



16.2.4 Demographic Data

- Appendix 16.2.4.1.1 Demographics (Safety Population) (I of II)
- Appendix 16.2.4.1.2 Demographics (Safety Population) (II of II)
- Appendix 16.2.4.2 Physical Examination (Safety Population)
- Appendix 16.2.4.3 Medical History (Safety Population)
- Appendix 16.2.4.4 Tobacco/Nicotine Use History (Safety Population)

Appendix 16.2.4.1.1 Demographics (Safety Population) (I of II)

Site	Subject Number	Product Group	Age (yrs)	Sex	Race	Ethnicity	Reproductive Status
001	1001	VLN non-mentholated	59	FEMALE	WHITE	NOT HISPANIC OR LATINO	POST-MENOPAUSAL
	1002	VLN non-mentholated	30	MALE	WHITE	NOT HISPANIC OR LATINO	
	1003	VLN mentholated	38	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	1007	VLN non-mentholated	37	MALE	WHITE	NOT HISPANIC OR LATINO	
	1008	VLN mentholated	48	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	1010	UB mentholated	32	MALE	WHITE	NOT HISPANIC OR LATINO	
	1011	UB non-mentholated	36	MALE	WHITE	NOT HISPANIC OR LATINO	
	1013	VLN non-mentholated	36	FEMALE	WHITE	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL
	1014	VLN mentholated	36	FEMALE	WHITE	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL
	1015	VLN mentholated	49	FEMALE	WHITE	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL
	1016	UB non-mentholated	54	MALE	WHITE	NOT HISPANIC OR LATINO	
	1017	UB mentholated	41	FEMALE	WHITE	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	1018	VLN mentholated	41	FEMALE	WHITE	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	1019	VLN non-mentholated	30	MALE	AMERICAN INDIAN OR ALASKA NATIVE	NOT HISPANIC OR LATINO	
	1020	VLN non-mentholated	36	FEMALE	WHITE	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL
	1021	UB non-mentholated	49	FEMALE	WHITE	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL
	1023	VLN non-mentholated	50	FEMALE	WHITE	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	1029	VLN mentholated	35	FEMALE	WHITE	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL
	1032	VLN mentholated	53	FEMALE	WHITE	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	1034	VLN non-mentholated	45	MALE	WHITE	NOT HISPANIC OR LATINO	
	1035	VLN non-mentholated	44	MALE	BLACK OR AFRICAN AMERICAN AND WHITE	NOT HISPANIC OR LATINO	
	1036	UB mentholated	38	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL
	1037	UB mentholated	29	MALE	WHITE	NOT HISPANIC OR LATINO	
	1038	VLN non-mentholated	39	FEMALE	WHITE	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	1042	VLN non-mentholated	47	MALE	WHITE	NOT HISPANIC OR LATINO	
	1045	UB non-mentholated	58	MALE	WHITE	NOT HISPANIC OR LATINO	
	1046	UB mentholated	45	MALE	WHITE	NOT HISPANIC OR LATINO	
	1050	VLN non-mentholated	33	FEMALE	WHITE	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	1051	UB mentholated	36	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SURGICALLY STERILE

Note: 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
 Site: 001 = Lincoln, 002 = High Point

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Appendix 16.2.4.1.1 Demographics (Safety Population) (I of II)

Site	Subject Number	Product Group	Age (yrs)	Sex	Race	Ethnicity	Reproductive Status
001	1052	VLN mentholated	31	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	1053	VLN mentholated	42	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	1054	UB non-mentholated	56	MALE	WHITE	NOT HISPANIC OR LATINO	
	1055	VLN mentholated	39	FEMALE	WHITE	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	1056	VLN non-mentholated	48	MALE	WHITE	NOT HISPANIC OR LATINO	
	1058	VLN non-mentholated	30	MALE	WHITE	NOT HISPANIC OR LATINO	
	1059	UB non-mentholated	38	MALE	WHITE	NOT HISPANIC OR LATINO	
	1060	VLN mentholated	55	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	1063	VLN mentholated	31	MALE	WHITE	NOT HISPANIC OR LATINO	
	1064	UB non-mentholated	34	MALE	WHITE	NOT HISPANIC OR LATINO	
	1066	VLN non-mentholated	62	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	1069	UB non-mentholated	40	FEMALE	WHITE	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	1070	VLN non-mentholated	53	MALE	WHITE	NOT HISPANIC OR LATINO	
	1071	VLN non-mentholated	42	MALE	WHITE	NOT HISPANIC OR LATINO	
	1072	VLN mentholated	59	MALE	WHITE	NOT HISPANIC OR LATINO	
	1074	VLN non-mentholated	42	MALE	WHITE	NOT HISPANIC OR LATINO	
	1075	UB non-mentholated	26	FEMALE	WHITE	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	1077	VLN non-mentholated	49	FEMALE	WHITE	NOT HISPANIC OR LATINO	POST-MENOPAUSAL
	1078	VLN non-mentholated	51	FEMALE	WHITE	NOT HISPANIC OR LATINO	POST-MENOPAUSAL
	1079	VLN mentholated	33	MALE	WHITE	NOT HISPANIC OR LATINO	
	1082	VLN non-mentholated	37	MALE	WHITE	NOT HISPANIC OR LATINO	
	1083	VLN non-mentholated	54	FEMALE	WHITE	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	1084	VLN non-mentholated	42	MALE	WHITE	NOT HISPANIC OR LATINO	
	1086	VLN non-mentholated	54	MALE	WHITE	NOT HISPANIC OR LATINO	
	1088	VLN mentholated	26	MALE	WHITE	NOT HISPANIC OR LATINO	
	1089	UB non-mentholated	60	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	1092	VLN mentholated	43	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL
	1094	VLN mentholated	46	MALE	ASIAN	NOT HISPANIC OR LATINO	
	1095	VLN mentholated	55	FEMALE	AMERICAN INDIAN OR ALASKA NATIVE AND WHITE	NOT HISPANIC OR LATINO	POST-MENOPAUSAL
	1096	VLN non-mentholated	42	FEMALE	WHITE	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL

Note: 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
 Site: 001 = Lincoln, 002 = High Point

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Appendix 16.2.4.1.1 Demographics (Safety Population) (I of II)

Site	Subject Number	Product Group	Age (yrs)	Sex	Race	Ethnicity	Reproductive Status
001	1097	VLN mentholated	30	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	1098	VLN non-mentholated	63	MALE	WHITE	NOT HISPANIC OR LATINO	
	1099	VLN non-mentholated	46	FEMALE	WHITE	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	1100	VLN non-mentholated	59	MALE	WHITE	NOT HISPANIC OR LATINO	
	1101	VLN non-mentholated	41	MALE	WHITE	NOT HISPANIC OR LATINO	
	1103	VLN non-mentholated	43	MALE	WHITE	NOT HISPANIC OR LATINO	
	1105	VLN non-mentholated	47	FEMALE	WHITE	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL
	1106	UB non-mentholated	42	MALE	WHITE	NOT HISPANIC OR LATINO	
	1107	VLN non-mentholated	45	MALE	WHITE	NOT HISPANIC OR LATINO	
	1108	UB non-mentholated	54	MALE	AMERICAN INDIAN OR ALASKA NATIVE AND WHITE	NOT HISPANIC OR LATINO	
	1109	UB non-mentholated	58	MALE	WHITE	NOT HISPANIC OR LATINO	
	1112	VLN non-mentholated	59	FEMALE	WHITE	NOT HISPANIC OR LATINO	POST-MENOPAUSAL
	1114	UB non-mentholated	26	FEMALE	WHITE	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL
	1115	VLN non-mentholated	29	MALE	WHITE	HISPANIC OR LATINO	
002	2002	UB mentholated	49	MALE	WHITE	HISPANIC OR LATINO	
	2003	VLN mentholated	41	FEMALE	WHITE	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	2007	VLN non-mentholated	57	FEMALE	WHITE	NOT HISPANIC OR LATINO	POST-MENOPAUSAL
	2008	VLN mentholated	42	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	2009	VLN non-mentholated	55	MALE	WHITE	NOT HISPANIC OR LATINO	
	2010	UB mentholated	27	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	2011	VLN mentholated	32	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL
	2014	VLN mentholated	37	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	2015	UB mentholated	57	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	POST-MENOPAUSAL
	2016	VLN mentholated	45	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL
	2017	VLN mentholated	30	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	2018	UB mentholated	26	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	2020	VLN mentholated	60	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	2021	VLN mentholated	31	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	2023	VLN mentholated	35	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	2024	UB non-mentholated	26	MALE	WHITE	NOT HISPANIC OR LATINO	

