated	4	29AUG2018	3	3	4	4	3	5	5	4	4	5	4.4	3.6
		6	13SEP2018	5	5	5	3	4	4	4	4	4	4	4.4	4.0
1018	VLN mentholated	-1	01AUG2018	2	2	2	2	3	2	2	2	2	2	2.0	2.2
		2	17AUG2018	1	1	1	1	1	1	1	1	1	1	1.0	1.0
1019	VLN non-mentholated	-1	01AUG2018	3	2	7	2	2	2	4	2	1	5	4.2	1.8
		2	17AUG2018	7	5	7	1	5	7	7	1	1	7	7.0	2.6
		4	29AUG2018	1	1	4	1	1	1	1	1	1	2	1.8	1.0
		6	13SEP2018	3	2	7	1	2	3	7	1	1	3	4.6	1.4
1020	VLN non-mentholated	-1	01AUG2018	3	3	5	1	1	3	3	1	1	4	3.6	1.4
		2	17AUG2018	7	6	7	3	5	7	7	5	1	7	7.0	4.0
		4	30AUG2018	6	5	7	4	3	6	6	1	1	7	6.4	2.8
		6	13SEP2018	7	7	7	7	7	7	7	7	7	7	7.0	7.0
1021	UB non-mentholated	-1	01AUG2018	5	5	5	4	5	5	5	4	2	5	5.0	4.0
		2	16AUG2018	4	4	4	2	4	4	2	2	2	4	3.6	2.8
		4	29AUG2018	4	4	4	2	4	4	4	2	1	2	3.6	2.6
		6	13SEP2018	4	4	4	2	1	3	3	1	1	4	3.6	1.8
1023	VLN non-mentholated	-1	01AUG2018	3	3	6	4	4	4	4	4	4	4	4.2	3.8
		2	17AUG2018	7	6	7	4	5	7	7	6	4	7	7.0	5.0
		4	30AUG2018	4	3	5	4	3	4	4	3	3	4	4.2	3.2
		6	13SEP2018	3	3	4	3	3	3	3	3	2	3	3.2	2.8
1029	VLN mentholated	-1	28AUG2018	1	1	2	2	2	2	2	2	2	2	1.8	1.8

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
1029	VLN mentholated	2	13SEP2018	5	6	6	5	5	6	6	6	4	6	5.8	5.2
		4	25SEP2018	3	3	3	4	3	4	3	3	4	3	3.2	3.4
		6	11OCT2018	7	7	7	5	7	7	7	5	5	7	7.0	5.8
1032	VLN mentholated	-1	27AUG2018	2	1	2	2	2	2	2	1	1	2	2.0	1.4
		2	13SEP2018	6	2	7	5	5	6	5	2	5	6	6.0	3.8
		4	25SEP2018	4	1	2	2	2	2	2	1	5	3	2.6	2.2
		6	10OCT2018	2	1	2	1	1	2	1	1	2	2	1.8	1.2
1034	VLN non-mentholated	-1	27AUG2018	5	6	7	7	7	7	7	5	6	6	6.4	6.2
		2	13SEP2018	7	7	7	7	7	7	7	7	7	7	7.0	7.0
		4	25SEP2018	6	6	7	6	7	6	7	6	6	7	6.6	6.2
		6	10OCT2018	4	3	4	3	4	4	4	5	6	4	4.0	4.2
1035	VLN non-mentholated	-1	27AUG2018	5	5	5	4	4	4	5	1	1	1	4.0	3.0
		2	12SEP2018	6	6	7	5	7	7	7	5	5	7	6.8	5.6
		4	25SEP2018	4	4	4	4	3	4	4	3	3	3	3.8	3.4
		6	11OCT2018	6	6	6	1	5	6	6	5	1	7	6.2	3.6
1036	UB mentholated	-1	28AUG2018	4	4	4	3	3	4	5	3	4	7	4.8	3.4
		4	24SEP2018	6	5	5	5	4	6	5	3	6	7	5.8	4.6
		6	10OCT2018	3	3	4	4	3	3	3	3	5	5	3.6	3.6
1037	UB mentholated	-1	28AUG2018	4	2	4	2	2	3	3	1	2	4	3.6	1.8
		2	12SEP2018	2	2	3	2	1	2	2	1	3	3	2.4	1.8
		4	25SEP2018	3	1	4	2	1	3	2	1	2	4	3.2	1.4
		6	10OCT2018	3	1	3	2	1	3	2	1	2	2	2.6	1.4

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
1038	VLN non-mentholated	-1	28AUG2018	6	4	6	1	1	3	4	1	1	4	4.6	1.6
		2	13SEP2018	4	4	4	1	2	3	4	2	1	6	4.2	2.0
		4	26SEP2018	3	4	3	3	1	1	2	1	1	1	2.0	2.0
		6	10OCT2018	3	3	4	1	2	2	2	1	1	5	3.2	1.6
1042	VLN non-mentholated	-1	28AUG2018	4	4	4	1	3	4	5	1	1	4	4.2	2.0
		2	13SEP2018	7	7	7	4	7	7	7	7	4	7	7.0	5.8
		4	25SEP2018	3	3	3	2	2	1	1	1	1	1	1.8	1.8
		6	11OCT2018	7	6	7	4	6	6	5	2	1	6	6.2	3.8
1045	UB non-mentholated	-1	28AUG2018	2	2	4	1	1	1	1	1	1	2	2.0	1.2
		2	11SEP2018	1	1	1	1	2	2	1	1	1	1	1.2	1.2
		4	25SEP2018	3	1	6	2	1	3	4	2	1	4	4.0	1.4
		6	09OCT2018	2	2	3	1	1	3	4	2	1	2	2.8	1.4
1046	UB mentholated	-1	28AUG2018	5	6	7	5	6	5	5	5	5	6	5.6	5.4
		2	11SEP2018	6	6	6	4	5	6	6	4	3	6	6.0	4.4
		4	24SEP2018	4	4	4	3	3	2	3	1	4	2	3.0	3.0
		6	09OCT2018	4	4	4	3	3	4	5	4	1	3	4.0	3.0
1050	VLN non-mentholated	-1	28AUG2018	6	3	4	4	2	2	3	3	3	3	3.6	3.0
		2	13SEP2018	4	4	4	4	2	3	3	3	3	3	3.4	3.2
		4	25SEP2018	4	4	4	4	2	4	3	3	2	6	4.2	3.0
		6	10OCT2018	3	4	4	4	4	4	4	4	4	4	3.8	4.0
1051	UB mentholated	-1	28AUG2018	4	3	3	3	3	3	3	2	2	5	3.6	2.6
		2	12SEP2018	4	3	3	3	3	4	4	2	3	5	4.0	2.8

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
1051	UB mentholated	4	24SEP2018	3	3	4	3	3	3	4	3	3	4	3.6	3.0
		6	10OCT2018	3	3	3	2	2	2	3	1	2	4	3.0	2.0
1052	VLN mentholated	-1	28AUG2018	4	3	4	1	2	4	3	3	1	3	3.6	2.0
		2	13SEP2018	4	3	4	1	3	4	3	2	1	4	3.8	2.0
		6	11OCT2018	4	3	5	1	3	4	4	2	1	4	4.2	2.0
1053	VLN mentholated	-1	28AUG2018	3	4	6	1	1	3	6	1	1	6	4.8	1.6
		2	12SEP2018	2	2	4	1	1	2	4	1	1	7	3.8	1.2
		4	26SEP2018	1	1	3	1	1	2	3	1	1	3	2.4	1.0
		6	11OCT2018	2	1	4	1	1	2	4	1	1	4	3.2	1.0
1054	UB non-mentholated	-1	27AUG2018	5	5	5	5	5	5	6	4	3	3	4.8	4.4
		2	11SEP2018	5	4	6	2	2	3	6	2	5	3	4.6	3.0
		4	25SEP2018	3	4	5	5	4	5	5	2	3	5	4.6	3.6
		6	10OCT2018	3	3	4	3	2	1	2	1	1	1	2.2	2.0
1055	VLN mentholated	-1	28AUG2018	7	7	7	4	7	7	7	7	4	7	7.0	5.8
		2	13SEP2018	3	3	7	3	4	3	4	3	1	7	4.8	2.8
		4	26SEP2018	3	1	7	2	1	1	4	1	1	4	3.8	1.2
		6	10OCT2018	1	1	1	1	1	1	1	1	1	1	1.0	1.0
1056	VLN non-mentholated	-1	27AUG2018	5	7	7	4	4	6	7	1	1	6	6.2	3.4
		2	13SEP2018	7	7	7	1	4	7	7	1	1	7	7.0	2.8
		4	26SEP2018	4	1	5	1	1	1	4	1	1	1	3.0	1.0
		6	11OCT2018	7	5	7	1	1	6	6	1	1	5	6.2	1.8

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
1058	VLN non-mentholated	-1	28AUG2018	4	4	4	4	4	4	4	4	4	4	4.0	4.0
		2	13SEP2018	7	6	7	4	7	7	7	6	4	7	7.0	5.4
		4	26SEP2018	6	5	4	4	4	4	4	4	4	4	4.4	4.2
		6	11OCT2018	4	4	4	4	4	4	3	2	3	3	3.6	3.4
1059	UB non-mentholated	-1	10SEP2018	6	5	6	3	3	5	4	3	3	4	5.0	3.4
		2	25SEP2018	5	4	5	4	5	5	4	5	3	4	4.6	4.2
		4	08OCT2018	4	5	3	4	4	5	4	3	3	4	4.0	3.8
		6	24OCT2018	5	4	4	3	3	5	4	3	2	5	4.6	3.0
1060	VLN mentholated	-1	10SEP2018	4	4	7	1	3	1	4	1	4	7	4.6	2.6
		2	26SEP2018	7	4	7	1	7	7	7	1	1	7	7.0	2.8
		4	09OCT2018	7	7	7	1	7	7	7	1	1	7	7.0	3.4
		6	24OCT2018	4	4	4	1	4	1	4	1	1	7	4.0	2.2
1063	VLN mentholated	-1	10SEP2018	6	7	6	4	5	6	6	4	1	5	5.8	4.2
		2	27SEP2018	4	4	6	3	3	4	5	2	1	6	5.0	2.6
		4	09OCT2018	2	3	2	2	1	3	2	1	1	2	2.2	1.6
		6	24OCT2018	2	2	3	1	1	2	1	1	1	2	2.0	1.2
1064	UB non-mentholated	-1	10SEP2018	3	3	3	3	3	3	3	1	3	3	3.0	2.6
		2	25SEP2018	3	3	6	3	3	4	4	2	2	2	3.8	2.6
1066	VLN non-mentholated	-1	11SEP2018	3	1	1	1	1	2	2	1	1	1	1.8	1.0
		2	26SEP2018	3	1	5	1	1	2	2	1	1	3	3.0	1.0
		4	09OCT2018	1	1	2	1	1	1	1	1	1	5	2.0	1.0
		6	23OCT2018	1	1	1	1	1	1	1	1	1	1	1.0	1.0

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
1069	UB non-mentholated	-1	11SEP2018	4	4	4	4	4	4	4	4	5	4	4.0	4.2
		2	26SEP2018	3	3	5	4	3	3	4	2	3	4	3.8	3.0
		4	09OCT2018	4	3	5	3	3	3	4	3	3	4	4.0	3.0
		6	24OCT2018	4	4	5	2	2	2	2	2	3	4	3.4	2.6
1070	VLN non-mentholated	-1	10SEP2018	7	6	7	5	5	6	7	5	4	7	6.8	5.0
		2	26SEP2018	5	5	7	4	4	6	6	4	4	7	6.2	4.2
		4	08OCT2018	4	4	3	3	2	3	5	2	2	3	3.6	2.6
		6	24OCT2018	3	2	3	2	1	1	2	2	1	2	2.2	1.6
1071	VLN non-mentholated	-1	10SEP2018	4	4	7	4	4	4	4	1	1	7	5.2	2.8
		2	25SEP2018	7	7	7	7	7	7	7	4	7	7	7.0	6.4
		4	08OCT2018	3	2	1	3	2	3	2	2	2	1	2.0	2.2
1072	VLN mentholated	-1	10SEP2018	4	2	3	1	2	3	3	1	1	3	3.2	1.4
		2	27SEP2018	3	1	3	1	1	3	3	1	1	3	3.0	1.0
		4	09OCT2018	4	7	4	7	1	4	4	1	1	1	3.4	3.4
1074	VLN non-mentholated	-1	10SEP2018	6	6	6	4	4	5	6	4	3	5	5.6	4.2
		2	26SEP2018	7	6	7	5	5	7	7	6	4	7	7.0	5.2
		4	09OCT2018	7	6	6	4	5	6	4	4	2	4	5.4	4.2
		6	23OCT2018	7	5	7	4	5	7	6	6	2	5	6.4	4.4
1075	UB non-mentholated	-1	10SEP2018	2	3	2	3	4	4	4	4	1	3	3.0	3.0
		2	26SEP2018	4	4	6	2	4	5	5	3	1	4	4.8	2.8
		4	09OCT2018	4	4	4	1	3	4	4	4	1	3	3.8	2.6
		6	24OCT2018	4	4	4	2	4	4	4	4	1	4	4.0	3.0

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
1077	VLN non-mentholated	-1	10SEP2018	2	1	2	1	1	2	2	1	2	1	1.8	1.2
		2	26SEP2018	3	3	5	1	1	3	5	3	1	3	3.8	1.8
		4	09OCT2018	3	1	3	1	1	2	3	1	1	2	2.6	1.0
		6	24OCT2018	3	2	3	1	1	3	3	1	1	3	3.0	1.2
1078	VLN non-mentholated	-1	11SEP2018	4	3	5	2	3	3	3	3	4	3	3.6	3.0
		2	25SEP2018	3	3	5	4	3	3	5	4	3	4	4.0	3.4
		4	09OCT2018	5	5	6	3	4	5	5	3	2	5	5.2	3.4
		6	24OCT2018	5	4	5	3	3	4	6	4	2	5	5.0	3.2
1079	VLN mentholated	-1	11SEP2018	5	4	6	4	4	4	5	3	3	4	4.8	3.6
		2	26SEP2018	4	4	5	4	4	5	6	4	3	6	5.2	3.8
		4	09OCT2018	5	5	5	5	4	6	5	5	4	6	5.4	4.6
		6	24OCT2018	2	1	2	2	1	1	1	1	1	1	1.4	1.2
1082	VLN non-mentholated	-1	10SEP2018	5	3	7	3	4	6	6	3	3	6	6.0	3.2
		2	26SEP2018	4	4	6	2	3	3	5	3	2	4	4.4	2.8
		4	09OCT2018	3	2	3	1	2	3	3	2	1	3	3.0	1.6
		6	24OCT2018	3	3	5	2	3	3	3	1	1	5	3.8	2.0
1083	VLN non-mentholated	-1	17SEP2018	3	3	4	4	2	2	2	2	4	2	2.6	3.0
		2	03OCT2018	5	5	5	4	4	4	4	5	4	4	4.4	4.4
		4	16OCT2018	2	2	4	4	2	2	2	1	3	5	3.0	2.4
		6	31OCT2018	2	2	5	2	2	3	2	2	3	3	3.0	2.2
1084	VLN non-mentholated	-1	17SEP2018	3	3	3	3	1	2	2	1	3	2	2.4	2.2
		2	03OCT2018	2	3	3	1	2	2	3	3	3	1	2.2	2.4