Note: VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
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Appendix 16.2.4.1.1 Demographics (Safety Population) (I of II)

Site	Subject Number	Product Group	Age (yrs)	Sex	Race	Ethnicity	Reproductive Status
002	2025	UB non-mentholated	59	MALE	WHITE	NOT HISPANIC OR LATINO	
	2028	VLN non-mentholated	36	MALE	WHITE	NOT HISPANIC OR LATINO	
	2029	UB mentholated	56	MALE	WHITE	NOT HISPANIC OR LATINO	
	2039	VLN mentholated	49	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	POST-MENOPAUSAL
	2050	UB mentholated	57	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	2052	VLN mentholated	54	MALE	WHITE	NOT HISPANIC OR LATINO	
	2057	VLN mentholated	52	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	2058	VLN mentholated	37	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL
	2059	UB mentholated	56	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	2060	VLN mentholated	37	FEMALE	BLACK OR AFRICAN AMERICAN	HISPANIC OR LATINO	SURGICALLY STERILE
	2064	VLN mentholated	52	MALE	WHITE	NOT HISPANIC OR LATINO	
	2066	VLN mentholated	30	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL
	2067	VLN non-mentholated	52	MALE	WHITE	NOT HISPANIC OR LATINO	
	2075	VLN mentholated	34	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	2076	VLN mentholated	42	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	2086	VLN non-mentholated	36	MALE	WHITE	NOT HISPANIC OR LATINO	
	2088	VLN mentholated	39	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	2092	VLN mentholated	50	FEMALE	WHITE	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	2099	VLN non-mentholated	52	MALE	WHITE	NOT HISPANIC OR LATINO	
	2100	UB mentholated	48	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	2108	VLN non-mentholated	60	FEMALE	WHITE	NOT HISPANIC OR LATINO	POST-MENOPAUSAL
	2110	UB mentholated	41	FEMALE	WHITE	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL
	2113	VLN mentholated	51	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	POST-MENOPAUSAL
	2115	VLN mentholated	46	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	2119	VLN mentholated	48	MALE	WHITE	NOT HISPANIC OR LATINO	
	2120	VLN non-mentholated	62	FEMALE	WHITE	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	2122	UB non-mentholated	60	MALE	WHITE	NOT HISPANIC OR LATINO	
	2125	UB mentholated	35	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	2126	VLN mentholated	37	MALE	WHITE	NOT HISPANIC OR LATINO	
	2136	VLN non-mentholated	64	MALE	WHITE	NOT HISPANIC OR LATINO	
	2140	UB non-mentholated	56	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	SURGICALLY STERILE

Note: 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
 Site: 001 = Lincoln, 002 = High Point

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Appendix 16.2.4.1.1 Demographics (Safety Population) (I of II)

Site	Subject Number	Product Group	Age (yrs)	Sex	Race	Ethnicity	Reproductive Status
002	2142	VLN non-mentholated	30	FEMALE	WHITE	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL
	2143	VLN non-mentholated	63	MALE	OTHER RACE	NOT HISPANIC OR LATINO	
	2158	UB non-mentholated	43	FEMALE	WHITE	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL
	2159	VLN non-mentholated	37	MALE	WHITE	NOT HISPANIC OR LATINO	
	2164	VLN non-mentholated	65	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	POST-MENOPAUSAL
	2168	VLN non-mentholated	32	FEMALE	WHITE	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL
	2169		42	MALE	WHITE	NOT HISPANIC OR LATINO	
	2170	UB non-mentholated	51	FEMALE	OTHER RACE	HISPANIC OR LATINO	SURGICALLY STERILE
	2175	UB mentholated	40	FEMALE	WHITE	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	2189	VLN mentholated	28	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	2211	VLN mentholated	29	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL
	2212	UB mentholated	32	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	2213	VLN mentholated	29	MALE	WHITE	NOT HISPANIC OR LATINO	
	2214		54	FEMALE	WHITE	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	2215	UB mentholated	59	FEMALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	POST-MENOPAUSAL
	2220	VLN non-mentholated	37	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	2224		42	FEMALE	WHITE	NOT HISPANIC OR LATINO	SURGICALLY STERILE
	2235	VLN mentholated	26	FEMALE	BLACK AND WHITE	NOT HISPANIC OR LATINO	OF CHILD-BEARING POTENTIAL
	2244	VLN non-mentholated	31	MALE	WHITE	NOT HISPANIC OR LATINO	
	2247	VLN mentholated	28	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	2251	UB non-mentholated	27	MALE	WHITE	NOT HISPANIC OR LATINO	
	2257	UB non-mentholated	55	FEMALE	WHITE	NOT HISPANIC OR LATINO	POST-MENOPAUSAL
	2259	UB mentholated	49	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	2269	VLN mentholated	48	MALE	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	
	2272	VLN mentholated	37	MALE	AMERICAN INDIAN OR ALASKA NATIVE	NOT HISPANIC OR LATINO	

Note: 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
 Site: 001 = Lincoln, 002 = High Point

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Appendix 16.2.4.1.2 Demographics (Safety Population) (II of II)

Site	Subject Number	Product Group	Age (yrs)	Sex	Height (cm)	Weight (kg)	BMI (kg/m ²)	Informed Consent Date	Informed Re-Consent Date	Informed Re-Consent Date 2
001	1001	VLN non-mentholated	59	FEMALE	155	64.2	26.7	02JUL2018	08AUG2018	06SEP2018
	1002	VLN non-mentholated	30	MALE	177	100.7	32.1	02JUL2018	08AUG2018	06SEP2018
	1003	VLN mentholated	38	MALE	171	78.6	26.9	03JUL2018	08AUG2018	06SEP2018
	1007	VLN non-mentholated	37	MALE	179	100.7	31.4	12JUL2018	08AUG2018	06SEP2018
	1008	VLN mentholated	48	MALE	172	89.8	30.4	12JUL2018	08AUG2018	06SEP2018
	1010	UB mentholated	32	MALE	173	67.9	22.7	13JUL2018	08AUG2018	06SEP2018
	1011	UB non-mentholated	36	MALE	178	83	26.2	13JUL2018	08AUG2018	06SEP2018
	1013	VLN non-mentholated	36	FEMALE	174	72.9	24.1	16JUL2018	31JUL2018	12SEP2018
	1014	VLN mentholated	36	FEMALE	154	64	27	16JUL2018	31JUL2018	12SEP2018
	1015	VLN mentholated	49	FEMALE	169	62.3	21.8	16JUL2018	31JUL2018	12SEP2018
	1016	UB non-mentholated	54	MALE	165	84.3	31	16JUL2018	31JUL2018	12SEP2018
	1017	UB mentholated	41	FEMALE	168	106.3	37.7	17JUL2018	31JUL2018	12SEP2018
	1018	VLN mentholated	41	FEMALE	168	78.9	28	17JUL2018	31JUL2018	
	1019	VLN non-mentholated	30	MALE	178	92.1	29.1	17JUL2018	31JUL2018	12SEP2018
	1020	VLN non-mentholated	36	FEMALE	161	103.1	39.8	17JUL2018	31JUL2018	12SEP2018
	1021	UB non-mentholated	49	FEMALE	164	83.1	30.9	17JUL2018	31JUL2018	12SEP2018
	1023	VLN non-mentholated	50	FEMALE	161	62.6	24.2	17JUL2018	31JUL2018	12SEP2018
	1029	VLN mentholated	35	FEMALE	164	95.9	35.7	26JUL2018	22AUG2018	11SEP2018
	1032	VLN mentholated	53	FEMALE	172	64.5	21.8	13AUG2018	11SEP2018	
	1034	VLN non-mentholated	45	MALE	180	107.2	33.1	13AUG2018	11SEP2018	
	1035	VLN non-mentholated	44	MALE	178	106	33.5	13AUG2018	11SEP2018	
	1036	UB mentholated	38	FEMALE	163	85.3	32.1	13AUG2018	11SEP2018	
	1037	UB mentholated	29	MALE	189	89.3	25	13AUG2018	11SEP2018	
	1038	VLN non-mentholated	39	FEMALE	159	81.8	32.4	13AUG2018	11SEP2018	
	1042	VLN non-mentholated	47	MALE	184	102.2	30.2	13AUG2018	11SEP2018	
	1045	UB non-mentholated	58	MALE	180	83.1	25.6	14AUG2018	11SEP2018	
	1046	UB mentholated	45	MALE	191	122.8	33.7	14AUG2018	11SEP2018	
	1050	VLN non-mentholated	33	FEMALE	161	90.1	34.8	14AUG2018	11SEP2018	
	1051	UB mentholated	36	FEMALE	162	103.1	39.3	14AUG2018	11SEP2018	
	1052	VLN mentholated	31	MALE	184	80.3	23.7	14AUG2018	11SEP2018	

Note: 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
 Site: 001 = Lincoln, 002 = High Point, BMI = Body Mass Index

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-DEM.SAS 18JUN2019 11:10

Appendix 16.2.4.1.2 Demographics (Safety Population) (II of II)

Site	Subject Number	Product Group	Age (yrs)	Sex	Height (cm)	Weight (kg)	BMI (kg/m ²)	Informed Consent Date	Informed Re-Consent Date	Informed Re-Consent Date 2
001	1053	VLN mentholated	42	MALE	168	84.9	30.1	14AUG2018	11SEP2018	
	1054	UB non-mentholated	56	MALE	179	119	37.1	14AUG2018	11SEP2018	
	1055	VLN mentholated	39	FEMALE	160	65.7	25.7	14AUG2018	11SEP2018	
	1056	VLN non-mentholated	48	MALE	173	70.9	23.7	14AUG2018	11SEP2018	
	1058	VLN non-mentholated	30	MALE	169	85	29.8	15AUG2018	11SEP2018	
	1059	UB non-mentholated	38	MALE	175	86	28.1	27AUG2018	30AUG2018	10SEP2018
	1060	VLN mentholated	55	MALE	165	74.3	27.3	27AUG2018	30AUG2018	10SEP2018
	1063	VLN mentholated	31	MALE	190	114.2	31.6	27AUG2018	30AUG2018	10SEP2018
	1064	UB non-mentholated	34	MALE	181	110.2	33.6	27AUG2018	30AUG2018	10SEP2018
	1066	VLN non-mentholated	62	MALE	182	82	24.8	27AUG2018	30AUG2018	10SEP2018
	1069	UB non-mentholated	40	FEMALE	179	125.1	39	28AUG2018	30AUG2018	10SEP2018
	1070	VLN non-mentholated	53	MALE	180	90	27.8	28AUG2018	30AUG2018	10SEP2018
	1071	VLN non-mentholated	42	MALE	173	118.7	39.7	28AUG2018	30AUG2018	10SEP2018
	1072	VLN mentholated	59	MALE	177	74.7	23.8	28AUG2018	30AUG2018	10SEP2018
	1074	VLN non-mentholated	42	MALE	179	105.4	32.9	28AUG2018	30AUG2018	10SEP2018
	1075	UB non-mentholated	26	FEMALE	175	66.2	21.6	28AUG2018	30AUG2018	10SEP2018
	1077	VLN non-mentholated	49	FEMALE	164	85.6	31.8	28AUG2018	30AUG2018	10SEP2018
	1078	VLN non-mentholated	51	FEMALE	182	73.4	22.2	28AUG2018	30AUG2018	10SEP2018
	1079	VLN mentholated	33	MALE	179	103.9	32.4	28AUG2018	30AUG2018	10SEP2018
	1082	VLN non-mentholated	37	MALE	186	91.8	26.5	30AUG2018	10SEP2018	
	1083	VLN non-mentholated	54	FEMALE	170	101.9	35.3	04SEP2018	07SEP2018	12SEP2018
	1084	VLN non-mentholated	42	MALE	178	73.2	23.1	04SEP2018	07SEP2018	12SEP2018
	1086	VLN non-mentholated	54	MALE	169	70.6	24.7	04SEP2018	07SEP2018	12SEP2018
	1088	VLN mentholated	26	MALE	176	86.2	27.8	04SEP2018	07SEP2018	12SEP2018
	1089	UB non-mentholated	60	FEMALE	169	55.1	19.3	04SEP2018	07SEP2018	12SEP2018
	1092	VLN mentholated	43	FEMALE	169	92.2	32.3	05SEP2018	07SEP2018	12SEP2018
	1094	VLN mentholated	46	MALE	173	77.2	25.8	05SEP2018	07SEP2018	12SEP2018
	1095	VLN mentholated	55	FEMALE	166	80.2	29.1	07SEP2018	12SEP2018	
	1096	VLN non-mentholated	42	FEMALE	168	94.1	33.3	07SEP2018	12SEP2018	
	1097	VLN mentholated	30	MALE	182	74.3	22.4	07SEP2018	12SEP2018	

Note: 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
 Site: 001 = Lincoln, 002 = High Point, BMI = Body Mass Index

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-DEM.SAS 18JUN2019 11:10

Appendix 16.2.4.1.2 Demographics (Safety Population) (II of II)

Site	Subject Number	Product Group	Age (yrs)	Sex	Height (cm)	Weight (kg)	BMI (kg/m ²)	Informed Consent Date	Informed Re-Consent Date	Informed Re-Consent Date 2
001	1098	VLN non-mentholated	63	MALE	171	73.3	25.1	18SEP2018		
	1099	VLN non-mentholated	46	FEMALE	170	103.6	35.8	18SEP2018		
	1100	VLN non-mentholated	59	MALE	166	78.5	28.5	18SEP2018		
	1101	VLN non-mentholated	41	MALE	177	70.5	22.5	18SEP2018		
	1103	VLN non-mentholated	43	MALE	185	88.2	25.8	18SEP2018		
	1105	VLN non-mentholated	47	FEMALE	168	54.3	19.2	19SEP2018		
	1106	UB non-mentholated	42	MALE	186	99.9	28.9	19SEP2018		
	1107	VLN non-mentholated	45	MALE	176	90.5	29.2	21SEP2018		
	1108	UB non-mentholated	54	MALE	177	86	27.5	21SEP2018		
	1109	UB non-mentholated	58	MALE	168	75.6	26.8	21SEP2018		
	1112	VLN non-mentholated	59	FEMALE	168	62.4	22.1	21SEP2018		
	1114	UB non-mentholated	26	FEMALE	159	54.7	21.6	24SEP2018		
	1115	VLN non-mentholated	29	MALE	173	118.6	39.6	24SEP2018		
002	2002	UB mentholated	49	MALE	164.1	74.7	27.7	29JUN2018	07AUG2018	
	2003	VLN mentholated	41	FEMALE	172.4	82	27.6	29JUN2018	31JUL2018	
	2007	VLN non-mentholated	57	FEMALE	159.2	57	22.5	29JUN2018	31JUL2018	
	2008	VLN mentholated	42	MALE	183	102.6	30.6	29JUN2018	31JUL2018	
	2009	VLN non-mentholated	55	MALE	184	104.5	30.9	29JUN2018	31JUL2018	
	2010	UB mentholated	27	MALE	176	105.9	34.2	29JUN2018	31JUL2018	
	2011	VLN mentholated	32	FEMALE	180.7	91.9	28.1	29JUN2018	31JUL2018	
	2014	VLN mentholated	37	MALE	181.2	79.5	24.2	02JUL2018	31JUL2018	
	2015	UB mentholated	57	FEMALE	166	109.6	39.8	02JUL2018	31JUL2018	
	2016	VLN mentholated	45	FEMALE	164.7	62.8	23.2	02JUL2018	31JUL2018	
	2017	VLN mentholated	30	MALE	177.1	78.1	24.9	02JUL2018	31JUL2018	
	2018	UB mentholated	26	FEMALE	164	88.6	32.9	02JUL2018	31JUL2018	
	2020	VLN mentholated	60	FEMALE	172	86.8	29.3	02JUL2018	31JUL2018	
	2021	VLN mentholated	31	MALE	178.2	82.4	25.9	02JUL2018	31JUL2018	
	2023	VLN mentholated	35	MALE	177.3	93.7	29.8	02JUL2018	31JUL2018	
	2024	UB non-mentholated	26	MALE	181.4	81.2	24.7	03JUL2018		
	2025	UB non-mentholated	59	MALE	174	106	35	03JUL2018	31JUL2018	