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
1084	VLN non-mentholated	4	16OCT2018	3	2	3	1	4	4	4	6	1	3	3.4	2.8
1086	VLN non-mentholated	-1	18SEP2018	5	3	1	1	3	4	2	3	3	1	2.6	2.6
		2	02OCT2018	6	6	6	6	6	6	6	6	6	6	6.0	6.0
		4	15OCT2018	4	3	4	4	3	4	3	3	5	3	3.6	3.6
		6	30OCT2018	3	6	6	5	3	3	3	3	4	6	4.2	4.2
1088	VLN mentholated	-1	18SEP2018	4	3	4	3	3	3	3	1	1	3	3.4	2.2
		2	03OCT2018	2	2	3	3	2	2	4	1	1	2	2.6	1.8
		4	16OCT2018	3	3	3	2	1	3	2	1	1	3	2.8	1.6
		6	31OCT2018	2	2	2	2	1	2	2	1	1	2	2.0	1.4
1089	UB non-mentholated	-1	17SEP2018	3	3	3	1	1	3	2	1	1	1	2.4	1.4
		2	02OCT2018	3	2	3	1	1	3	3	1	1	3	3.0	1.2
		4	15OCT2018	2	1	1	1	1	1	1	1	1	1	1.2	1.0
		6	30OCT2018	2	2	2	1	1	2	2	1	1	2	2.0	1.2
1092	VLN mentholated	-1	18SEP2018	4	2	5	1	1	3	4	1	1	3	3.8	1.2
		2	03OCT2018	4	1	4	1	2	3	3	1	1	2	3.2	1.2
		4	16OCT2018	3	1	3	1	1	2	2	1	1	2	2.4	1.0
		6	31OCT2018	2	6	4	1	1	2	2	1	1	3	2.6	2.0
1094	VLN mentholated	-1	18SEP2018	3	3	3	3	3	3	3	3	3	3	3.0	3.0
		2	02OCT2018	5	4	4	2	2	3	3	2	1	1	3.2	2.2
		4	15OCT2018	3	3	3	3	3	3	3	3	1	3	3.0	2.6
		6	31OCT2018	5	5	5	2	3	4	5	2	1	4	4.6	2.6

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
1095	VLN mentholated	-1	17SEP2018	3	3	2	2	1	1	1	1	1	1	1.6	1.6
		2	02OCT2018	3	1	2	1	1	1	1	1	1	1	1.6	1.0
		4	15OCT2018	1	2	1	2	1	4	3	1	4	4	2.6	2.0
		6	30OCT2018	2	3	2	2	2	3	2	1	5	2	2.2	2.6
1096	VLN non-mentholated	-1	18SEP2018	2	1	2	2	2	1	1	2	1	2	1.6	1.6
		2	27SEP2018	7	7	7	3	4	7	7	3	1	7	7.0	3.6
		4	16OCT2018	1	1	4	1	1	1	4	1	1	6	3.2	1.0
		6	31OCT2018	2	6	2	6	6	2	4	6	6	2	2.4	6.0
1097	VLN mentholated	-1	18SEP2018	6	2	1	2	1	1	1	1	1	2	2.2	1.4
		2	03OCT2018	1	1	1	1	1	1	1	1	1	1	1.0	1.0
		4	16OCT2018	5	4	4	4	4	4	4	1	1	7	4.8	2.8
		6	31OCT2018	1	1	1	1	1	1	1	1	1	7	2.2	1.0
1098	VLN non-mentholated	-1	04OCT2018	2	2	2	2	1	1	1	1	2	3	1.8	1.6
		6	16NOV2018	5	4	6	3	3	4	5	2	2	6	5.2	2.8
1099	VLN non-mentholated	-1	04OCT2018	3	5	5	6	5	3	5	2	6	4	4.0	4.8
		2	19OCT2018	6	7	6	6	7	7	7	6	1	6	6.4	5.4
		4	01NOV2018	5	3	4	5	3	3	3	2	2	2	3.4	3.0
		6	16NOV2018	6	6	7	2	7	6	7	6	2	7	6.6	4.6
1100	VLN non-mentholated	-1	04OCT2018	2	2	2	2	2	2	2	2	2	2	2.0	2.0
		2	19OCT2018	3	4	4	3	4	3	4	4	3	4	3.6	3.6
		4	01NOV2018	3	2	2	2	2	2	2	2	2	2	2.2	2.0
		6	16NOV2018	2	2	2	2	2	2	2	2	2	2	2.0	2.0

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
 Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
 Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
1101	VLN non-mentholated	-1	03OCT2018	5	4	7	1	2	3	5	3	5	7	5.4	3.0
		6	16NOV2018	5	5	6	4	7	7	7	7	6	7	6.4	5.8
1103	VLN non-mentholated	-1	03OCT2018	5	4	7	3	4	5	6	3	2	7	6.0	3.2
		2	19OCT2018	5	5	5	3	3	3	3	2	2	5	4.2	3.0
		4	01NOV2018	4	2	4	4	3	6	6	2	2	5	5.0	2.6
		6	16NOV2018	6	4	5	2	5	3	5	6	3	5	4.8	4.0
1105	VLN non-mentholated	-1	03OCT2018	3	2	3	1	2	3	4	2	1	6	3.8	1.6
		2	19OCT2018	7	6	7	2	7	7	7	3	1	7	7.0	3.8
		4	02NOV2018	5	3	5	1	5	4	5	2	1	5	4.8	2.4
		6	16NOV2018	6	5	7	1	4	7	7	1	1	6	6.6	2.4
1106	UB non-mentholated	-1	04OCT2018	1	2	2	3	2	2	2	2	2	3	2.0	2.2
		2	19OCT2018	3	2	2	2	2	2	2	2	3	2	2.2	2.2
		4	31OCT2018	3	2	3	4	2	3	3	2	3	3	3.0	2.6
		6	16NOV2018	1	1	1	2	2	2	2	2	2	2	1.6	1.8
1107	VLN non-mentholated	-1	04OCT2018	6	6	6	6	6	6	5	5	4	4	5.4	5.4
		2	19OCT2018	5	5	5	4	5	6	6	4	4	4	5.2	4.4
		4	02NOV2018	3	4	4	4	4	4	4	6	5	3	3.6	4.6
		6	16NOV2018	5	5	5	4	4	5	5	3	2	4	4.8	3.6
1108	UB non-mentholated	-1	03OCT2018	3	3	3	3	1	2	2	2	2	5	3.0	2.2
		2	18OCT2018	4	3	4	4	3	4	4	3	3	5	4.2	3.2
		4	31OCT2018	4	3	4	2	4	4	4	1	1	2	3.6	2.2
		6	15NOV2018	6	4	7	4	4	5	5	3	2	7	6.0	3.4

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
1109	UB non-mentholated	-1	04OCT2018	4	4	1	1	1	1	1	1	1	1	1.6	1.6
		2	19OCT2018	1	1	1	1	1	1	1	1	1	4	1.6	1.0
		4	01NOV2018	1	1	1	1	1	1	1	1	1	1	1.0	1.0
		6	16NOV2018	1	1	1	1	1	1	2	1	1	1	1.2	1.0
1112	VLN non-mentholated	-1	03OCT2018	2	3	3	2	2	2	3	1	1	4	2.8	1.8
		2	19OCT2018	3	3	3	3	3	3	3	3	3	3	3.0	3.0
		4	02NOV2018	4	4	5	3	4	5	4	2	2	6	4.8	3.0
		6	16NOV2018	6	5	5	3	5	5	6	4	2	6	5.6	3.8
1114	UB non-mentholated	-1	03OCT2018	2	1	5	5	2	2	5	2	2	5	3.8	2.4
		2	18OCT2018	4	5	7	5	5	5	5	2	2	6	5.4	3.8
		4	01NOV2018	1	2	5	3	3	2	2	2	2	5	3.0	2.4
		6	15NOV2018	5	5	3	3	3	3	3	1	1	2	3.2	2.6
1115	VLN non-mentholated	-1	03OCT2018	2	2	1	1	1	2	1	1	1	1	1.4	1.2
		2	19OCT2018	5	2	5	1	2	4	4	1	1	3	4.2	1.4
		4	02NOV2018	5	3	1	1	1	1	1	1	1	1	1.8	1.4
2002	UB mentholated	-1	23JUL2018	6	6	6	6	6	6	6	5	5	6	6.0	5.6
		2	08AUG2018	6	6	6	6	6	6	6	5	5	6	6.0	5.6
		4	21AUG2018	6	6	6	6	6	6	6	5	5	6	6.0	5.6
		6	05SEP2018	6	6	6	6	6	6	6	5	5	6	6.0	5.6
2003	VLN mentholated	-1	16JUL2018	7	7	7	2	7	7	7	7	1	7	7.0	4.8
		2	31JUL2018	7	7	7	1	7	7	7	7	1	7	7.0	4.6
		4	14AUG2018	7	4	7	2	7	7	7	7	1	7	7.0	4.2

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
2003	VLN mentholated	6	28AUG2018	7	7	7	1	7	7	7	7	1	7	7.0	4.6
2007	VLN non-mentholated	-1	16JUL2018	3	3	6	6	5	6	6	5	4	6	5.4	4.6
		2	01AUG2018	6	4	6	4	4	6	6	5	4	7	6.2	4.2
		4	14AUG2018	6	5	7	5	5	6	6	5	4	6	6.2	4.8
		6	29AUG2018	5	5	7	4	4	6	7	4	4	6	6.2	4.2
2008	VLN mentholated	-1	16JUL2018	7	7	7	5	7	7	7	3	3	7	7.0	5.0
		2	01AUG2018	5	5	5	5	5	5	6	3	3	5	5.2	4.2
		4	14AUG2018	5	5	5	4	5	5	5	5	6	6	5.2	5.0
		6	28AUG2018	5	5	5	3	4	3	5	5	5	5	4.6	4.4
2009	VLN non-mentholated	-1	16JUL2018	5	4	4	5	5	5	6	2	3	5	5.0	3.8
		2	31JUL2018	4	4	3	4	4	4	4	2	2	5	4.0	3.2
		4	14AUG2018	2	3	2	3	3	3	4	3	3	6	3.4	3.0
2010	UB mentholated	-1	17JUL2018	4	4	4	4	4	4	4	4	4	4	4.0	4.0
		2	01AUG2018	4	4	4	4	4	4	4	4	4	4	4.0	4.0
		4	14AUG2018	4	4	4	3	3	3	3	3	3	3	3.4	3.2
		6	29AUG2018	4	3	3	3	3	3	3	3	3	3	3.2	3.0
2011	VLN mentholated	-1	16JUL2018	5	7	7	4	7	6	7	7	3	7	6.4	5.6
		2	31JUL2018	7	7	7	5	7	7	7	7	5	7	7.0	6.2
		4	13AUG2018	7	7	7	5	5	5	7	6	3	5	6.2	5.2
		6	28AUG2018	4	6	5	3	4	4	4	4	1	5	4.4	3.6
2014	VLN mentholated	-1	17JUL2018	2	2	2	2	1	2	4	1	1	3	2.6	1.4

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
2014	VLN mentholated	2	01AUG2018	5	3	4	2	2	5	5	2	2	4	4.6	2.2
		4	14AUG2018	4	2	4	2	2	4	4	2	1	2	3.6	1.8
		6	29AUG2018	4	2	4	2	1	5	5	1	1	3	4.2	1.4
2015	UB mentholated	-1	17JUL2018	1	7	6	4	5	6	5	5	3	5	4.6	4.8
		2	31JUL2018	6	6	6	3	6	6	6	6	2	6	6.0	4.6
		4	13AUG2018	5	6	7	3	5	4	6	6	2	5	5.4	4.4
		6	28AUG2018	6	7	7	3	6	7	7	7	3	7	6.8	5.2
2016	VLN mentholated	-1	16JUL2018	5	4	5	4	4	4	4	4	4	4	4.4	4.0
		2	01AUG2018	3	3	3	3	3	3	3	3	3	3	3.0	3.0
2017	VLN mentholated	-1	16JUL2018	3	3	3	3	3	4	3	2	6	3	3.2	3.4
		2	01AUG2018	4	3	3	4	4	4	5	3	6	3	3.8	4.0
		4	13AUG2018	4	3	6	2	4	4	4	4	4	6	4.8	3.4
		6	28AUG2018	5	5	5	4	5	5	5	3	1	5	5.0	3.6
2018	UB mentholated	-1	16JUL2018	7	7	7	7	4	7	7	4	7	7	7.0	5.8
		2	01AUG2018	7	7	7	3	7	7	7	1	5	7	7.0	4.6
		4	14AUG2018	4	4	4	5	1	1	3	1	1	6	3.6	2.4
		6	29AUG2018	7	7	7	4	7	7	7	3	1	7	7.0	4.4
2020	VLN mentholated	-1	16JUL2018	1	1	7	1	1	1	7	1	7	7	4.6	2.2
		2	31JUL2018	1	1	1	1	1	1	1	1	1	1	1.0	1.0
		4	13AUG2018	4	4	6	4	4	4	4	4	1	4	4.4	3.4
		6	28AUG2018	4	4	5	4	4	4	4	4	4	4	4.2	4.0