Note: 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
 Site: 001 = Lincoln, 002 = High Point, BMI = Body Mass Index

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-DEM.SAS 18JUN2019 11:10

Appendix 16.2.4.1.2 Demographics (Safety Population) (II of II)

Site	Subject Number	Product Group	Age (yrs)	Sex	Height (cm)	Weight (kg)	BMI (kg/m ²)	Informed Consent Date	Informed Re-Consent Date	Informed Re-Consent Date 2
002	2028	VLN non-mentholated	36	MALE	180	84.3	26	06JUL2018	31JUL2018	
	2029	UB mentholated	56	MALE	179.1	86.7	27	09JUL2018	07AUG2018	
	2039	VLN mentholated	49	FEMALE	177.2	80.8	25.7	13JUL2018	07AUG2018	
	2050	UB mentholated	57	MALE	168	79.9	28.3	20JUL2018	02AUG2018	19SEP2018
	2052	VLN mentholated	54	MALE	171.5	73.7	25.1	20JUL2018	02AUG2018	19SEP2018
	2057	VLN mentholated	52	MALE	174.9	85.1	27.8	23JUL2018	02AUG2018	19SEP2018
	2058	VLN mentholated	37	FEMALE	168.7	96	33.7	23JUL2018	02AUG2018	19SEP2018
	2059	UB mentholated	56	FEMALE	165.2	83.5	30.6	23JUL2018	02AUG2018	19SEP2018
	2060	VLN mentholated	37	FEMALE	176.4	87.8	28.2	23JUL2018	02AUG2018	19SEP2018
	2064	VLN mentholated	52	MALE	172.8	90	30.1	23JUL2018	02AUG2018	19SEP2018
	2066	VLN mentholated	30	FEMALE	167.5	103.6	36.9	23JUL2018	02AUG2018	19SEP2018
	2067	VLN non-mentholated	52	MALE	188.5	111.3	31.3	23JUL2018	02AUG2018	19SEP2018
	2075	VLN mentholated	34	MALE	191.2	100.3	27.4	30JUL2018	02AUG2018	
	2076	VLN mentholated	42	MALE	168.2	81.9	28.9	30JUL2018	15SEP2018	
	2086	VLN non-mentholated	36	MALE	183.5	76.4	22.7	03AUG2018	15SEP2018	
	2088	VLN mentholated	39	FEMALE	177.5	88	27.9	03AUG2018	15SEP2018	
	2092	VLN mentholated	50	FEMALE	156.3	57.8	23.7	06AUG2018	15SEP2018	
	2099	VLN non-mentholated	52	MALE	170.1	114.3	39.5	09AUG2018	15SEP2018	
	2100	UB mentholated	48	FEMALE	168.6	86.3	30.4	09AUG2018	15SEP2018	
	2108	VLN non-mentholated	60	FEMALE	158.6	63.5	25.2	13AUG2018	15SEP2018	
	2110	UB mentholated	41	FEMALE	149.7	67	29.9	13AUG2018	06SEP2018	
	2113	VLN mentholated	51	FEMALE	162.4	70.9	26.9	15AUG2018		
	2115	VLN mentholated	46	FEMALE	174.8	99.5	32.6	15AUG2018	06SEP2018	
	2119	VLN mentholated	48	MALE	163.3	88.1	33	20AUG2018	06SEP2018	
	2120	VLN non-mentholated	62	FEMALE	155.7	93.9	38.7	20AUG2018	06SEP2018	
	2122	UB non-mentholated	60	MALE	175.2	84.4	27.5	20AUG2018	06SEP2018	
	2125	UB mentholated	35	MALE	196.8	97	25	21AUG2018	06SEP2018	
	2126	VLN mentholated	37	MALE	168.7	78.6	27.6	21AUG2018	06SEP2018	
	2136	VLN non-mentholated	64	MALE	184.5	107.1	31.5	27AUG2018	06SEP2018	
	2140	UB non-mentholated	56	FEMALE	163.5	75.2	28.1	30AUG2018	18SEP2018	

Note: 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
 Site: 001 = Lincoln, 002 = High Point, BMI = Body Mass Index

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-DEM.SAS 18JUN2019 11:10

Appendix 16.2.4.1.2 Demographics (Safety Population) (II of II)

Site	Subject Number	Product Group	Age (yrs)	Sex	Height (cm)	Weight (kg)	BMI (kg/m ²)	Informed Consent Date	Informed Re-Consent Date	Informed Re-Consent Date 2
002	2142	VLN non-mentholated	30	FEMALE	165.5	73.3	26.8	31AUG2018	18SEP2018	
	2143	VLN non-mentholated	63	MALE	179.4	71.3	22.2	04SEP2018	18SEP2018	
	2158	UB non-mentholated	43	FEMALE	159	85.4	33.8	18SEP2018		
	2159	VLN non-mentholated	37	MALE	156.8	56.8	23.1	19SEP2018		
	2164	VLN non-mentholated	65	FEMALE	158	83.3	33.4	27SEP2018		
	2168	VLN non-mentholated	32	FEMALE	154.4	74.4	31.2	28SEP2018		
	2169		42	MALE				28SEP2018		
	2170	UB non-mentholated	51	FEMALE	166.3	76	27.5	28SEP2018		
	2175	UB mentholated	40	FEMALE	156.3	72.7	29.8	01OCT2018		
	2189	VLN mentholated	28	MALE	169	67.4	23.6	04OCT2018		
	2211	VLN mentholated	29	FEMALE	163	54.8	20.6	10OCT2018		
	2212	UB mentholated	32	MALE	174.8	84.2	27.6	10OCT2018		
	2213	VLN mentholated	29	MALE	178	106.3	33.6	10OCT2018		
	2214		54	FEMALE				10OCT2018		
	2215	UB mentholated	59	FEMALE	161	56.7	21.9	10OCT2018		
	2220	VLN non-mentholated	37	MALE	173.8	84.2	27.9	11OCT2018		
	2224		42	FEMALE				11OCT2018		
	2235	VLN mentholated	26	FEMALE	174	114.1	37.7	19OCT2018		
	2244	VLN non-mentholated	31	MALE	183.8	116.4	34.5	25OCT2018		
	2247	VLN mentholated	28	MALE	174.9	80	26.2	06NOV2018		
	2251	UB non-mentholated	27	MALE	181.4	74.9	22.8	09NOV2018		
	2257	UB non-mentholated	55	FEMALE	151	61.7	27.1	14NOV2018		
	2259	UB mentholated	49	MALE	172.5	119.1	40	14NOV2018		
	2269	VLN mentholated	48	MALE	186	101.3	29.3	26NOV2018		
	2272	VLN mentholated	37	MALE	169.5	68.6	23.9	28NOV2018		

Note: VLN non-mentholated = Non-mentholated VLN cigarettes
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 UB mentholated = Subjects' UB mentholated filtered cigarettes
 Site: 001 = Lincoln, 002 = High Point, BMI = Body Mass Index

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-DEM.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1001	Screen	02JUL2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1002	Screen	02JUL2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		

Note: NCS = Not Clinically Significant, ND = Not Done, IPV = Inactivated Polio Vaccine
 HEENT = Head, Ears, Eyes, Nose or Throat, CI = Color Index
 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-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1002	Screen	02JUL2018	VLN non-mentholated	YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1003	Screen	03JUL2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1007	Screen	12JUL2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		

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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

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1007	Screen	12JUL2018	VLN non-mentholated	YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
1008	Screen	12JUL2018	VLN mentholated	YES	Thyroid (Endocrine)	NORMAL		
				YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1010	Screen	13JUL2018	UB mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		

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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
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1010	Screen	13JUL2018	UB mentholated	YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1011	Screen	13JUL2018	UB non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	ABNORMAL	MULTIPLE CRIES	NCS
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		

Note: NCS = Not Clinically Significant, ND = Not Done, IPV = Inactivated Polio Vaccine

HEENT = Head, Ears, Eyes, Nose or Throat, CI = Color Index

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-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1011	Screen	13JUL2018	UB non-mentholated	YES YES	Skin Thyroid (Endocrine)	NORMAL NORMAL		
1013	Screen	16JUL2018	VLN non-mentholated	YES YES YES YES YES YES YES YES YES YES YES YES YES YES YES YES YES	Abdomen Back/Neck Chest Dentition Extremities General Appearance Heart HEENT Lungs Lymph Nodes Musculoskeletal Neurological Oral Cavity Oropharynx Skin Thyroid (Endocrine)	NORMAL NORMAL NORMAL ABNORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL	POOR DENTITION	NCS
1014	Screen	16JUL2018	VLN mentholated	YES YES YES YES YES YES YES YES YES YES	Abdomen Back/Neck Chest Dentition Extremities General Appearance Heart HEENT Lungs	NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL NORMAL		

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 HEENT = Head, Ears, Eyes, Nose or Throat, CI = Color Index
 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-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1014	Screen	16JUL2018	VLN mentholated	YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1015	Screen	16JUL2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1016	Screen	16JUL2018	UB non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		

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 HEENT = Head, Ears, Eyes, Nose or Throat, CI = Color Index
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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

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1016	Screen	16JUL2018	UB non-mentholated	YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	ABNORMAL	SOFT II/VI SYSTOLIC MURMUR	NCS
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1017	Screen	17JUL2018	UB mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		

Note: NCS = Not Clinically Significant, ND = Not Done, IPV = Inactivated Polio Vaccine
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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1017	Screen	17JUL2018	UB mentholated	YES	Thyroid (Endocrine)	NORMAL		
1018	Screen	17JUL2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
	END OF STUDY	15AUG2018	VLN mentholated	YES	Symptom Driven Physical	NORMAL		
1019	Screen	17JUL2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1019	Screen	17JUL2018	VLN non-mentholated	YES	Lungs	NORMAL	THICKENED AREA ON THE TONGUE, RESULTED FROM TRAUMA TO THE TONGUE RESULTING IN A SCAR	NCS
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	ABNORMAL		
1020	Screen	17JUL2018	VLN non-mentholated	YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
				YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1020	Screen	17JUL2018	VLN non-mentholated	YES	Thyroid (Endocrine)	NORMAL		
1021	Screen	17JUL2018	UB non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1023	Screen	17JUL2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		

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

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1023	Screen	17JUL2018	VLN non-mentholated	YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
	FOLLOW-UP		VLN non-mentholated	ND	Symptom Driven Physical		LOST TO FOLLOW UP	
1029	Screen	26JUL2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	ABNORMAL	MILD WHEEZES THAT CHANGE CHARACTER WITH COUGHING	NCS
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1032	Screen	13AUG2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1034	Screen	13AUG2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1034	Screen	13AUG2018	VLN non-mentholated	YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1035	Screen	13AUG2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1036	Screen	13AUG2018	UB mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1036	Screen	13AUG2018	UB mentholated	YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
1037	Screen	13AUG2018	UB mentholated	YES	Thyroid (Endocrine)	NORMAL		
				YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1038	Screen	13AUG2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1038	Screen	13AUG2018	VLN non-mentholated	YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
	UNSCHEDULED	28AUG2018	VLN non-mentholated	ND	Abdomen		NOT REQUIRED FOR EXAM	
				ND	Back/Neck		NOT REQUIRED FOR EXAM	
				ND	Chest		NOT REQUIRED FOR EXAM	
				ND	Extremities		NOT REQUIRED FOR EXAM	
				ND	General Appearance		NOT REQUIRED FOR EXAM	
				ND	Heart		NOT REQUIRED FOR EXAM	

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1038	UNSCHEDULED	28AUG2018	VLN non-mentholated	YES	HEENT	ABNORMAL	MINIMAL ERYTHEMA RIGHT EYE. SUBJECT STATES THAT SHE IS ALLERGIC TO PERFUME THAT HER ROOM MATE HAS SPRAYED ON THE SHEETS	NCS
				ND	Lungs		NOT REQUIRED FOR EXAM	
				ND	Lymph Nodes		NOT REQUIRED FOR EXAM	
				ND	Musculoskeletal		NOT REQUIRED FOR EXAM	
				ND	Neurological		NOT REQUIRED FOR EXAM	
				ND	Oral Cavity		NOT REQUIRED FOR EXAM	
				ND	Oropharynx		NOT REQUIRED FOR EXAM	
				ND	Other			
				ND	Skin		NOT REQUIRED FOR EXAM	
				ND	Thyroid (Endocrine)		NOT REQUIRED FOR EXAM	
1042	Screen	13AUG2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1042	Screen	13AUG2018	VLN non-mentholated	YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1045	Screen	14AUG2018	UB non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1045	Screen	14AUG2018	UB non-mentholated	YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1046	Screen	14AUG2018	UB mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
1050	Screen	14AUG2018	VLN non-mentholated	YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
				YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lungs	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1050	Screen	14AUG2018	VLN non-mentholated	YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1051	Screen	14AUG2018	UB mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1052	Screen	14AUG2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1052	Screen	14AUG2018	VLN mentholated	YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
1053	Screen	14AUG2018	VLN mentholated	YES	Thyroid (Endocrine)	NORMAL		
				YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		

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HEENT = Head, Ears, Eyes, Nose or Throat, CI = Color Index

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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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1054	Screen	14AUG2018	UB non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1055	Screen	14AUG2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1055	Screen	14AUG2018	VLN mentholated	YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1056	Screen	14AUG2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1058	Screen	15AUG2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1058	Screen	15AUG2018	VLN non-mentholated	YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
1059	Screen	27AUG2018	UB non-mentholated	YES	Thyroid (Endocrine)	NORMAL		
				YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	ABNORMAL	EDENTULOUS	NCS
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1060	Screen	27AUG2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1060	Screen	27AUG2018	VLN mentholated	YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	ABNORMAL	PIGMENTED LESIONS ON TONGUE	NCS
				YES	Oropharynx	NORMAL		
				YES	Skin	ABNORMAL	POST SURGICAL SCARS LEFT FOREARM	NCS
1063	Screen	27AUG2018	VLN mentholated	YES	Thyroid (Endocrine)	NORMAL		
				YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1063	Screen	27AUG2018	VLN mentholated	YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1064	Screen	27AUG2018	UB non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
1066	Screen	27AUG2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1066	Screen	27AUG2018	VLN non-mentholated	YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1069	Screen	28AUG2018	UB non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1070	Screen	28AUG2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	ABNORMAL	DENTURES UPPER FULL SET	NCS
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1071	Screen	28AUG2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1071	Screen	28AUG2018	VLN non-mentholated	YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1072	Screen	28AUG2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1074	Screen	28AUG2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	ABNORMAL	DENTAL CARIES AND MISSING TEETH	NCS