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
2021	VLN mentholated	-1	17JUL2018	2	2	3	2	1	2	2	1	1	3	2.4	1.4
		2	01AUG2018	1	1	1	1	1	2	1	1	1	2	1.4	1.0
		4	14AUG2018	1	1	1	1	1	1	1	1	1	3	1.4	1.0
		6	28AUG2018	1	1	1	1	1	1	1	1	1	1	1.0	1.0
2023	VLN mentholated	-1	17JUL2018	3	4	2	1	1	1	3	1	1	1	2.0	1.6
		2	01AUG2018	1	1	1	1	1	1	1	1	1	1	1.0	1.0
		4	14AUG2018	2	2	2	1	1	1	1	1	1	1	1.4	1.2
		6	28AUG2018	1	1	1	1	1	1	1	1	1	1	1.0	1.0
2024	UB non-mentholated	-1	17JUL2018	5	1	7	5	4	5	5	1	1	7	5.8	2.4
2025	UB non-mentholated	-1	16JUL2018	4	4	4	2	3	4	4	2	2	4	4.0	2.6
		2	01AUG2018	4	4	4	2	2	4	4	2	2	3	3.8	2.4
		4	13AUG2018	4	3	3	1	2	3	3	1	1	2	3.0	1.6
		6	28AUG2018	4	3	5	2	3	3	4	2	2	4	4.0	2.4
2028	VLN non-mentholated	-1	17JUL2018	5	5	7	7	7	7	7	7	7	7	6.6	6.6
		2	01AUG2018	4	4	4	4	4	5	4	4	7	7	4.8	4.6
		4	13AUG2018	3	3	3	3	2	1	1	1	3	2	2.0	2.4
		6	29AUG2018	1	1	1	1	1	2	1	1	1	1	1.2	1.0
2029	UB mentholated	-1	24JUL2018	3	3	5	3	3	4	4	4	3	3	3.8	3.2
		2	08AUG2018	4	4	4	4	3	4	4	2	3	4	4.0	3.2
		4	21AUG2018	3	3	5	2	3	2	2	1	1	2	2.8	2.0
		6	05SEP2018	4	4	5	2	3	3	4	4	2	4	4.0	3.0

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
2039	VLN mentholated	2	08AUG2018	4	4	4	4	4	4	4	4	3	4	4.0	3.8
		4	21AUG2018	4	4	4	3	4	5	4	3	1	4	4.2	3.0
		6	04SEP2018	4	4	4	1	3	2	4	1	1	3	3.4	2.0
2050	UB mentholated	-1	08AUG2018	5	5	5	5	5	5	4	2	4	5	4.8	4.2
		2	23AUG2018	6	6	6	6	6	6	6	1	2	6	6.0	4.2
		4	04SEP2018	4	4	4	5	3	3	3	1	3	2	3.2	3.2
		6	20SEP2018	5	4	4	4	5	5	5	5	2	5	4.8	4.0
2052	VLN mentholated	-1	08AUG2018	4	4	4	2	3	3	5	2	2	4	4.0	2.6
		2	23AUG2018	2	2	2	1	2	2	2	2	2	2	2.0	1.8
		4	05SEP2018	3	3	4	1	1	3	5	1	1	4	3.8	1.4
		6	20SEP2018	2	2	2	2	2	2	2	2	1	2	2.0	1.8
2057	VLN mentholated	-1	08AUG2018	4	3	4	2	4	4	4	2	2	4	4.0	2.6
		2	23AUG2018	2	3	4	2	2	2	2	1	2	2	2.4	2.0
		4	05SEP2018	4	3	5	2	4	4	5	1	2	4	4.4	2.4
		6	20SEP2018	4	4	5	2	3	3	3	2	2	2	3.4	2.6
2058	VLN mentholated	-1	08AUG2018	4	4	4	4	4	4	4	4	1	5	4.2	3.4
		2	23AUG2018	1	4	7	1	1	1	3	7	4	4	3.2	3.4
		4	05SEP2018	2	2	5	4	5	3	4	4	1	4	3.6	3.2
		6	19SEP2018	4	4	4	4	4	4	4	4	1	3	3.8	3.4
2059	UB mentholated	-1	07AUG2018	5	4	6	1	6	4	6	4	6	6	5.4	4.2
		2	23AUG2018	4	4	6	4	3	4	7	4	5	5	5.2	4.0
		4	04SEP2018	5	5	5	3	3	3	6	5	3	5	4.8	3.8

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
2059	UB mentholated	6	19SEP2018	3	4	6	3	3	3	6	3	6	4	4.4	3.8
2060	VLN mentholated	-1	07AUG2018	4	4	5	2	3	4	3	2	1	3	3.8	2.4
		2	23AUG2018	4	3	4	1	2	5	3	1	1	5	4.2	1.6
		4	05SEP2018	4	3	6	2	2	3	4	2	1	6	4.6	2.0
		6	19SEP2018	2	3	5	2	1	1	4	1	1	4	3.2	1.6
2064	VLN mentholated	-1	08AUG2018	4	5	4	1	1	2	5	2	1	3	3.6	2.0
		2	23AUG2018	2	3	4	1	2	1	3	1	1	1	2.2	1.6
		4	05SEP2018	2	2	1	2	2	2	5	1	1	3	2.6	1.6
		6	20SEP2018	2	2	2	1	2	2	4	2	1	2	2.4	1.6
2066	VLN mentholated	-1	08AUG2018	3	4	5	3	3	4	4	1	3	3	3.8	2.8
		2	23AUG2018	7	4	5	4	4	4	5	1	4	6	5.4	3.4
		4	05SEP2018	5	4	4	4	4	4	4	1	1	4	4.2	2.8
		6	19SEP2018	2	2	2	2	2	2	2	2	2	2	2.0	2.0
2067	VLN non-mentholated	-1	08AUG2018	4	4	5	3	4	5	4	4	3	4	4.4	3.6
		2	23AUG2018	3	3	4	4	4	5	4	4	4	4	4.0	3.8
		4	05SEP2018	3	3	3	3	3	3	2	3	3	3	2.8	3.0
		6	20SEP2018	3	3	3	3	4	3	3	3	3	4	3.2	3.2
2075	VLN mentholated	-1	08AUG2018	3	3	1	1	2	7	7	1	1	7	5.0	1.6
2076	VLN mentholated	-1	01SEP2018	4	4	4	4	4	4	7	4	4	4	4.6	4.0
		2	15SEP2018	3	3	3	1	1	1	3	1	1	1	2.2	1.4
		4	29SEP2018	3	2	3	1	1	2	2	1	1	3	2.6	1.2

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
2076	VLN mentholated	6	13OCT2018	1	1	2	1	2	2	2	1	1	2	1.8	1.2
2086	VLN non-mentholated	-1	01SEP2018	4	4	4	1	4	4	3	1	1	4	3.8	2.2
		2	15SEP2018	7	3	7	4	4	4	4	4	1	4	5.2	3.2
		4	29SEP2018	1	2	2	1	2	1	1	1	1	1	1.2	1.4
2088	VLN mentholated	-1	01SEP2018	3	2	3	2	2	3	3	1	1	2	2.8	1.6
		2	15SEP2018	4	3	3	1	2	3	3	2	1	2	3.0	1.8
		4	29SEP2018	3	3	3	2	2	3	3	2	2	2	2.8	2.2
		6	13OCT2018	2	2	2	1	2	2	2	1	1	1	1.8	1.4
2092	VLN mentholated	-1	01SEP2018	1	1	1	1	1	1	1	1	1	1	1.0	1.0
		2	15SEP2018	1	1	1	1	1	1	1	1	1	1	1.0	1.0
		4	29SEP2018	1	1	1	1	1	1	1	1	1	1	1.0	1.0
		6	13OCT2018	3	1	3	1	1	3	3	1	1	1	2.6	1.0
2099	VLN non-mentholated	-1	01SEP2018	2	2	2	2	2	2	2	2	2	2	2.0	2.0
		2	16SEP2018	2	2	3	1	1	1	1	1	1	1	1.6	1.2
		4	29SEP2018	4	3	5	1	1	3	3	2	1	5	4.0	1.6
		6	13OCT2018	2	2	3	1	1	1	2	2	1	3	2.2	1.4
2100	UB mentholated	-1	01SEP2018	4	1	1	1	1	2	2	1	1	1	2.0	1.0
		2	16SEP2018	1	1	1	1	1	1	1	1	1	1	1.0	1.0
		4	29SEP2018	1	1	1	1	1	1	1	1	1	2	1.2	1.0
		6	13OCT2018	3	1	2	1	1	2	2	1	1	1	2.0	1.0
2108	VLN non-mentholated	-1	31AUG2018	7	4	7	4	6	7	7	3	3	7	7.0	4.0

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
2108	VLN non-mentholated	2	15SEP2018	7	6	7	7	6	7	7	5	5	7	7.0	5.8
		4	29SEP2018	3	3	6	4	3	5	6	2	3	7	5.4	3.0
		6	13OCT2018	4	3	3	2	2	4	4	1	2	6	4.2	2.0
2110	UB mentholated	-1	06SEP2018	1	1	1	1	1	1	1	1	1	1	1.0	1.0
		2	21SEP2018	1	1	1	1	1	1	1	1	1	1	1.0	1.0
		4	05OCT2018	1	1	1	1	1	1	1	1	1	1	1.0	1.0
		6	20OCT2018	1	1	1	1	1	1	1	1	1	1	1.0	1.0
2113	VLN mentholated	-1	06SEP2018	7	7	7	7	7	7	7	7	7	7	7.0	7.0
		2	21SEP2018	7	7	7	7	7	7	7	6	7	7	7.0	6.8
2115	VLN mentholated	-1	06SEP2018	5	5	6	6	5	5	6	5	5	7	5.8	5.2
		2	21SEP2018	4	5	5	4	3	4	5	3	4	5	4.6	3.8
2119	VLN mentholated	-1	06SEP2018	3	1	2	1	2	4	2	1	2	2	2.6	1.4
		2	21SEP2018	4	1	2	3	2	1	3	1	1	1	2.2	1.6
		4	04OCT2018	3	2	1	2	1	2	2	1	3	3	2.2	1.8
		6	19OCT2018	4	2	2	1	1	2	2	1	1	1	2.2	1.2
2120	VLN non-mentholated	-1	07SEP2018	7	4	7	2	2	7	7	2	2	7	7.0	2.4
		2	21SEP2018	5	1	7	2	1	6	7	1	2	6	6.2	1.4
		4	04OCT2018	4	2	5	3	2	6	3	1	2	5	4.6	2.0
		6	20OCT2018	4	1	2	2	2	3	4	1	2	2	3.0	1.6
2122	UB non-mentholated	-1	06SEP2018	4	4	1	3	4	4	5	2	5	4	3.6	3.6
		2	22SEP2018	3	3	4	4	4	3	4	2	3	3	3.4	3.2

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
2122	UB non-mentholated	4	05OCT2018	3	4	5	3	4	4	4	2	3	4	4.0	3.2
		6	19OCT2018	4	4	1	3	4	3	3	3	2	1	2.4	3.2
2125	UB mentholated	-1	06SEP2018	4	4	5	3	3	3	3	1	3	4	3.8	2.8
		2	21SEP2018	5	4	5	3	3	3	4	1	1	4	4.2	2.4
		4	05OCT2018	4	4	4	2	2	3	4	1	1	5	4.0	2.0
		6	19OCT2018	3	3	3	3	2	2	2	1	1	2	2.4	2.0
2126	VLN mentholated	-1	06SEP2018	4	4	4	4	4	4	4	3	1	3	3.8	3.2
		2	21SEP2018	2	2	3	1	1	2	2	1	1	1	2.0	1.2
		4	04OCT2018	2	2	2	1	1	2	2	1	1	2	2.0	1.2
		6	19OCT2018	2	2	5	2	2	3	2	1	1	3	3.0	1.6
2136	VLN non-mentholated	-1	07SEP2018	3	3	5	2	3	3	3	1	2	5	3.8	2.2
		2	22SEP2018	3	3	4	2	2	4	4	2	2	5	4.0	2.2
		4	05OCT2018	3	3	3	2	3	3	4	1	2	5	3.6	2.2
2140	UB non-mentholated	-1	23SEP2018	5	5	5	5	5	5	4	4	6	4	4.6	5.0
		2	08OCT2018	6	6	7	5	7	7	7	5	2	7	6.8	5.0
		4	21OCT2018	5	5	5	5	3	3	3	3	4	3	3.8	4.0
		6	05NOV2018	6	6	6	4	7	7	7	5	1	7	6.6	4.6
2142	VLN non-mentholated	-1	24SEP2018	6	6	7	3	5	7	7	5	3	7	6.8	4.4
2143	VLN non-mentholated	-1	23SEP2018	4	4	5	3	4	4	4	3	5	5	4.4	3.8
		2	08OCT2018	6	6	6	5	5	5	5	5	6	6	5.6	5.4
		4	22OCT2018	3	3	4	4	4	4	4	2	4	5	4.0	3.4

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
2143	VLN non-mentholated	6	05NOV2018	3	4	3	3	3	3	3	2	4	6	3.6	3.2
2158	UB non-mentholated	-1	19OCT2018	5	3	5	2	5	5	5	3	3	5	5.0	3.2
		2	03NOV2018	3	3	4	2	2	2	2	2	4	2	2.6	2.6
2159	VLN non-mentholated	-1	20OCT2018	7	7	7	7	5	5	5	5	7	5	5.8	6.2
		2	03NOV2018	5	5	5	5	5	5	5	4	5	5	5.0	4.8
		4	16NOV2018	5	5	5	5	5	5	5	5	5	5	5.0	5.0
		6	01DEC2018	5	5	5	5	5	5	5	5	5	5	5.0	5.0
2164	VLN non-mentholated	-1	19OCT2018	6	6	6	6	6	6	6	2	1	6	6.0	4.2
		2	03NOV2018	7	7	7	3	7	7	7	3	2	5	6.6	4.4
		4	17NOV2018	7	7	7	1	7	7	7	2	1	7	7.0	3.6
		6	01DEC2018	7	7	7	1	7	7	7	1	1	7	7.0	3.4
2168	VLN non-mentholated	-1	19OCT2018	7	7	7	5	5	7	7	4	1	7	7.0	4.4
		2	04NOV2018	7	7	7	4	5	6	6	5	2	6	6.4	4.6
		4	17NOV2018	6	6	7	4	3	5	5	3	1	6	5.8	3.4
		6	01DEC2018	6	4	6	3	5	5	5	4	1	7	5.8	3.4
2170	UB non-mentholated	-1	19OCT2018	1	1	1	1	1	3	2	1	7	7	2.8	2.2
		2	03NOV2018	1	1	1	1	1	1	1	1	7	2	1.2	2.2
		4	17NOV2018	7	7	7	5	7	7	7	6	7	7	7.0	6.4
		6	02DEC2018	3	3	3	5	3	3	3	5	5	1	2.6	4.2
2175	UB mentholated	-1	19OCT2018	4	4	4	4	4	4	4	4	4	4	4.0	4.0
		2	04NOV2018	4	4	4	4	4	4	5	4	4	4	4.2	4.0