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1074	Screen	28AUG2018	VLN non-mentholated	YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1075	Screen	28AUG2018	UB non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1077	Screen	28AUG2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1078	Screen	28AUG2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1078	Screen	28AUG2018	VLN non-mentholated	YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1079	Screen	28AUG2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1082	Screen	30AUG2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1082	Screen	30AUG2018	VLN non-mentholated	YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
1083	Screen	04SEP2018	VLN non-mentholated	YES	Thyroid (Endocrine)	NORMAL		
				YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1084	Screen	04SEP2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1084	Screen	04SEP2018	VLN non-mentholated	YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1086	Screen	04SEP2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	ABNORMAL	EDENTULOUS UPPER AND JAW	NCS
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1086	Screen	04SEP2018	VLN non-mentholated	YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1088	Screen	04SEP2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1089	Screen	04SEP2018	UB non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		

Note: NCS = Not Clinically Significant, ND = Not Done, IPV = Inactivated Polio Vaccine
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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
 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1089	Screen	04SEP2018	UB non-mentholated	YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1092	Screen	05SEP2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1094	Screen	05SEP2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1094	Screen	05SEP2018	VLN mentholated	YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	ABNORMAL	TWO SMALL KELOIDS RIGHT ANTECUBITAL FOSSA	NCS
				YES	Thyroid (Endocrine)	NORMAL		
1095	Screen	07SEP2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		

Note: NCS = Not Clinically Significant, ND = Not Done, IPV = Inactivated Polio Vaccine
 HEENT = Head, Ears, Eyes, Nose or Throat, CI = Color Index
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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1095	Screen	07SEP2018	VLN mentholated	YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
	UNSCHEDULED	18SEP2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	ABNORMAL	GENERALIZED ERYTHEMATOUS MACULAR RASH ON FOREARMS, PALMS, TRUNK AND FACE. CONSISTENT WITH CONTACT DERMATITIS TO TOILETRIES	NCS
				YES	Thyroid (Endocrine)	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1096	Screen	07SEP2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1097	Screen	07SEP2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		

Note: NCS = Not Clinically Significant, ND = Not Done, IPV = Inactivated Polio Vaccine

HEENT = Head, Ears, Eyes, Nose or Throat, CI = Color Index

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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

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1097	Screen	07SEP2018	VLN mentholated	YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1098	Screen	18SEP2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1099	Screen	18SEP2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1099	Screen	18SEP2018	VLN non-mentholated	YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
1100	Screen	18SEP2018	VLN non-mentholated	YES	Thyroid (Endocrine)	NORMAL		
				YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	ABNORMAL	DENTAL CARIES AND MISSING TEETH	NCS
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		

Note: NCS = Not Clinically Significant, ND = Not Done, IPV = Inactivated Polio Vaccine
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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1101	Screen	18SEP2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1103	Screen	18SEP2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1103	Screen	18SEP2018	VLN non-mentholated	YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1105	Screen	19SEP2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1106	Screen	19SEP2018	UB non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	ABNORMAL	POOR DENTITION. DENTURES ON TOP. NO ACTIVE DISEASE	NCS

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1106	Screen	19SEP2018	UB non-mentholated	YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1107	Screen	21SEP2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1108	Screen	21SEP2018	UB non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1109	Screen	21SEP2018	UB non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		

Note: NCS = Not Clinically Significant, ND = Not Done, IPV = Inactivated Polio Vaccine
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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1109	Screen	21SEP2018	UB non-mentholated	YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1112	Screen	21SEP2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
1114	Screen	24SEP2018	UB non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
1114	Screen	24SEP2018	UB non-mentholated	YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
1115	Screen	24SEP2018	VLN non-mentholated	YES	Thyroid (Endocrine)	NORMAL		
				YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Dentition	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2002	Screen	29JUN2018	UB mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		

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 VLN mentholated = Mentholated VLN cigarettes
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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2002	Screen	29JUN2018	UB mentholated	YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2003	Screen	29JUN2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2003	Screen	29JUN2018	VLN mentholated	YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2007	Screen	29JUN2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2008	Screen	06JUL2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		

Note: NCS = Not Clinically Significant, ND = Not Done, IPV = Inactivated Polio Vaccine
 HEENT = Head, Ears, Eyes, Nose or Throat, CI = Color Index
 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-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2008	Screen	06JUL2018	VLN mentholated	YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2009	Screen	29JUN2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2010	Screen	29JUN2018	UB mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2010	Screen	29JUN2018	UB mentholated	YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2011	Screen	29JUN2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2014	Screen	02JUL2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2015	Screen	02JUL2018	UB mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2015	Screen	02JUL2018	UB mentholated	YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2016	Screen	02JUL2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
2017	Screen	02JUL2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2017	Screen	02JUL2018	VLN mentholated	YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2018	Screen	02JUL2018	UB mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
				YES	Symptom Driven Physical	NORMAL		
	UNSCHEDULED	14AUG2018	UB mentholated	YES				

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2020	Screen	02JUL2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
				YES	Symptom Driven Physical	NORMAL		
2021	Screen	29AUG2018	VLN mentholated	END OF STUDY				
				YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2021	Screen	02JUL2018	VLN mentholated	YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2023	Screen	02JUL2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2023	UNSCHEDULED	28AUG2018	VLN mentholated	YES	Skin	ABNORMAL	BILATERAL ARMS AND BILATERAL ANKLES WITH ERYTHMATOUS RAISED AREAS, DIFFUSE, NON TENDER TO PALPATION	NCS
	END OF STUDY	29AUG2018	VLN mentholated	YES	Skin	ABNORMAL	FLEA BITES ARMS AND ANKLES. NO SUPERINFECTION	NCS
2024	Screen	03JUL2018	UB non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2025	Screen	03JUL2018	UB non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2028	Screen	06JUL2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		

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 HEENT = Head, Ears, Eyes, Nose or Throat, CI = Color Index
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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2028	Screen	06JUL2018	VLN non-mentholated	YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2029	Screen	09JUL2018	UB mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2039	Screen	13JUL2018	VLN mentholated	YES	Symptom Driven	NORMAL		
				YES	Physical			
				YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2039	Screen	13JUL2018	VLN mentholated	YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2050	Screen	20JUL2018	UB mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		

Note: NCS = Not Clinically Significant, ND = Not Done, IPV = Inactivated Polio Vaccine
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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2052	Screen	20JUL2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
	UNSCHEDULED	22AUG2018	VLN mentholated	YES	Thyroid (Endocrine)	NORMAL		
				YES	Symptom Driven	NORMAL		
					Physical			
	UNSCHEDULED	05SEP2018	VLN mentholated	YES	Symptom Driven	NORMAL		
					Physical			
2057	Screen	23JUL2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		

Note: NCS = Not Clinically Significant, ND = Not Done, IPV = Inactivated Polio Vaccine
 HEENT = Head, Ears, Eyes, Nose or Throat, CI = Color Index
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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2057	Screen	23JUL2018	VLN mentholated	YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2058	Screen	23JUL2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2059	Screen	23JUL2018	UB mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2059	Screen	23JUL2018	UB mentholated	YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
	UNSCHEDULED	23AUG2018	UB mentholated	YES	Thyroid (Endocrine)	NORMAL		
				YES	HEENT	ABNORMAL	HEALING ABSCESS L PARANASAL REGION NO PURULENCE	NCS
	UNSCHEDULED	05SEP2018	UB mentholated	YES	Symptom Driven Physical	NORMAL		
	UNSCHEDULED	19SEP2018	UB mentholated	YES	Symptom Driven Physical	NORMAL		
	END OF STUDY	20SEP2018	UB mentholated	YES	Skin	ABNORMAL	TENDER TO PALPATE SCALP	NCS
2060	Screen	23JUL2018	VLN mentholated	ND	Abdomen			
				ND	Back/Neck			
				ND	Chest			
				ND	Extremities			
				ND	General Appearance			

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 HEENT = Head, Ears, Eyes, Nose or Throat, CI = Color Index
 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-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2060	Screen	23JUL2018	VLN mentholated	ND	Heart			
				ND	HEENT			
				ND	Lungs			
				ND	Lymph Nodes			
				ND	Musculoskeletal			
				ND	Neurological			
				ND	Oral Cavity			
				ND	Oropharynx			
				ND	Other			
				ND	Skin			
				ND	Thyroid (Endocrine)			
2064	Screen	23JUL2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		

Note: NCS = Not Clinically Significant, ND = Not Done, IPV = Inactivated Polio Vaccine
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 VLN mentholated = Mentholated VLN cigarettes
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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2066	Screen	23JUL2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2067	Screen	23JUL2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		

Note: NCS = Not Clinically Significant, ND = Not Done, IPV = Inactivated Polio Vaccine
 HEENT = Head, Ears, Eyes, Nose or Throat, CI = Color Index
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 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-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2067	Screen	23JUL2018	VLN non-mentholated	YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
				YES	Symptom Driven Physical	NORMAL		
2075	Screen	30JUL2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2076	Screen	30JUL2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2076	Screen	30JUL2018	VLN mentholated	YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2086	Screen	03AUG2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		

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 HEENT = Head, Ears, Eyes, Nose or Throat, CI = Color Index
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 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2086	END OF STUDY	29SEP2018	VLN non-mentholated	YES	Oropharynx	ABNORMAL	MILD ERYTHEMA OROPHARYNX NO COBBLE STONING NOTED NO VISIBLE DRAINAGE	NCS
2088	Screen	03AUG2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2092	Screen	06AUG2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2092	Screen	06AUG2018	VLN mentholated	YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2099	Screen	09AUG2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	ABNORMAL	MID LUMBAR SPINE SCAR DUE TO HERNIATED DISC REPAIR	NCS
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2099	Screen	09AUG2018	VLN non-mentholated	YES	Skin	ABNORMAL	MID ABDOMEN SCAR DUE TO HERNIA REPAIR	NCS
				YES	Thyroid (Endocrine)	NORMAL		
2100	Screen	09AUG2018	UB mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2108	Screen	13AUG2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2108	Screen	13AUG2018	VLN non-mentholated	YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2110	Screen	13AUG2018	UB mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2113	Screen	15AUG2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2113	Screen	15AUG2018	VLN mentholated	YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2115	Screen	15AUG2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2115	Screen	15AUG2018	VLN mentholated	YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2119	Screen	20AUG2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	ABNORMAL	LEFT ANKLE	NCS
							SWELLING LIMITED	
							RANGE OF MOTION	
							DUE TO POST	
							SURGICAL SCAR-	
							LEFT KNEE	
							FLEXION TO 90	
							DEGREE DUE TO	
							POST SURGICAL	
							SCAR	
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2120	Screen	20AUG2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	ABNORMAL	RIGHT UPPER NOSE - INFLAMMATION- ERYTHEMIA NO DISCHARGE; DUE TO BASEL CELL CANCER REMOVAL	NCS
				YES	Thyroid (Endocrine)	NORMAL		
2122	Screen	20AUG2018	UB non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		

Note: NCS = Not Clinically Significant, ND = Not Done, IPV = Inactivated Polio Vaccine
 HEENT = Head, Ears, Eyes, Nose or Throat, CI = Color Index
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 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2122	Screen	20AUG2018	UB non-mentholated	YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
2125	Screen	21AUG2018	UB mentholated	YES	Thyroid (Endocrine)	NORMAL		
				YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		

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 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2125	UNSCHEDULED	21SEP2018	UB mentholated	YES	Musculoskeletal	ABNORMAL	RIGHT KNEE MILD SWELLING;NO ERYTHEMA, NON TENDER TO PALPITATION, LIMITED LATERAL AND MEDIAL RANGE OF MOTION DUE TO PAIN. SLIGHT ABNORMAL GAIT	NCS
	UNSCHEDULED	22SEP2018	UB mentholated	YES	Musculoskeletal	ABNORMAL	RIGHT KNEE MINIMAL SWELLING; NO OTHER FINDING, FULL RANGE OF MOTION, GAIT NOT IMPAIRED.	NCS

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2125	UNSCHEDULED	19OCT2018	UB mentholated	YES	Musculoskeletal	ABNORMAL	R KNEE MILD SWELLING NONTENDER TO PALPATION. FULL RANGE OF MOTION EXTENSION/FLEXIO N. LIMITED RANGE OF MOTION VARUS/VALGUS STRESS DUE TO PAIN/ GAIT NORMAL	NCS
	END OF STUDY	20OCT2018	UB mentholated	YES	Musculoskeletal	ABNORMAL	SWELLING OF R KNEE MINIMAL LIMITATION OF MOTION	NCS
	UNSCHEDULED	05NOV2018	UB mentholated	YES	Musculoskeletal	ABNORMAL	R KNEE NO SWELLING; FULL RANGE FLEXION/EXTENSIO N. LIMITED WITH VARUS/VALGUS STRESS DUE TO PAIN. GAIT NORMAL	NCS
2126	Screen	21AUG2018	VLN mentholated	YES	Abdomen	NORMAL		

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 VLN non-mentholated = Non-mentholated VLN cigarettes
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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2126	Screen	21AUG2018	VLN mentholated	YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2136	Screen	27AUG2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		

Note: NCS = Not Clinically Significant, ND = Not Done, IPV = Inactivated Polio Vaccine
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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2136	Screen	27AUG2018	VLN non-mentholated	ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2140	Screen	30AUG2018	UB non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
	UNSCHEDULED	22OCT2018	UB non-mentholated	YES	Symptom Driven Physical	NORMAL		
2142	Screen	31AUG2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2142	Screen	31AUG2018	VLN non-mentholated	YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2143	Screen	04SEP2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2158	Screen	18SEP2018	UB non-mentholated	YES	Abdomen	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2158	Screen	18SEP2018	UB non-mentholated	YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2159	Screen	19SEP2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2159	Screen	19SEP2018	VLN non-mentholated	ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
	UNSCHEDULED	20OCT2018	VLN non-mentholated	YES	Oral Cavity	ABNORMAL	MULTIPLE MISSING TEETH AND DECAYED TEETH. NO EVIDENCE OF ABSCESS FORMATION	NCS
2164	Screen	27SEP2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2168	Screen	28SEP2018	VLN non-mentholated	YES	Abdomen	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2168	Screen	28SEP2018	VLN non-mentholated	YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2170	Screen	28SEP2018	UB non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		

Note: NCS = Not Clinically Significant, ND = Not Done, IPV = Inactivated Polio Vaccine
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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2170	Screen	28SEP2018	UB non-mentholated	ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2175	Screen	01OCT2018	UB mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
2189	Screen	04OCT2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2189	Screen	04OCT2018	VLN mentholated	YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2211	Screen	10OCT2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2212	Screen	10OCT2018	UB mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2212	Screen	10OCT2018	UB mentholated	YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2213	Screen	10OCT2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2213	Screen	10OCT2018	VLN mentholated	YES	Thyroid (Endocrine)	NORMAL		
2215	Screen	10OCT2018	UB mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2220	Screen	11OCT2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2220	Screen	11OCT2018	VLN non-mentholated	YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2235	Screen	19OCT2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
2244	Screen	25OCT2018	VLN non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2244	Screen	25OCT2018	VLN non-mentholated	YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2247	Screen	06NOV2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2247	UNSCHEDULED	22DEC2018	VLN mentholated	YES	Skin	ABNORMAL	URTICARIAL WELTS RESOLVED; MINIMAL AREAS OF MINIMAL ERYTHEMA (AREAS INVOLVED BACK AND FOREARM	NCS
2251	Screen	09NOV2018	UB non-mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
2257	Screen	14NOV2018	UB non-mentholated	YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
				YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2257	Screen	14NOV2018	UB non-mentholated	YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
	UNSCHEDULED	18JAN2019	UB non-mentholated	YES	Thyroid (Endocrine)	NORMAL		
				YES	Skin	ABNORMAL	R LATERAL PLANTAR SURFACE OF FOOT OPEN AREA FROM SURGICAL REMOVAL OF PLANTER WART, NO SIGNS OF INFECTION WOUND BED PINK, MOIST, TENDER TO PALPATION 1.5 CM X 1.5 CM ROUND	NCS