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
2175	UB mentholated	4	17NOV2018	5	5	7	4	4	6	6	4	1	7	6.2	3.6
		6	01DEC2018	4	4	4	4	4	4	4	4	4	4	4.0	4.0
2189	VLN mentholated	-1	19OCT2018	7	5	7	5	6	6	7	4	4	7	6.8	4.8
2211	VLN mentholated	-1	19OCT2018	7	7	7	7	7	7	7	7	7	7	7.0	7.0
		2	03NOV2018	7	7	7	7	7	7	7	7	7	7	7.0	7.0
		4	16NOV2018	7	7	7	7	7	7	7	7	7	7	7.0	7.0
		6	01DEC2018	7	7	7	7	7	7	7	6	6	7	7.0	6.6
2212	UB mentholated	-1	19OCT2018	6	5	6	5	6	6	6	5	4	6	6.0	5.0
		2	03NOV2018	6	6	6	6	6	6	6	5	3	7	6.2	5.2
		4	18NOV2018	5	4	5	3	4	4	4	4	1	5	4.6	3.2
		6	02DEC2018	6	5	6	4	5	5	5	4	3	6	5.6	4.2
2213	VLN mentholated	-1	19OCT2018	7	7	7	7	7	7	7	7	7	7	7.0	7.0
		2	03NOV2018	7	7	7	7	7	7	7	4	6	7	7.0	6.2
		4	17NOV2018	7	7	7	1	7	7	7	7	4	7	7.0	5.2
		6	02DEC2018	7	7	7	7	7	7	7	7	7	7	7.0	7.0
2215	UB mentholated	-1	19OCT2018	4	6	5	3	4	3	5	1	3	6	4.6	3.4
		2	03NOV2018	4	4	3	1	3	4	3	1	1	4	3.6	2.0
		4	16NOV2018	3	1	3	1	1	1	1	1	4	1	1.8	1.6
		6	01DEC2018	3	4	4	3	5	5	5	1	3	5	4.4	3.2
2220	VLN non-mentholated	-1	20OCT2018	2	2	1	1	1	4	3	1	1	2	2.4	1.2
		2	04NOV2018	5	5	5	1	1	4	5	1	1	4	4.6	1.8

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
2220	VLN non-mentholated	4	16NOV2018	4	3	2	1	1	3	2	1	1	2	2.6	1.4
		6	02DEC2018	4	3	2	2	1	3	2	1	1	2	2.6	1.6
2235	VLN mentholated	-1	03NOV2018	4	4	5	3	4	4	4	4	2	4	4.2	3.4
		2	18NOV2018	4	4	4	4	4	6	6	1	1	4	4.8	2.8
		4	01DEC2018	6	6	6	2	4	6	6	2	1	6	6.0	3.0
		6	15DEC2018	4	5	4	4	4	5	5	3	2	5	4.6	3.6
2244	VLN non-mentholated	-1	03NOV2018	4	2	6	2	2	4	5	2	3	4	4.6	2.2
		2	18NOV2018	7	5	5	3	5	6	7	4	5	7	6.4	4.4
		4	01DEC2018	2	2	2	1	2	2	3	2	2	3	2.4	1.8
		6	15DEC2018	3	2	4	2	3	2	5	1	4	3	3.4	2.4
2247	VLN mentholated	-1	06DEC2018	7	7	7	7	7	7	7	5	6	6	6.8	6.4
2251	UB non-mentholated	-1	07DEC2018	6	5	7	4	4	6	6	5	1	7	6.4	3.8
		2	22DEC2018	5	4	6	2	3	5	5	2	1	5	5.2	2.4
		4	04JAN2019	4	3	7	3	4	5	5	2	1	6	5.4	2.6
		6	18JAN2019	7	6	7	1	5	6	7	2	1	7	6.8	3.0
2257	UB non-mentholated	-1	06DEC2018	3	3	4	4	2	2	4	2	5	3	3.2	3.2
		2	22DEC2018	5	4	6	4	4	5	5	2	5	7	5.6	3.8
		4	04JAN2019	5	4	6	4	5	5	6	2	5	7	5.8	4.0
		6	19JAN2019	2	3	4	5	2	3	2	1	5	4	3.0	3.2
2259	UB mentholated	-1	06DEC2018	6	5	6	6	6	7	7	6	7	7	6.6	6.0
		2	22DEC2018	3	3	3	4	3	3	3	3	4	3	3.0	3.4

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.13 QSU-Brief Response and Factor Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*										Factor 1 Score	Factor 2 Score
				1	2	3	4	5	6	7	8	9	10		
2259	UB mentholated	4	03JAN2019	3	3	3	4	3	5	5	3	6	4	4.0	3.8
		6	18JAN2019	4	4	4	4	4	6	6	6	6	6	5.2	4.8
2269	VLN mentholated	-1	06DEC2018	4	2	2	1	3	1	2	1	2	3	2.4	1.8
		2	22DEC2018	2	2	2	2	1	1	1	1	2	1	1.4	1.6
		4	03JAN2019	2	2	1	2	7	3	5	1	2	3	2.8	2.8
		6	18JAN2019	2	1	4	2	1	3	5	1	4	7	4.2	1.8
2272	VLN mentholated	-1	06DEC2018	3	4	6	4	3	1	2	2	4	6	3.6	3.4
		2	21DEC2018	3	4	4	3	2	2	3	3	4	4	3.2	3.2
		4	04JAN2019	3	3	3	3	3	2	3	2	4	5	3.2	3.0
		6	18JAN2019	3	3	3	3	3	3	3	3	3	3	3.0	3.0

Note: * 1. I have a desire to smoke right now; 2. Nothing would be better than smoking right now; 3. If it were possible, I probably would smoke right now; 4. I could control things better right now if I could smoke; 5. All I want right now is a cigarette; 6. I have an urge for a cigarette; 7. A cigarette would taste good now; 8. I would do almost anything for a cigarette now; 9. Smoking would make me less depressed; 10. I am going to smoke as soon as possible
Factor 1: Average of Questions 1, 3, 6, 7, and 10; Factor 2: Average of Questions 2, 4, 5, 8, and 9
Scale: 1 = Strongly disagree, 7 = Strongly agree. Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
1001	VLN non-mentholated	-1	24JUL2018	3	3	0	2	1	0	0	0	0	0	0	3	0	0	0	12
		2	09AUG2018	1	1	0	2	2	1	0	2	3	0	0	3	0	0	0	15
		4	22AUG2018	0	0	0	1	0	0	0	1	1	0	0	2	0	0	0	5
		6	06SEP2018	2	1	0	3	2	0	1	1	2	0	0	3	0	0	0	15
1002	VLN non-mentholated	-1	24JUL2018	0	0	0	2	0	0	0	0	0	0	0	3	0	0	0	5
		2	09AUG2018	2	3	0	4	4	4	0	0	0	0	0	0	0	0	0	17
		6	07SEP2018	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	30
1003	VLN mentholated	-1	24JUL2018	1	1	0	1	0	0	1	0	1	0	0	0	0	0	0	5
		2	09AUG2018	1	1	0	2	0	1	1	0	1	0	0	0	0	0	1	8
		6	06SEP2018	1	2	0	2	0	2	1	1	1	0	0	0	1	0	0	11
1007	VLN non-mentholated	-1	24JUL2018	1	0	0	2	0	1	0	0	1	0	0	0	1	0	0	6
		2	09AUG2018	0	0	0	4	0	1	0	0	0	0	0	0	0	0	0	5
		4	22AUG2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		6	06SEP2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1008	VLN mentholated	-1	24JUL2018	0	1	0	2	1	0	0	1	1	0	0	1	1	0	0	8
		2	09AUG2018	0	0	0	2	1	1	1	0	1	0	0	1	1	0	0	8
		4	22AUG2018	0	0	0	2	0	0	1	0	1	0	0	0	0	0	0	4
		6	07SEP2018	0	0	0	2	0	0	1	1	1	0	0	1	0	0	0	6
1010	UB mentholated	-1	25JUL2018	1	0	0	1	0	0	1	1	0	0	1	0	1	0	0	6
		2	09AUG2018	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	16
		4	22AUG2018	1	1	0	1	0	3	0	1	1	0	0	1	2	0	0	11
		6	06SEP2018	1	1	1	2	1	1	2	1	1	0	0	0	3	0	0	14

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
1011	UB non-mentholated	-1	24JUL2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	09AUG2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		4	22AUG2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		6	06SEP2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1013	VLN non-mentholated	-1	01AUG2018	1	2	0	3	1	1	2	2	0	0	1	2	2	0	0	17
		2	17AUG2018	0	2	0	3	0	1	1	1	0	1	1	2	0	1	0	13
		4	30AUG2018	1	0	1	2	0	2	2	2	0	0	1	2	3	2	0	18
		6	13SEP2018	1	1	1	2	0	0	1	1	1	1	2	2	1	0	0	14
1014	VLN mentholated	-1	01AUG2018	0	0	0	2	0	0	0	0	1	0	0	0	0	0	0	3
		2	16AUG2018	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
		4	29AUG2018	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	2
		6	14SEP2018	1	0	0	1	0	1	1	0	1	0	0	0	0	0	0	5
1015	VLN mentholated	-1	31JUL2018	2	2	0	2	0	0	0	1	2	0	0	2	1	0	0	12
		2	17AUG2018	0	1	0	0	0	2	1	1	1	1	1	1	0	0	0	9
		4	30AUG2018	0	0	0	2	0	2	2	0	1	3	0	2	0	0	0	12
		6	13SEP2018	0	0	0	1	0	0	1	1	0	0	0	1	0	0	1	5
1016	UB non-mentholated	-1	31JUL2018	0	1	1	2	0	1	1	1	1	0	0	1	1	0	1	11
		2	16AUG2018	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0	2
		4	29AUG2018	0	1	0	1	0	0	0	0	0	0	0	1	0	0	0	3
		6	13SEP2018	1	1	1	1	1	1	1	1	1	1	1	2	1	0	1	15
1017	UB mentholated	-1	01AUG2018	0	0	0	2	1	0	2	1	0	0	2	3	0	1	0	12
		2	16AUG2018	0	0	1	2	0	0	0	0	1	0	1	2	0	0	0	7
		4	29AUG2018	0	0	0	2	0	0	0	0	0	0	0	2	1	0	2	7

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
1017	UB mentholated	6	13SEP2018	2	1	0	2	1	0	0	0	0	1	1	2	0	0	0	10
1018	VLN mentholated	-1	01AUG2018	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
		2	17AUG2018	0	0	0	0	0	0	0	0	0	0	1	1	3	3	0	8
1019	VLN non-mentholated	-1	01AUG2018	1	1	0	1	0	2	0	0	1	0	0	1	0	0	0	7
		2	17AUG2018	0	1	0	4	0	0	0	0	0	0	0	1	0	0	0	6
		4	29AUG2018	0	0	0	2	0	0	0	0	0	0	0	1	0	0	0	3
		6	13SEP2018	0	0	0	1	0	1	0	0	0	0	0	1	0	0	0	3
1020	VLN non-mentholated	-1	01AUG2018	1	0	0	3	0	0	0	0	0	0	0	0	0	0	0	4
		2	17AUG2018	0	0	0	4	2	0	0	0	4	0	0	0	0	0	0	10
		4	30AUG2018	2	0	0	4	2	1	0	0	0	0	2	0	0	3	0	14
		6	13SEP2018	2	2	2	4	4	2	0	0	2	1	1	2	0	3	2	27
1021	UB non-mentholated	-1	01AUG2018	0	0	0	3	0	0	0	0	0	0	0	1	0	0	0	4
		2	16AUG2018	1	0	0	2	0	1	0	2	1	0	0	0	0	0	0	7
		4	29AUG2018	1	0	0	2	0	0	0	0	1	0	0	0	0	0	0	4
		6	13SEP2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1023	VLN non-mentholated	-1	01AUG2018	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0	9
		2	17AUG2018	2	2	1	4	2	3	2	3	3	1	0	0	0	0	0	23
		4	30AUG2018	0	0	0	2	0	0	0	0	1	0	0	0	0	0	0	3
		6	13SEP2018	1	1	0	1	1	2	1	1	1	1	0	0	0	0	0	10
1029	VLN mentholated	-1	28AUG2018	0	1	0	0	1	0	1	2	1	0	0	1	1	0	0	8
		2	13SEP2018	2	2	2	2	2	1	1	1	1	0	0	1	0	0	0	15
		4	25SEP2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
1029	VLN mentholated	6	11OCT2018	1	1	1	3	2	1	2	1	1	0	0	1	0	0	0	14
1032	VLN mentholated	-1	27AUG2018	0	0	0	0	0	1	1	1	1	1	0	0	1	0	0	6
		2	13SEP2018	4	3	3	4	2	3	4	2	3	3	0	0	2	0	0	33
		4	25SEP2018	2	2	3	2	2	2	4	3	3	0	0	0	3	0	0	26
		6	10OCT2018	3	1	3	1	1	2	2	2	3	1	0	0	1	0	0	20
1034	VLN non-mentholated	-1	27AUG2018	2	2	1	3	2	2	2	2	2	2	1	2	1	1	2	27
		2	13SEP2018	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	16
		4	25SEP2018	2	2	1	3	2	2	2	2	1	2	2	1	1	2	1	26
		6	10OCT2018	2	2	1	3	2	1	2	1	2	2	2	1	2	1	0	24
1035	VLN non-mentholated	-1	27AUG2018	3	3	2	4	3	4	3	3	4	0	0	1	0	0	0	30
		2	12SEP2018	2	2	2	4	1	1	0	0	0	0	0	0	0	0	0	12
		4	25SEP2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		6	11OCT2018	2	2	1	4	0	0	0	0	0	0	0	0	0	0	0	9
1036	UB mentholated	-1	28AUG2018	2	2	1	3	2	3	2	2	2	3	0	0	0	0	0	22
		4	24SEP2018	3	3	3	3	3	1	2	3	3	0	0	0	0	0	0	24
		6	10OCT2018	1	1	1	1	1	1	1	1	2	3	1	1	1	1	1	18
1037	UB mentholated	-1	28AUG2018	0	0	0	2	1	0	1	2	2	2	0	0	1	0	0	11
		2	12SEP2018	1	0	1	1	1	0	2	1	2	1	0	1	2	0	1	14
		4	25SEP2018	1	1	1	2	1	0	1	1	2	0	0	0	2	0	0	12
		6	10OCT2018	1	0	1	1	0	1	1	1	2	0	0	0	1	0	0	9
1038	VLN non-mentholated	-1	28AUG2018	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	2
		2	13SEP2018	1	0	0	1	0	0	1	1	0	0	0	3	0	0	0	7

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
1038	VLN non-mentholated	4	26SEP2018	1	0	0	1	0	0	1	1	0	0	0	1	2	0	0	7
		6	10OCT2018	2	1	0	2	0	0	1	1	1	3	0	2	2	0	0	15
1042	VLN non-mentholated	-1	28AUG2018	1	1	0	1	1	0	0	1	1	0	0	0	0	0	0	6
		2	13SEP2018	3	2	1	4	1	1	0	3	3	0	0	0	0	0	0	18
		4	25SEP2018	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
		6	11OCT2018	0	1	0	3	0	0	1	0	0	0	0	0	0	0	0	5
1045	UB non-mentholated	-1	28AUG2018	0	0	0	1	0	2	0	0	0	1	0	2	0	1	2	9
		2	11SEP2018	0	0	0	1	0	2	1	1	1	3	1	1	1	2	0	14
		4	25SEP2018	1	2	0	2	0	0	1	2	1	1	0	2	1	0	1	14
		6	09OCT2018	0	0	0	2	0	0	1	2	2	1	1	2	2	0	1	14
1046	UB mentholated	-1	28AUG2018	0	0	0	3	0	0	0	0	1	0	0	1	1	0	0	6
		2	11SEP2018	0	2	0	3	0	2	0	0	2	0	0	1	1	0	0	11
		4	24SEP2018	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	3
		6	09OCT2018	0	0	0	2	0	0	0	0	1	0	0	2	1	0	0	6
1050	VLN non-mentholated	-1	28AUG2018	1	1	1	1	1	1	1	1	1	1	1	3	2	1	2	19
		2	13SEP2018	3	3	1	2	3	3	3	3	2	2	2	3	1	1	3	35
		4	25SEP2018	1	1	1	3	2	2	4	3	2	0	2	3	2	0	0	26
		6	10OCT2018	2	2	1	1	1	3	1	1	1	1	1	1	1	1	1	19
1051	UB mentholated	-1	28AUG2018	0	0	0	1	0	0	0	0	0	0	0	2	0	0	0	3
		2	12SEP2018	0	0	0	3	0	0	1	0	0	0	0	0	0	0	0	4
		4	24SEP2018	0	0	0	2	2	2	1	1	0	0	0	1	0	0	0	9
		6	10OCT2018	1	0	0	1	0	0	0	0	0	0	1	1	1	0	0	5

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
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VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
1052	VLN mentholated	-1	28AUG2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		2	13SEP2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		6	11OCT2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1053	VLN mentholated	-1	28AUG2018	0	0	0	2	0	0	0	0	0	0	0	1	0	0	0	3
		2	12SEP2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		4	26SEP2018	0	0	0	1	0	0	0	1	0	0	0	1	0	0	1	4
		6	11OCT2018	0	0	0	0	0	0	2	1	0	0	0	3	0	0	3	9
1054	UB non-mentholated	-1	27AUG2018	2	2	2	3	2	2	3	3	3	0	0	0	1	0	0	23
		2	11SEP2018	0	0	0	1	1	2	2	2	2	0	0	0	0	0	0	10
		4	25SEP2018	0	0	0	2	2	1	2	2	2	0	0	1	2	0	0	14
		6	10OCT2018	1	0	0	1	0	0	0	1	0	0	0	0	0	0	0	3
1055	VLN mentholated	-1	28AUG2018	3	0	0	4	0	0	0	0	3	0	0	0	0	0	0	10
		2	13SEP2018	0	0	0	1	0	0	4	0	0	2	0	0	0	0	0	7
		4	26SEP2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		6	10OCT2018	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
1056	VLN non-mentholated	-1	27AUG2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	13SEP2018	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	4
		4	26SEP2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		6	11OCT2018	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	3
1058	VLN non-mentholated	-1	28AUG2018	2	0	1	1	2	1	1	1	1	1	0	0	0	0	0	11
		2	13SEP2018	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
		4	26SEP2018	2	2	2	2	2	2	2	2	3	2	2	2	2	2	2	31
		6	11OCT2018	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	15

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
1059	UB non-mentholated	-1	10SEP2018	1	1	1	3	1	2	2	1	1	0	1	2	1	0	0	17
		2	25SEP2018	2	1	3	2	1	3	2	1	2	1	2	1	2	2	0	25
		4	08OCT2018	3	2	3	2	1	2	3	3	2	0	0	1	1	2	0	25
		6	24OCT2018	1	2	3	2	1	3	3	1	3	0	1	1	2	2	0	25
1060	VLN mentholated	-1	10SEP2018	3	3	1	2	0	0	0	0	0	0	0	1	0	0	1	11
		2	26SEP2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		4	09OCT2018	0	0	0	4	2	0	0	0	1	0	0	0	0	0	0	7
		6	24OCT2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1063	VLN mentholated	-1	10SEP2018	0	0	0	2	0	2	2	1	1	0	0	0	0	0	0	8
		2	27SEP2018	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	3
		4	09OCT2018	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	2
		6	24OCT2018	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
1064	UB non-mentholated	-1	10SEP2018	1	1	1	1	1	3	1	2	2	0	0	0	0	0	0	13
		2	25SEP2018	0	1	0	2	0	0	0	3	2	0	0	0	0	0	0	8
1066	VLN non-mentholated	-1	11SEP2018	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0	2
		2	26SEP2018	0	0	0	1	0	1	0	0	0	0	0	1	0	0	0	3
		4	09OCT2018	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
		6	23OCT2018	0	0	0	1	1	0	0	0	0	0	0	1	0	0	0	3
1069	UB non-mentholated	-1	11SEP2018	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	26
		2	26SEP2018	0	2	2	2	2	2	1	1	1	0	0	1	1	0	0	15
		4	09OCT2018	2	2	2	2	2	2	0	1	2	1	0	2	0	0	1	19
		6	24OCT2018	1	1	0	1	1	0	1	1	1	0	1	2	0	0	1	11

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
1070	VLN non-mentholated	-1	10SEP2018	1	1	1	4	1	1	1	1	2	0	0	0	0	0	0	13
		2	26SEP2018	1	1	1	3	1	1	1	1	1	0	0	0	0	0	0	11
		4	08OCT2018	0	0	0	1	0	0	0	0	0	0	0	0	2	0	0	3
		6	24OCT2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1071	VLN non-mentholated	-1	10SEP2018	0	2	0	3	0	2	3	3	2	0	0	0	1	0	0	16
		2	25SEP2018	3	3	1	4	3	3	3	3	3	0	0	0	0	0	0	26
		4	08OCT2018	3	3	1	1	2	4	4	3	3	1	1	1	0	0	0	27
1072	VLN mentholated	-1	10SEP2018	0	0	0	1	0	0	1	0	0	0	0	1	2	0	0	5
		2	27SEP2018	0	0	0	1	0	0	1	0	0	0	0	1	1	0	0	4
		4	09OCT2018	0	0	0	2	0	0	2	0	0	0	0	1	2	0	0	7
1074	VLN non-mentholated	-1	10SEP2018	1	1	0	3	1	1	0	1	1	0	0	0	1	0	0	10
		2	26SEP2018	2	2	0	4	1	0	0	1	2	0	0	0	0	0	0	12
		4	09OCT2018	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	3
		6	23OCT2018	0	0	0	3	1	2	1	0	0	0	0	0	0	1	0	8
1075	UB non-mentholated	-1	10SEP2018	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	2
		2	26SEP2018	0	0	0	3	0	1	0	0	0	0	0	0	0	0	0	4
		4	09OCT2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		6	24OCT2018	0	0	0	2	0	2	0	0	0	0	0	0	0	0	0	4
1077	VLN non-mentholated	-1	10SEP2018	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0	2
		2	26SEP2018	0	0	0	2	1	1	2	1	0	0	0	1	0	0	0	8
		4	09OCT2018	0	0	0	1	0	0	0	0	1	0	0	0	0	1	0	3
		6	24OCT2018	0	0	0	1	0	0	1	0	0	0	0	1	0	0	0	3

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
1078	VLN non-mentholated	-1	11SEP2018	0	2	1	2	1	3	3	3	2	1	0	1	2	0	0	21
		2	25SEP2018	0	1	1	2	1	3	1	2	1	0	2	0	1	0	0	15
		4	09OCT2018	0	0	1	2	1	1	2	2	1	0	0	1	1	0	0	12
		6	24OCT2018	0	1	1	1	0	0	2	2	2	2	0	0	0	0	0	11
1079	VLN mentholated	-1	11SEP2018	2	1	0	2	0	0	1	3	1	0	0	1	1	0	0	12
		2	26SEP2018	3	3	2	3	1	4	3	3	4	2	0	2	0	0	0	30
		4	09OCT2018	2	2	1	2	1	3	2	2	2	0	0	0	0	0	0	17
		6	24OCT2018	0	0	0	0	1	2	2	2	1	0	0	2	1	0	1	12
1082	VLN non-mentholated	-1	10SEP2018	2	2	0	3	2	2	0	1	2	0	0	1	0	0	0	15
		2	26SEP2018	1	1	0	2	1	2	1	1	1	0	0	0	0	0	0	10
		4	09OCT2018	1	1	0	2	2	2	1	0	1	0	0	1	0	0	0	11
		6	24OCT2018	1	0	0	2	1	2	1	0	0	0	0	2	0	0	0	9
1083	VLN non-mentholated	-1	17SEP2018	0	0	0	1	1	0	1	1	1	0	0	3	0	0	0	8
		2	03OCT2018	1	2	1	3	3	2	2	2	2	3	2	3	2	0	0	28
		4	16OCT2018	1	2	1	2	2	3	3	3	3	2	0	1	1	0	0	24
		6	31OCT2018	2	2	2	1	1	1	3	3	3	2	2	2	0	0	0	24
1084	VLN non-mentholated	-1	17SEP2018	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	15
		2	03OCT2018	1	1	0	0	0	0	0	0	0	0	0	1	0	0	0	3
		4	16OCT2018	1	1	0	1	0	0	0	0	0	0	0	0	0	0	2	5
1086	VLN non-mentholated	-1	18SEP2018	2	1	1	1	2	4	4	4	3	3	0	1	0	0	0	26
		2	02OCT2018	2	3	1	3	2	3	3	3	3	3	0	1	0	2	0	29
		4	15OCT2018	3	3	3	2	3	4	3	2	2	3	0	3	0	0	0	31
		6	30OCT2018	3	3	3	3	3	1	3	0	0	0	0	3	0	0	0	22

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
1088	VLN mentholated	-1	18SEP2018	1	1	0	1	0	0	0	0	0	0	1	1	0	0	0	5
		2	03OCT2018	1	1	1	1	0	0	0	0	0	0	0	2	0	0	0	6
		4	16OCT2018	0	0	0	1	0	0	0	0	1	0	0	1	0	0	0	3
		6	31OCT2018	1	0	0	0	0	0	1	1	1	0	0	1	1	0	0	6
1089	UB non-mentholated	-1	17SEP2018	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0	2
		2	02OCT2018	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
		4	15OCT2018	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	2
		6	30OCT2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1092	VLN mentholated	-1	18SEP2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		2	03OCT2018	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	2
		4	16OCT2018	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
		6	31OCT2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1094	VLN mentholated	-1	18SEP2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	02OCT2018	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	2
		4	15OCT2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		6	31OCT2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1095	VLN mentholated	-1	17SEP2018	0	2	0	1	0	0	0	2	1	0	0	1	0	0	0	7
		2	02OCT2018	0	0	1	1	1	1	3	2	1	0	0	3	0	0	0	13
		4	15OCT2018	2	2	3	3	3	3	3	2	2	0	1	3	2	0	1	30
		6	30OCT2018	0	1	3	1	2	2	3	2	2	0	0	2	1	0	0	19
1096	VLN non-mentholated	-1	18SEP2018	3	1	0	1	1	0	1	3	3	0	0	0	2	0	0	15
		2	27SEP2018	3	2	0	4	1	3	2	4	4	0	0	3	2	3	2	33
		4	16OCT2018	3	3	0	3	0	3	2	3	3	0	0	4	4	2	3	33

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
1096	VLN non-mentholated	6	31OCT2018	0	0	0	3	0	3	0	0	3	0	0	0	0	0	0	9
1097	VLN mentholated	-1	18SEP2018	0	0	0	0	0	4	0	0	0	0	0	0	0	0	0	4
		2	03OCT2018	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	3
		4	16OCT2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		6	31OCT2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1098	VLN non-mentholated	-1	04OCT2018	0	1	0	1	1	0	0	1	1	0	0	1	0	0	1	7
		6	16NOV2018	0	1	0	2	1	0	0	0	0	0	0	1	2	0	1	8
1099	VLN non-mentholated	-1	04OCT2018	0	0	0	1	0	0	0	0	1	0	0	1	0	0	0	3
		2	19OCT2018	2	1	0	4	0	0	0	1	1	0	0	0	0	0	0	9
		4	01NOV2018	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
		6	16NOV2018	1	0	0	3	0	0	0	0	1	0	0	0	0	0	0	5
1100	VLN non-mentholated	-1	04OCT2018	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	2
		2	19OCT2018	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	30
		4	01NOV2018	2	2	0	1	1	1	3	3	3	2	2	0	4	3	1	28
		6	16NOV2018	2	2	1	1	2	1	3	3	2	1	2	1	3	2	2	28
1101	VLN non-mentholated	-1	03OCT2018	2	3	2	3	3	3	4	3	3	2	0	3	3	3	1	38
		6	16NOV2018	3	3	4	4	3	2	4	3	3	3	2	3	4	3	2	46
1103	VLN non-mentholated	-1	03OCT2018	1	1	0	3	0	0	0	1	1	0	0	0	0	0	0	7
		2	19OCT2018	0	1	0	2	1	0	0	1	0	0	0	0	0	0	0	5
		4	01NOV2018	0	0	0	3	0	0	0	0	0	0	0	0	2	0	0	5
		6	16NOV2018	2	1	0	1	0	0	4	0	1	0	0	0	4	0	0	13

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
1105	VLN non-mentholated	-1	03OCT2018	0	3	0	4	0	0	2	0	0	0	0	1	0	1	0	11
		2	19OCT2018	0	2	0	4	0	0	0	2	1	0	0	0	0	0	0	9
		4	02NOV2018	3	2	0	3	2	3	1	2	2	0	0	0	0	0	0	18
		6	16NOV2018	0	2	0	3	0	2	0	2	0	0	0	0	0	0	0	9
1106	UB non-mentholated	-1	04OCT2018	2	1	1	2	2	1	1	2	2	2	1	1	1	1	1	21
		2	19OCT2018	2	1	2	3	3	3	3	0	0	1	0	1	0	1	1	21
		4	31OCT2018	3	3	0	4	2	0	0	0	3	0	0	0	0	0	0	15
		6	16NOV2018	1	1	1	1	1	1	1	1	1	2	1	1	1	1	1	16
1107	VLN non-mentholated	-1	04OCT2018	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	30
		2	19OCT2018	2	2	2	3	2	2	2	2	3	1	1	0	1	1	0	24
		4	02NOV2018	1	1	1	3	2	2	2	2	2	1	0	1	0	0	0	18
		6	16NOV2018	2	2	2	3	3	1	1	0	1	1	0	0	0	0	0	16
1108	UB non-mentholated	-1	03OCT2018	0	0	0	2	0	1	3	1	1	0	0	0	1	0	0	9
		2	18OCT2018	1	0	0	2	0	0	3	2	1	0	0	0	2	0	0	11
		4	31OCT2018	1	0	0	2	0	1	2	1	1	0	0	0	3	0	0	11
		6	15NOV2018	2	2	1	3	2	2	2	2	2	0	0	0	2	0	0	20
1109	UB non-mentholated	-1	04OCT2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	19OCT2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		4	01NOV2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		6	16NOV2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1112	VLN non-mentholated	-1	03OCT2018	1	1	0	3	1	0	0	1	0	0	0	0	0	0	0	7
		2	19OCT2018	0	1	1	3	1	2	1	2	3	0	0	2	1	0	1	18
		4	02NOV2018	0	1	0	2	1	0	0	2	3	0	0	0	0	0	0	9

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
1112	VLN non-mentholated	6	16NOV2018	1	2	0	2	1	1	1	1	1	1	0	2	0	0	1	14
1114	UB non-mentholated	-1	03OCT2018	0	0	0	1	1	0	2	1	1	0	0	1	1	0	0	8
		2	18OCT2018	2	1	0	3	3	0	1	0	2	0	1	1	0	0	0	14
		4	01NOV2018	0	0	0	1	1	1	1	1	2	0	0	1	1	0	1	10
		6	15NOV2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
1115	VLN non-mentholated	-1	03OCT2018	1	0	0	1	0	1	1	1	1	0	0	0	0	0	0	6
		2	19OCT2018	0	1	0	2	0	3	0	2	1	0	0	1	1	0	0	11
		4	02NOV2018	1	1	0	2	0	3	3	1	1	0	0	2	0	0	0	14
2002	UB mentholated	-1	23JUL2018	2	2	3	3	3	3	2	3	2	0	0	1	0	0	1	25
		2	08AUG2018	3	3	3	3	2	1	2	2	2	3	0	1	0	0	0	25
		4	21AUG2018	2	2	2	3	3	2	2	2	2	2	2	2	2	0	2	30
		6	05SEP2018	3	0	0	3	3	2	0	0	0	0	0	2	1	0	0	14
2003	VLN mentholated	-1	16JUL2018	1	0	0	4	0	0	0	2	4	0	0	0	0	0	0	11
		2	31JUL2018	2	0	0	4	3	0	0	2	2	0	0	2	0	2	1	18
		4	14AUG2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		6	28AUG2018	0	0	0	4	0	2	0	0	0	0	0	0	0	0	0	6
2007	VLN non-mentholated	-1	16JUL2018	1	2	1	3	2	0	4	3	2	0	0	0	1	0	0	19
		2	01AUG2018	1	1	0	3	1	1	3	2	2	0	0	0	2	0	0	16
		4	14AUG2018	0	1	0	3	0	0	3	2	2	0	0	1	2	0	0	14
		6	29AUG2018	1	1	1	3	0	1	3	1	2	0	0	0	0	0	1	14
2008	VLN mentholated	-1	16JUL2018	3	2	1	4	3	2	2	3	4	3	2	1	1	1	1	33
		2	01AUG2018	1	2	0	3	2	2	3	3	3	1	0	2	2	2	0	26

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
2008	VLN mentholated	4	14AUG2018	2	2	2	2	2	1	3	3	2	1	1	1	1	2	1	26
		6	28AUG2018	1	1	0	2	2	1	1	3	2	0	0	0	1	0	0	14
2009	VLN non-mentholated	-1	16JUL2018	2	3	2	3	2	1	1	2	2	1	0	1	0	0	0	20
		2	31JUL2018	1	1	3	2	1	4	2	2	2	3	1	0	1	1	1	25
		4	14AUG2018	1	1	1	2	2	2	1	1	2	2	2	1	1	1	1	21
2010	UB mentholated	-1	17JUL2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		2	01AUG2018	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
		4	14AUG2018	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
		6	29AUG2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
2011	VLN mentholated	-1	16JUL2018	1	0	0	4	1	1	0	0	2	0	0	0	0	0	0	9
		2	31JUL2018	2	2	1	4	1	1	0	0	1	0	0	0	0	0	0	12
		4	13AUG2018	2	1	0	3	1	2	0	0	1	0	0	0	0	0	0	10
		6	28AUG2018	2	1	0	3	0	1	0	1	2	0	0	0	0	0	1	11
2014	VLN mentholated	-1	17JUL2018	0	0	0	1	0	0	0	0	0	1	0	0	0	0	0	2
		2	01AUG2018	0	0	0	2	0	1	0	1	0	1	0	0	0	0	0	5
		4	14AUG2018	0	0	0	1	1	2	0	0	1	0	0	0	0	0	0	5
		6	29AUG2018	0	0	0	2	0	0	1	0	0	0	0	0	0	0	0	3
2015	UB mentholated	-1	17JUL2018	1	1	1	3	2	2	1	2	2	2	3	1	2	1	1	25
		2	31JUL2018	0	0	0	4	0	1	1	0	0	0	0	0	0	0	0	6
		4	13AUG2018	1	1	0	2	1	1	1	2	1	1	1	1	1	0	0	14
		6	28AUG2018	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	15
2016	VLN mentholated	-1	16JUL2018	1	0	0	2	0	0	0	0	0	0	0	0	0	0	0	3

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
2016	VLN mentholated	2	01AUG2018	3	3	2	3	2	2	2	2	2	2	2	2	2	0	0	29
2017	VLN mentholated	-1	16JUL2018	0	0	1	2	0	4	0	0	0	0	0	0	0	0	0	7
		2	01AUG2018	1	0	0	2	0	1	2	2	0	0	0	0	0	0	0	8
		4	13AUG2018	0	0	0	2	0	1	0	0	0	0	0	0	0	0	0	3
		6	28AUG2018	0	0	0	3	0	3	0	0	0	0	0	0	0	0	0	6
2018	UB mentholated	-1	16JUL2018	0	0	0	3	0	0	0	0	1	0	0	0	0	0	0	4
		2	01AUG2018	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	3
		4	14AUG2018	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
		6	29AUG2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2020	VLN mentholated	-1	16JUL2018	0	4	0	0	0	0	2	4	1	0	0	2	0	0	1	14
		2	31JUL2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		4	13AUG2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		6	28AUG2018	0	1	0	2	0	0	3	3	3	2	0	2	0	2	2	20
2021	VLN mentholated	-1	17JUL2018	0	0	0	2	0	1	1	1	1	0	0	0	0	0	0	6
		2	01AUG2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		4	14AUG2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		6	28AUG2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2023	VLN mentholated	-1	17JUL2018	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0	2
		2	01AUG2018	0	0	0	1	0	0	0	0	0	2	0	1	0	0	0	4
		4	14AUG2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		6	28AUG2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2024	UB non-mentholated	-1	17JUL2018	0	0	0	3	0	0	0	0	0	0	0	2	2	0	0	7

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
 Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
 Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
2025	UB non-mentholated	-1	16JUL2018	1	1	1	2	0	0	0	1	1	0	0	1	0	0	0	8
		2	01AUG2018	1	0	1	2	1	1	1	1	0	1	0	1	0	0	0	10
		4	13AUG2018	1	1	0	2	0	1	1	1	0	0	0	0	1	0	0	8
		6	28AUG2018	1	1	1	2	1	1	1	0	0	0	0	1	0	0	0	9
2028	VLN non-mentholated	-1	17JUL2018	3	2	3	4	3	2	0	0	3	0	0	3	0	0	0	23
		2	01AUG2018	3	3	3	3	3	2	2	2	3	1	1	3	0	0	0	29
		4	13AUG2018	1	1	3	1	2	2	2	1	1	0	0	4	1	1	0	20
		6	29AUG2018	1	0	1	0	0	0	0	0	0	0	0	3	0	0	0	5
2029	UB mentholated	-1	24JUL2018	0	0	0	1	1	0	1	2	2	0	0	2	1	0	0	10
		2	08AUG2018	1	0	0	2	0	0	1	1	2	1	0	2	0	0	0	10
		4	21AUG2018	0	1	0	1	0	0	1	1	1	0	0	1	1	0	0	7
		6	05SEP2018	0	0	0	2	0	0	0	0	0	0	0	1	0	0	0	3
2039	VLN mentholated	2	08AUG2018	0	0	0	1	0	0	2	2	0	1	0	0	0	2	0	8
		4	21AUG2018	0	0	0	2	0	0	2	2	0	0	0	0	0	0	0	6
		6	04SEP2018	0	0	0	2	0	0	1	0	0	2	0	0	0	0	0	5
2050	UB mentholated	-1	08AUG2018	0	1	0	2	1	2	3	2	1	2	0	0	0	0	0	14
		2	23AUG2018	0	0	0	2	0	1	1	0	0	0	0	0	0	0	0	4
		4	04SEP2018	0	0	0	1	0	1	0	0	0	1	0	1	0	1	0	5
		6	20SEP2018	1	1	1	1	1	1	1	1	1	1	0	1	0	0	0	11
2052	VLN mentholated	-1	08AUG2018	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
		2	23AUG2018	0	0	0	1	0	0	0	0	0	0	0	1	0	0	1	3
		4	05SEP2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	1	3
		6	20SEP2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
2057	VLN mentholated	-1	08AUG2018	0	1	0	2	0	0	1	1	1	0	0	0	0	0	0	6
		2	23AUG2018	1	0	0	1	1	0	1	1	0	0	0	0	1	0	0	6
		4	05SEP2018	0	1	0	2	1	0	1	1	0	0	0	0	0	0	0	6
		6	20SEP2018	0	0	0	1	0	0	1	1	0	0	0	0	0	0	0	3
2058	VLN mentholated	-1	08AUG2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	23AUG2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		4	05SEP2018	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
		6	19SEP2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2059	UB mentholated	-1	07AUG2018	0	0	1	2	0	1	0	0	1	0	1	1	1	0	0	8
		2	23AUG2018	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
		4	04SEP2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		6	19SEP2018	0	0	0	1	0	1	1	1	0	0	0	0	0	0	0	4
2060	VLN mentholated	-1	07AUG2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		2	23AUG2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		4	05SEP2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		6	19SEP2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2064	VLN mentholated	-1	08AUG2018	0	0	0	1	0	0	0	0	1	0	0	1	0	0	0	3
		2	23AUG2018	0	0	0	1	0	0	0	0	0	0	0	1	0	0	1	3
		4	05SEP2018	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0	2
		6	20SEP2018	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
2066	VLN mentholated	-1	08AUG2018	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	2
		2	23AUG2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		4	05SEP2018	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	3

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
2066	VLN mentholated	6	19SEP2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2067	VLN non-mentholated	-1	08AUG2018	1	1	1	2	2	2	2	2	3	1	0	1	0	0	2	20
		2	23AUG2018	3	3	3	4	3	1	3	3	3	1	0	2	0	0	1	30
		4	05SEP2018	1	2	1	1	1	1	2	1	2	1	1	1	1	1	2	19
		6	20SEP2018	1	2	1	2	1	2	2	2	2	1	1	1	1	1	1	21
2075	VLN mentholated	-1	08AUG2018	0	0	0	4	0	0	0	1	0	0	0	2	0	0	0	7
2076	VLN mentholated	-1	01SEP2018	0	0	0	4	0	2	0	0	0	0	0	0	2	0	0	8
		2	15SEP2018	0	0	0	0	0	4	4	4	2	0	0	0	0	0	0	14
		4	29SEP2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		6	13OCT2018	0	0	0	2	0	1	0	0	0	0	0	0	0	0	0	3
2086	VLN non-mentholated	-1	01SEP2018	0	1	0	2	0	1	3	2	1	1	0	1	2	0	0	14
		2	15SEP2018	3	2	0	4	2	2	0	2	3	0	0	0	0	0	1	19
		4	29SEP2018	0	0	0	1	0	1	1	0	0	0	0	0	0	0	1	4
2088	VLN mentholated	-1	01SEP2018	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
		2	15SEP2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		4	29SEP2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		6	13OCT2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2092	VLN mentholated	-1	01SEP2018	2	0	0	2	2	0	3	2	2	0	0	0	0	0	0	13
		2	15SEP2018	0	1	1	2	1	0	2	1	1	0	0	0	0	0	0	9
		4	29SEP2018	1	1	0	2	2	0	2	1	0	0	0	0	0	0	0	9
		6	13OCT2018	0	0	0	1	0	0	2	0	0	0	0	0	0	0	0	3

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
2099	VLN non-mentholated	-1	01SEP2018	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
		2	16SEP2018	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0	2
		4	29SEP2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		6	13OCT2018	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0	2
2100	UB mentholated	-1	01SEP2018	0	0	0	0	0	1	1	0	0	2	0	0	0	0	0	4
		2	16SEP2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		4	29SEP2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		6	13OCT2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2108	VLN non-mentholated	-1	31AUG2018	0	0	0	3	3	2	1	2	1	0	0	2	0	0	0	14
		2	15SEP2018	2	2	2	3	3	2	3	2	3	1	2	3	3	0	1	32
		4	29SEP2018	1	2	1	3	2	3	2	2	2	0	2	3	3	0	1	27
		6	13OCT2018	1	1	2	2	1	3	3	3	2	0	1	3	2	0	1	25
2110	UB mentholated	-1	06SEP2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	21SEP2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		4	05OCT2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		6	20OCT2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2113	VLN mentholated	-1	06SEP2018	4	4	4	4	4	0	3	3	4	0	0	0	0	0	0	30
		2	21SEP2018	2	3	2	4	2	0	0	1	3	0	0	0	1	0	0	18
2115	VLN mentholated	-1	06SEP2018	2	3	3	4	3	3	3	2	3	3	0	0	1	1	0	31
		2	21SEP2018	1	1	1	3	1	1	2	0	2	2	0	2	0	4	2	22
2119	VLN mentholated	-1	06SEP2018	1	1	1	2	2	0	1	1	1	0	0	1	1	0	0	12
		2	21SEP2018	2	0	2	1	1	0	2	2	2	1	0	1	1	0	0	15

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
2119	VLN mentholated	4	04OCT2018	2	2	1	2	0	1	1	1	3	1	0	1	0	0	0	15
		6	19OCT2018	2	1	0	2	1	0	0	1	1	0	0	1	0	0	0	9
2120	VLN non-mentholated	-1	07SEP2018	2	2	1	4	1	1	1	2	2	1	0	0	1	0	3	21
		2	21SEP2018	0	1	0	3	0	1	1	0	0	0	0	0	0	0	0	6
		4	04OCT2018	0	1	0	2	1	2	1	2	2	1	1	2	3	1	1	20
		6	20OCT2018	0	1	0	1	0	2	1	1	1	1	0	1	3	0	3	15
2122	UB non-mentholated	-1	06SEP2018	1	0	0	3	0	1	0	0	0	2	0	0	0	0	0	7
		2	22SEP2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		4	05OCT2018	0	0	1	2	0	0	0	0	0	0	0	0	0	0	0	3
		6	19OCT2018	0	0	0	2	2	0	0	0	1	0	0	0	0	0	0	5
2125	UB mentholated	-1	06SEP2018	0	1	0	2	0	0	0	0	0	0	0	0	0	0	0	3
		2	21SEP2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		4	05OCT2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		6	19OCT2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2126	VLN mentholated	-1	06SEP2018	0	0	0	1	0	0	1	1	1	0	0	0	0	0	0	4
		2	21SEP2018	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
		4	04OCT2018	0	0	0	1	0	2	2	1	0	0	0	2	0	0	0	8
		6	19OCT2018	0	0	0	2	0	0	1	0	0	0	0	0	0	0	0	3
2136	VLN non-mentholated	-1	07SEP2018	1	2	2	3	0	0	0	1	2	0	0	2	1	0	0	14
		2	22SEP2018	2	3	1	3	1	2	2	2	3	1	1	2	1	1	2	27
		4	05OCT2018	2	2	1	3	1	1	1	2	1	0	0	2	1	0	2	19
2140	UB non-mentholated	-1	23SEP2018	0	0	0	1	0	0	1	0	0	0	0	0	1	2	0	5

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
2140	UB non-mentholated	2	08OCT2018	0	0	0	4	0	0	0	0	0	0	0	0	2	0	0	6
		4	21OCT2018	0	0	0	2	0	0	1	0	0	0	0	1	1	0	1	6
		6	05NOV2018	0	0	0	4	0	0	2	1	0	0	0	0	2	0	0	9
2142	VLN non-mentholated	-1	24SEP2018	1	1	0	4	0	1	3	2	0	0	0	1	0	0	0	13
2143	VLN non-mentholated	-1	23SEP2018	0	0	1	2	3	1	1	1	1	3	0	2	1	0	0	16
		2	08OCT2018	2	1	2	4	3	1	1	3	3	4	1	3	1	0	0	29
		4	22OCT2018	1	1	2	2	3	1	0	2	2	4	1	3	1	0	0	23
		6	05NOV2018	0	0	2	1	1	0	0	1	2	4	0	2	0	0	0	13
2158	UB non-mentholated	-1	19OCT2018	2	1	1	2	1	1	2	2	1	0	0	1	0	0	0	14
		2	03NOV2018	1	0	0	2	1	1	0	0	1	0	0	0	0	0	0	6
2159	VLN non-mentholated	-1	20OCT2018	2	2	1	4	2	1	3	2	4	0	0	0	2	0	0	23
		2	03NOV2018	2	2	2	2	1	2	2	2	2	0	0	0	0	0	0	17
		4	16NOV2018	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	30
		6	01DEC2018	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	30
2164	VLN non-mentholated	-1	19OCT2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		2	03NOV2018	0	0	0	3	0	1	0	0	0	0	0	0	0	0	0	4
		4	17NOV2018	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	3
		6	01DEC2018	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1
2168	VLN non-mentholated	-1	19OCT2018	2	2	0	3	2	1	1	1	3	0	0	1	0	0	0	16
		2	04NOV2018	3	3	1	3	2	1	1	1	3	1	0	0	0	0	1	20
		4	17NOV2018	0	1	0	2	0	0	0	0	2	0	0	0	0	0	0	5
		6	01DEC2018	2	1	0	3	1	0	0	0	2	0	0	0	0	0	0	9

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
2170	UB non-mentholated	-1	19OCT2018	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
		2	03NOV2018	3	0	0	1	2	0	0	1	1	0	2	1	0	1	0	12
		4	17NOV2018	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	3
		6	02DEC2018	3	3	0	1	0	0	0	0	0	0	0	0	0	0	0	7
2175	UB mentholated	-1	19OCT2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	04NOV2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		4	17NOV2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		6	01DEC2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2189	VLN mentholated	-1	19OCT2018	0	0	0	3	1	1	0	0	2	0	0	1	1	0	0	9
2211	VLN mentholated	-1	19OCT2018	0	2	1	3	0	3	3	2	4	0	0	0	0	0	0	18
		2	03NOV2018	1	3	0	4	2	3	3	2	4	0	0	0	0	0	0	22
		4	16NOV2018	2	2	0	4	0	3	2	2	2	0	0	0	0	0	0	17
		6	01DEC2018	0	0	0	2	0	2	0	0	0	0	0	0	0	0	0	4
2212	UB mentholated	-1	19OCT2018	1	2	1	3	1	1	1	2	2	0	0	0	0	0	0	14
		2	03NOV2018	1	1	0	3	1	1	0	1	2	0	0	0	0	0	0	10
		4	18NOV2018	0	1	0	3	1	1	0	1	1	0	0	0	0	1	0	9
		6	02DEC2018	1	1	0	2	1	1	1	1	0	0	0	0	0	0	0	8
2213	VLN mentholated	-1	19OCT2018	0	0	0	4	0	2	0	0	0	0	0	0	0	0	0	6
		2	03NOV2018	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	4
		4	17NOV2018	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	4
		6	02DEC2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2215	UB mentholated	-1	19OCT2018	2	0	0	2	0	2	0	1	0	0	0	0	0	0	0	7

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
2215	UB mentholated	2	03NOV2018	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	2
		4	16NOV2018	1	0	0	1	0	2	0	1	1	0	0	0	0	0	0	6
		6	01DEC2018	0	0	0	3	0	1	0	0	0	0	0	0	0	0	0	4
2220	VLN non-mentholated	-1	20OCT2018	0	0	0	1	0	1	0	2	0	0	0	0	0	0	0	4
		2	04NOV2018	0	1	0	3	0	0	1	3	0	0	0	0	0	0	0	8
		4	16NOV2018	0	0	0	2	0	1	1	1	1	0	0	0	0	0	0	6
		6	02DEC2018	0	0	0	1	0	0	1	1	0	0	0	0	0	0	0	3
2235	VLN mentholated	-1	03NOV2018	2	2	1	3	0	1	0	2	2	0	0	1	0	1	0	15
		2	18NOV2018	0	0	0	3	0	0	0	0	1	0	0	1	0	1	0	6
		4	01DEC2018	2	1	0	3	0	0	0	1	1	0	0	1	0	1	0	10
		6	15DEC2018	0	0	0	4	1	0	1	0	1	0	0	1	0	1	0	9
2244	VLN non-mentholated	-1	03NOV2018	2	1	3	3	1	2	2	1	2	1	0	0	1	1	0	20
		2	18NOV2018	2	3	3	3	1	2	2	1	2	0	0	2	0	1	0	22
		4	01DEC2018	2	2	1	3	2	2	0	0	2	1	1	1	0	0	0	17
		6	15DEC2018	2	2	2	3	1	2	0	2	3	2	1	2	0	1	0	23
2247	VLN mentholated	-1	06DEC2018	0	3	0	3	0	0	0	2	0	0	0	0	0	0	0	8
2251	UB non-mentholated	-1	07DEC2018	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
		2	22DEC2018	0	0	0	2	0	0	0	1	1	0	0	0	0	0	0	4
		4	04JAN2019	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		6	18JAN2019	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
2257	UB non-mentholated	-1	06DEC2018	1	0	0	1	0	2	3	2	3	0	0	1	0	0	0	13
		2	22DEC2018	1	1	0	3	1	2	3	2	3	0	0	1	0	0	0	17

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke; 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night; 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
Subjects used their own usual brand cigarettes at Week -1.
VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.14 MNWS-R Response and Total Score (Safety Population)

Subject Number	Product Group	Study Week	Date	Question*															Total Score
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
2257	UB non-mentholated	4	04JAN2019	0	1	1	3	1	0	0	0	3	0	0	1	0	0	0	10
		6	19JAN2019	0	1	0	1	0	1	3	3	4	0	0	2	0	0	0	15
2259	UB mentholated	-1	06DEC2018	3	3	3	3	3	3	3	3	3	3	2	1	1	1	1	36
		2	22DEC2018	3	3	3	3	3	3	3	2	3	2	1	1	2	1	1	34
		4	03JAN2019	2	2	2	3	3	3	2	2	2	2	0	0	0	0	1	24
		6	18JAN2019	2	2	2	2	3	3	3	3	3	3	1	0	0	0	0	27
2269	VLN mentholated	-1	06DEC2018	0	2	1	2	1	2	2	2	2	2	1	0	1	0	1	19
		2	22DEC2018	1	0	1	1	0	1	1	1	1	1	1	1	1	1	1	13
		4	03JAN2019	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	15
		6	18JAN2019	0	1	1	2	3	1	3	2	1	1	1	0	0	1	1	18
2272	VLN mentholated	-1	06DEC2018	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	2
		2	21DEC2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		4	04JAN2019	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		6	18JAN2019	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Note: * 1. Angry, irritable, frustrated; 2. Anxious, nervous; 3. Depressed mood, sad; 4. Desire or craving to smoke;
 5. Difficulty concentrating; 6. Increased appetite, hungry, weight gain; 7. Insomnia, sleep problems, awakening at night;
 8. Restless; 9. Impatient; 10. Constipation; 11. Dizziness; 12. Coughing; 13. Dreaming or nightmares; 14. Nausea; 15. Sore throat
 Scale: 0 = none; 1 = slight; 2 = mild; 3 = moderate; 4 = severe
 Subjects used their own usual brand cigarettes at Week -1.
 VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
1001	VLN non-mentholated	-1	24JUL2018	10
		2	09AUG2018	2
		4	22AUG2018	6
		6	06SEP2018	1
1002	VLN non-mentholated	-1	24JUL2018	10
		2	09AUG2018	10
		6	07SEP2018	6
1003	VLN mentholated	-1	24JUL2018	6
		2	09AUG2018	1
		6	06SEP2018	1
1007	VLN non-mentholated	-1	24JUL2018	5
		2	09AUG2018	10
		4	22AUG2018	10
		6	06SEP2018	10
1008	VLN mentholated	-1	24JUL2018	8
		2	09AUG2018	4
		4	22AUG2018	10
		6	07SEP2018	8
1010	UB mentholated	-1	25JUL2018	6
		2	09AUG2018	7
		4	22AUG2018	7
		6	06SEP2018	6
1011	UB non-mentholated	-1	24JUL2018	10
		2	09AUG2018	10
		4	22AUG2018	10

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
1011	UB non-mentholated	6	06SEP2018	10
1013	VLN non-mentholated	-1	01AUG2018	6
		2	17AUG2018	3
		4	30AUG2018	6
		6	13SEP2018	2
1014	VLN mentholated	-1	01AUG2018	6
		2	16AUG2018	1
		4	29AUG2018	1
		6	14SEP2018	1
1015	VLN mentholated	-1	31JUL2018	8
		2	17AUG2018	1
		4	30AUG2018	1
		6	13SEP2018	1
1016	UB non-mentholated	-1	31JUL2018	8
		2	16AUG2018	6
		4	29AUG2018	5
		6	13SEP2018	6
1017	UB mentholated	-1	01AUG2018	8
		2	16AUG2018	8
		4	29AUG2018	9
		6	13SEP2018	7
1018	VLN mentholated	-1	01AUG2018	3
		2	17AUG2018	5
1019	VLN non-mentholated	-1	01AUG2018	8

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
1019	VLN non-mentholated	2	17AUG2018	4
		4	29AUG2018	1
		6	13SEP2018	1
1020	VLN non-mentholated	-1	01AUG2018	6
		2	17AUG2018	1
		4	30AUG2018	1
		6	13SEP2018	2
1021	UB non-mentholated	-1	01AUG2018	6
		2	16AUG2018	6
		4	29AUG2018	5
		6	13SEP2018	5
1023	VLN non-mentholated	-1	01AUG2018	6
		2	17AUG2018	4
		4	30AUG2018	4
		6	13SEP2018	4
1029	VLN mentholated	-1	28AUG2018	9
		2	13SEP2018	9
		4	25SEP2018	5
		6	11OCT2018	10
1032	VLN mentholated	-1	27AUG2018	10
		2	13SEP2018	9
		4	25SEP2018	5
		6	10OCT2018	9
1034	VLN non-mentholated	-1	27AUG2018	6
		2	13SEP2018	7

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
1034	VLN non-mentholated	4	25SEP2018	7
		6	10OCT2018	6
1035	VLN non-mentholated	-1	27AUG2018	9
		2	12SEP2018	3
		4	25SEP2018	3
		6	11OCT2018	4
1036	UB mentholated	-1	28AUG2018	7
		4	24SEP2018	7
		6	10OCT2018	6
1037	UB mentholated	-1	28AUG2018	8
		2	12SEP2018	6
		4	25SEP2018	7
		6	10OCT2018	7
1038	VLN non-mentholated	-1	28AUG2018	10
		2	13SEP2018	1
		4	26SEP2018	1
		6	10OCT2018	1
1042	VLN non-mentholated	-1	28AUG2018	5
		2	13SEP2018	2
		4	25SEP2018	1
		6	11OCT2018	1
1045	UB non-mentholated	-1	28AUG2018	6
		2	11SEP2018	4
		4	25SEP2018	4
		6	09OCT2018	6

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
1046	UB mentholated	-1	28AUG2018	6
		2	11SEP2018	8
		4	24SEP2018	7
		6	09OCT2018	6
1050	VLN non-mentholated	-1	28AUG2018	7
		2	13SEP2018	1
		4	25SEP2018	1
		6	10OCT2018	4
1051	UB mentholated	-1	28AUG2018	7
		2	12SEP2018	10
		4	24SEP2018	9
		6	10OCT2018	9
1052	VLN mentholated	-1	28AUG2018	5
		2	13SEP2018	4
		6	11OCT2018	5
1053	VLN mentholated	-1	28AUG2018	10
		2	12SEP2018	1
		4	26SEP2018	1
		6	11OCT2018	1
1054	UB non-mentholated	-1	27AUG2018	8
		2	11SEP2018	5
		4	25SEP2018	5
		6	10OCT2018	5
1055	VLN mentholated	-1	28AUG2018	5
		2	13SEP2018	1

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
1055	VLN mentholated	4	26SEP2018	1
		6	10OCT2018	1
1056	VLN non-mentholated	-1	27AUG2018	10
		2	13SEP2018	10
		4	26SEP2018	7
		6	11OCT2018	10
1058	VLN non-mentholated	-1	28AUG2018	7
		2	13SEP2018	10
		4	26SEP2018	5
		6	11OCT2018	4
1059	UB non-mentholated	-1	10SEP2018	8
		2	25SEP2018	8
		4	08OCT2018	10
		6	24OCT2018	10
1060	VLN mentholated	-1	10SEP2018	10
		2	26SEP2018	5
		4	09OCT2018	5
		6	24OCT2018	5
1063	VLN mentholated	-1	10SEP2018	8
		2	27SEP2018	2
		4	09OCT2018	1
		6	24OCT2018	1
1064	UB non-mentholated	-1	10SEP2018	10
		2	25SEP2018	8

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
1066	VLN non-mentholated	-1	11SEP2018	8
		2	26SEP2018	2
		4	09OCT2018	2
		6	23OCT2018	2
1069	UB non-mentholated	-1	11SEP2018	10
		2	26SEP2018	10
		4	09OCT2018	8
		6	24OCT2018	8
1070	VLN non-mentholated	-1	10SEP2018	8
		2	26SEP2018	1
		4	08OCT2018	1
		6	24OCT2018	1
1071	VLN non-mentholated	-1	10SEP2018	7
		2	25SEP2018	1
		4	08OCT2018	1
1072	VLN mentholated	-1	10SEP2018	5
		2	27SEP2018	6
		4	09OCT2018	1
1074	VLN non-mentholated	-1	10SEP2018	6
		2	26SEP2018	2
		4	09OCT2018	2
		6	23OCT2018	2
1075	UB non-mentholated	-1	10SEP2018	6
		2	26SEP2018	5
		4	09OCT2018	5

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
1075	UB non-mentholated	6	24OCT2018	5
1077	VLN non-mentholated	-1	10SEP2018	4
		2	26SEP2018	3
		4	09OCT2018	3
		6	24OCT2018	3
1078	VLN non-mentholated	-1	11SEP2018	8
		2	25SEP2018	9
		4	09OCT2018	9
		6	24OCT2018	9
1079	VLN mentholated	-1	11SEP2018	7
		2	26SEP2018	1
		4	09OCT2018	1
		6	24OCT2018	2
1082	VLN non-mentholated	-1	10SEP2018	7
		2	26SEP2018	2
		4	09OCT2018	2
		6	24OCT2018	1
1083	VLN non-mentholated	-1	17SEP2018	10
		2	03OCT2018	1
		4	16OCT2018	1
		6	31OCT2018	1
1084	VLN non-mentholated	-1	17SEP2018	3
		2	03OCT2018	3
1086	VLN non-mentholated	-1	18SEP2018	8

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
1086	VLN non-mentholated	2	02OCT2018	2
		4	15OCT2018	5
		6	30OCT2018	1
1088	VLN mentholated	-1	18SEP2018	3
		2	03OCT2018	2
		4	16OCT2018	3
		6	31OCT2018	1
1089	UB non-mentholated	-1	17SEP2018	3
		2	02OCT2018	1
		4	15OCT2018	2
		6	30OCT2018	2
1092	VLN mentholated	-1	18SEP2018	8
		2	03OCT2018	1
		4	16OCT2018	1
		6	31OCT2018	1
1094	VLN mentholated	-1	18SEP2018	5
		2	02OCT2018	3
		4	15OCT2018	3
		6	31OCT2018	1
1095	VLN mentholated	-1	17SEP2018	2
		2	02OCT2018	1
		4	15OCT2018	3
		6	30OCT2018	6
1096	VLN non-mentholated	-1	18SEP2018	8
		2	27SEP2018	1

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
1096	VLN non-mentholated	4	16OCT2018	1
		6	31OCT2018	1
1097	VLN mentholated	-1	18SEP2018	10
		2	03OCT2018	1
		4	16OCT2018	1
		6	31OCT2018	1
1098	VLN non-mentholated	-1	04OCT2018	8
		6	16NOV2018	3
1099	VLN non-mentholated	-1	04OCT2018	8
		2	19OCT2018	4
		4	01NOV2018	2
		6	16NOV2018	8
1100	VLN non-mentholated	-1	04OCT2018	3
		2	19OCT2018	6
		4	01NOV2018	6
		6	16NOV2018	3
1101	VLN non-mentholated	-1	03OCT2018	8
		6	16NOV2018	8
1103	VLN non-mentholated	-1	03OCT2018	10
		2	19OCT2018	1
		4	01NOV2018	2
		6	16NOV2018	1
1105	VLN non-mentholated	-1	03OCT2018	10
		2	19OCT2018	2

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
1105	VLN non-mentholated	4	02NOV2018	1
		6	16NOV2018	2
1106	UB non-mentholated	-1	04OCT2018	5
		2	19OCT2018	6
		4	31OCT2018	9
		6	16NOV2018	3
1107	VLN non-mentholated	-1	04OCT2018	8
		2	19OCT2018	3
		4	02NOV2018	2
		6	16NOV2018	4
1108	UB non-mentholated	-1	03OCT2018	10
		2	18OCT2018	8
		4	31OCT2018	9
		6	15NOV2018	9
1109	UB non-mentholated	-1	04OCT2018	10
		2	19OCT2018	10
		4	01NOV2018	10
		6	16NOV2018	10
1112	VLN non-mentholated	-1	03OCT2018	9
		2	19OCT2018	1
		4	02NOV2018	1
		6	16NOV2018	1
1114	UB non-mentholated	-1	03OCT2018	10
		2	18OCT2018	10
		4	01NOV2018	10

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
1114	UB non-mentholated	6	15NOV2018	4
1115	VLN non-mentholated	-1	03OCT2018	5
		2	19OCT2018	7
		4	02NOV2018	3
2002	UB mentholated	-1	23JUL2018	10
		2	08AUG2018	10
		4	21AUG2018	8
		6	05SEP2018	8
2003	VLN mentholated	-1	16JUL2018	6
		2	31JUL2018	5
		4	14AUG2018	3
		6	28AUG2018	3
2007	VLN non-mentholated	-1	16JUL2018	10
		2	01AUG2018	8
		4	14AUG2018	1
		6	29AUG2018	1
2008	VLN mentholated	-1	16JUL2018	6
		2	01AUG2018	5
		4	14AUG2018	6
		6	28AUG2018	3
2009	VLN non-mentholated	-1	16JUL2018	6
		2	31JUL2018	4
		4	14AUG2018	5
2010	UB mentholated	-1	17JUL2018	5

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
2010	UB mentholated	2	01AUG2018	4
		4	14AUG2018	4
		6	29AUG2018	5
2011	VLN mentholated	-1	16JUL2018	5
		2	31JUL2018	7
		4	13AUG2018	1
		6	28AUG2018	7
2014	VLN mentholated	-1	17JUL2018	8
		2	01AUG2018	2
		4	14AUG2018	3
		6	29AUG2018	2
2015	UB mentholated	-1	17JUL2018	3
		2	31JUL2018	8
		4	13AUG2018	7
		6	28AUG2018	8
2016	VLN mentholated	-1	16JUL2018	8
		2	01AUG2018	8
2017	VLN mentholated	-1	16JUL2018	8
		2	01AUG2018	3
		4	13AUG2018	3
		6	28AUG2018	4
2018	UB mentholated	-1	16JUL2018	10
		2	01AUG2018	10
		4	14AUG2018	7
		6	29AUG2018	8

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
2020	VLN mentholated	-1	16JUL2018	10
		2	31JUL2018	1
		4	13AUG2018	1
		6	28AUG2018	1
2021	VLN mentholated	-1	17JUL2018	3
		2	01AUG2018	1
		4	14AUG2018	1
		6	28AUG2018	1
2023	VLN mentholated	-1	17JUL2018	7
		2	01AUG2018	5
		4	14AUG2018	1
		6	28AUG2018	1
2024	UB non-mentholated	-1	17JUL2018	10
2025	UB non-mentholated	-1	16JUL2018	4
		2	01AUG2018	7
		4	13AUG2018	6
		6	28AUG2018	6
2028	VLN non-mentholated	-1	17JUL2018	10
		2	01AUG2018	7
		4	13AUG2018	3
		6	29AUG2018	2
2029	UB mentholated	-1	24JUL2018	6
		2	08AUG2018	6
		4	21AUG2018	5
		6	05SEP2018	5

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
2039	VLN mentholated	2	08AUG2018	7
		4	21AUG2018	7
		6	04SEP2018	2
2050	UB mentholated	-1	08AUG2018	7
		2	23AUG2018	4
		4	04SEP2018	7
		6	20SEP2018	5
2052	VLN mentholated	-1	08AUG2018	6
		2	23AUG2018	1
		4	05SEP2018	1
		6	20SEP2018	1
2057	VLN mentholated	-1	08AUG2018	3
		2	23AUG2018	3
		4	05SEP2018	4
		6	20SEP2018	2
2058	VLN mentholated	-1	08AUG2018	10
		2	23AUG2018	4
		4	05SEP2018	1
		6	19SEP2018	2
2059	UB mentholated	-1	07AUG2018	7
		2	23AUG2018	6
		4	04SEP2018	3
		6	19SEP2018	7
2060	VLN mentholated	-1	07AUG2018	8
		2	23AUG2018	1

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
2060	VLN mentholated	4	05SEP2018	2
		6	19SEP2018	1
2064	VLN mentholated	-1	08AUG2018	7
		2	23AUG2018	1
		4	05SEP2018	7
		6	20SEP2018	4
2066	VLN mentholated	-1	08AUG2018	7
		2	23AUG2018	5
		4	05SEP2018	3
		6	19SEP2018	3
2067	VLN non-mentholated	-1	08AUG2018	5
		2	23AUG2018	1
		4	05SEP2018	1
		6	20SEP2018	3
2075	VLN mentholated	-1	08AUG2018	5
2076	VLN mentholated	-1	01SEP2018	10
		2	15SEP2018	1
		4	29SEP2018	1
		6	13OCT2018	1
2086	VLN non-mentholated	-1	01SEP2018	5
		2	15SEP2018	6
		4	29SEP2018	5
2088	VLN mentholated	-1	01SEP2018	7
		2	15SEP2018	1

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
2088	VLN mentholated	4	29SEP2018	3
		6	13OCT2018	3
2092	VLN mentholated	-1	01SEP2018	9
		2	15SEP2018	2
		4	29SEP2018	1
		6	13OCT2018	1
2099	VLN non-mentholated	-1	01SEP2018	10
		2	16SEP2018	10
		4	29SEP2018	5
		6	13OCT2018	5
2100	UB mentholated	-1	01SEP2018	2
		2	16SEP2018	5
		4	29SEP2018	8
		6	13OCT2018	7
2108	VLN non-mentholated	-1	31AUG2018	10
		2	15SEP2018	2
		4	29SEP2018	2
		6	13OCT2018	2
2110	UB mentholated	-1	06SEP2018	3
		2	21SEP2018	3
		4	05OCT2018	1
		6	20OCT2018	4
2113	VLN mentholated	-1	06SEP2018	6
		2	21SEP2018	5

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
2115	VLN mentholated	-1	06SEP2018	9
		2	21SEP2018	1
2119	VLN mentholated	-1	06SEP2018	6
		2	21SEP2018	4
		4	04OCT2018	9
		6	19OCT2018	4
2120	VLN non-mentholated	-1	07SEP2018	10
		2	21SEP2018	4
		4	04OCT2018	2
		6	20OCT2018	1
2122	UB non-mentholated	-1	06SEP2018	6
		2	22SEP2018	2
		4	05OCT2018	6
		6	19OCT2018	8
2125	UB mentholated	-1	06SEP2018	6
		2	21SEP2018	6
		4	05OCT2018	3
		6	19OCT2018	3
2126	VLN mentholated	-1	06SEP2018	5
		2	21SEP2018	3
		4	04OCT2018	6
		6	19OCT2018	5
2136	VLN non-mentholated	-1	07SEP2018	10
		2	22SEP2018	1
		4	05OCT2018	1

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
2140	UB non-mentholated	-1	23SEP2018	9
		2	08OCT2018	8
		4	21OCT2018	10
		6	05NOV2018	10
2142	VLN non-mentholated	-1	24SEP2018	10
2143	VLN non-mentholated	-1	23SEP2018	6
		2	08OCT2018	6
		4	22OCT2018	7
		6	05NOV2018	8
2158	UB non-mentholated	-1	19OCT2018	5
		2	03NOV2018	5
2159	VLN non-mentholated	-1	20OCT2018	8
		2	03NOV2018	7
		4	16NOV2018	8
		6	01DEC2018	5
2164	VLN non-mentholated	-1	19OCT2018	8
		2	03NOV2018	5
		4	17NOV2018	6
		6	01DEC2018	9
2168	VLN non-mentholated	-1	19OCT2018	6
		2	04NOV2018	6
		4	17NOV2018	5
		6	01DEC2018	5
2170	UB non-mentholated	-1	19OCT2018	10

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
2170	UB non-mentholated	2	03NOV2018	10
		4	17NOV2018	10
		6	02DEC2018	10
2175	UB mentholated	-1	19OCT2018	7
		2	04NOV2018	8
		4	17NOV2018	10
		6	01DEC2018	7
2189	VLN mentholated	-1	19OCT2018	8
2211	VLN mentholated	-1	19OCT2018	10
		2	03NOV2018	10
		4	16NOV2018	10
		6	01DEC2018	10
2212	UB mentholated	-1	19OCT2018	7
		2	03NOV2018	7
		4	18NOV2018	6
		6	02DEC2018	6
2213	VLN mentholated	-1	19OCT2018	7
		2	03NOV2018	1
		4	17NOV2018	7
		6	02DEC2018	1
2215	UB mentholated	-1	19OCT2018	8
		2	03NOV2018	5
		4	16NOV2018	9
		6	01DEC2018	10

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
2220	VLN non-mentholated	-1	20OCT2018	7
		2	04NOV2018	3
		4	16NOV2018	5
		6	02DEC2018	3
2235	VLN mentholated	-1	03NOV2018	10
		2	18NOV2018	10
		4	01DEC2018	10
		6	15DEC2018	10
2244	VLN non-mentholated	-1	03NOV2018	10
		2	18NOV2018	1
		4	01DEC2018	3
		6	15DEC2018	2
2247	VLN mentholated	-1	06DEC2018	8
2251	UB non-mentholated	-1	07DEC2018	8
		2	22DEC2018	10
		4	04JAN2019	9
		6	18JAN2019	7
2257	UB non-mentholated	-1	06DEC2018	7
		2	22DEC2018	8
		4	04JAN2019	8
		6	19JAN2019	7
2259	UB mentholated	-1	06DEC2018	8
		2	22DEC2018	8
		4	03JAN2019	9
		6	18JAN2019	8

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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Appendix 16.2.6.15 Perceived Health Risk Scale (Safety Population)

Subject Number	Product Group	Study Week	Date	Perceived Health Risk Scale*
2269	VLN mentholated	-1	06DEC2018	7
		2	22DEC2018	3
		4	03JAN2019	2
		6	18JAN2019	7
2272	VLN mentholated	-1	06DEC2018	7
		2	21DEC2018	1
		4	04JAN2019	5
		6	18JAN2019	1

Note: * Indicate your perception of the risk of becoming addicted to the cigarette you are currently using

Scale: 1 = Very low risk, 10 = Very high risk

Subjects used their own usual brand cigarettes at Week -1.

VLN non-mentholated = Non-mentholated VLN cigarettes; VLN mentholated = Mentholated VLN cigarettes;

UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes; UB mentholated = Subjects' UB mentholated filtered cigarette

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