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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

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2257	END OF STUDY	19JAN2019	UB non-mentholated	YES	Skin	ABNORMAL	HEALING OVER, PLANTER SURFACE RIGHT FOOT POST PLANTAR WART REMOVAL 1.5 CM X 1.5 CM; NO EVIDENCE OF INFECTION	NCS
2259	Screen	14NOV2018	UB mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2269	Screen	26NOV2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		

Note: NCS = Not Clinically Significant, ND = Not Done, IPV = Inactivated Polio Vaccine
 HEENT = Head, Ears, Eyes, Nose or Throat, CI = Color Index
 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-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2269	Screen	26NOV2018	VLN mentholated	YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		
				YES	Thyroid (Endocrine)	NORMAL		
2272	Screen	28NOV2018	VLN mentholated	YES	Abdomen	NORMAL		
				YES	Back/Neck	NORMAL		
				YES	Chest	NORMAL		
				YES	Extremities	NORMAL		
				YES	General Appearance	NORMAL		
				YES	Heart	NORMAL		
				YES	HEENT	NORMAL		
				YES	Lungs	NORMAL		
				YES	Lymph Nodes	NORMAL		
				YES	Musculoskeletal	NORMAL		
				YES	Neurological	NORMAL		
				YES	Oral Cavity	NORMAL		
				YES	Oropharynx	NORMAL		
				ND	Other			
				YES	Skin	NORMAL		

Note: NCS = Not Clinically Significant, ND = Not Done, IPV = Inactivated Polio Vaccine
 HEENT = Head, Ears, Eyes, Nose or Throat, CI = Color Index
 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-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.2 Physical Examination (Safety Population)

Subject Number	Visit		Product Group	Was PE Done?	System	Result	Comment	Clinical Significance
	Name	Date						
2272	Screen	28NOV2018	VLN mentholated	YES	Thyroid (Endocrine)	NORMAL		

Note: NCS = Not Clinically Significant, ND = Not Done, IPV = Inactivated Polio Vaccine
 HEENT = Head, Ears, Eyes, Nose or Throat, CI = Color Index
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 VLN mentholated = Mentholated VLN cigarettes
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes
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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-PHY.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
1001	YES	Screen	02JUL2018	VLN non-mentholated	1	POST MENOPAUSAL	2012		YES
					2	CATARACTS	2016	AUG2016	NO
					3	SURGERY TO REPAIR CATARACTS	AUG2016	AUG2016	NO
1003	YES	Screen	03JUL2018	VLN mentholated	1	DIFFICULTY SWALLOWING	OCT2017	OCT2017	NO
1010	YES	Screen	13JUL2018	UB mentholated	1	ALLERGY TO PENICILLIN	1999		YES
					2	ALLERGY TO AMOXICILLIN	1986		YES
					3	ASTHMA (EXERCISE INDUCED)	2000	JUL2003	NO
					4	INGUINAL HERNIA	2013	2013	NO
					5	SURGERY TO REPAIR INGUINAL HERNIA	2013	2013	NO
1011	YES	Screen	13JUL2018	UB non-mentholated	1	ALLERGY TO PENICILLIN	1992		YES
					2	VENTRICULAR TRIGEMINY	2009		YES
					3	APPENDICITIS	12SEP1999	12SEP1999	NO
					4	APPENDECTOMY	12SEP1999	12SEP1999	NO
1013	YES	Screen	16JUL2018	VLN non-mentholated	1	DRUG ABUSE	JAN2008	MAR2008	NO
1014	YES	Screen	16JUL2018	VLN mentholated	1	CESAREAN SECTION	15OCT2012	15OCT2012	NO
1015	YES	Screen	16JUL2018	VLN mentholated	1	ALLERGY TO CODEINE	1989		YES

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
1015	YES	Screen	16JUL2018	VLN mentholated	2	ALLERGY TO SULFA DRUG	1989		YES
					3	HAYFEVER	1981		YES
					4	ALLERGY TO MOLD/MILDEW	1981		YES
					5	ALLERGY TO STRAWBERRIES	1979		YES
					6	MIGRAINE	1998		YES
					7	THYROID, UNDERACTIVE (HYPO)	AUG1999		YES
					8	MONONUCLEOSIS	1986	1986	NO
					9	ALLERGY TO RASPBERRIES	1979		YES
					10	SURGERY FOR BREAST IMPLANTS	2013	2013	NO
					11	SURGERY TO REMOVE THYROID	AUG2017	AUG2017	NO
					12	TONSILLITIS	1989	1989	NO
					13	TONSILLECTOMY	1989	1989	NO
1016	YES	Screen	16JUL2018	UB non-mentholated	1	CYST IN MIDDLE FINGER DRAINED	1992	1992	NO
					2	SOFT II/VI SYSTOLIC MURMUR	16JUL2018		YES
1017	YES	Screen	17JUL2018	UB mentholated	1	ALLERGY TO AMOXICILLIN	2003		YES
					2	ALLERGY TO KEFLEX	1998		YES
					3	ALLERGY TO ERYTHROMYCIN	1987		YES
					4	TUBAL LIGATION	JUN2014	JUN2014	NO

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 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
1017	YES	Screen	17JUL2018	UB mentholated	5	TONSILLITIS	1998	1998	NO
					6	TONSILLECTOMY	1998	1998	NO
					7	GALLSTONES	AUG2014	AUG2014	NO
					8	SURGERY TO REMOVE GALLBLADDER	AUG2014	AUG2014	NO
					9	BROKEN DISC IN BACK (DUE TO INJURY)	APR2006	DEC2006	NO
					10	LOWER LUMBAR FUSION	DEC2006	DEC2006	NO
					11	ANXIETY, CHRONIC	OCT2015	APR2016	NO
					12	CESAREAN SECTION	02FEB1995	02FEB1995	NO
1018	YES	Screen	17JUL2018	VLN mentholated	1	ALLERGY TO PENICILLIN	15JUN1977		YES
					2	TUBAL LIGATION	NOV2008	NOV2008	NO
					3	BROKEN ARM	1985	1985	NO
					4	SURGERY TO INSERT PIN INTO BROKEN ARM FOR REPAIR	1985	1985	NO
1019	YES	Screen	17JUL2018	VLN non-mentholated	1	ALLERGY TO PENICILLIN	30JUN1988		YES
					2	CLUB FOOT	30JUN1988	JUL1988	NO
					3	SURGERY TO REPAIR CLUB FOOT	JUL1988	JUL1988	NO
					4	SCAR ON TONGUE (DUE TO CAR ACCIDENT)	01MAY2007		YES
					5	CAR ACCIDENT	01MAY2007	01MAY2007	NO
1020	YES	Screen	17JUL2018	VLN non-mentholated	1	HAYFEVER	1999	1999	NO
					2	BUNIONECTOMY	2006	2006	NO
					3	BUNION	2006	2006	NO

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
1021	YES	Screen	17JUL2018	UB non-mentholated	1	SURGERY TO REPLACE RIGHT KNEE ANTERIOR CRUCIATE LIGAMENT	2001	2001	NO
					2	SURGERY TO REPAIR RIGHT KNEE MENISCUS	2001	2001	NO
					3	GALLSTONES	2009	2009	NO
					4	SURGERY TO REMOVE GALLBLADDER	2009	2009	NO
					5	EXERCISE INJURY (ANTERIOR CRUCIATE LIGAMENT POPPED)	2001	2001	NO
1023	YES	Screen	17JUL2018	VLN non-mentholated	1	HYSTERECTOMY	1995	1995	NO
					2	ABNORMAL MENSTRUAL BLEEDING	1995	1995	NO
					3	SURGERY TO REPLACE RIGHT THUMB JOINT	MAR1999	MAR1999	NO
					4	SURGERY TO REPAIR RIGHT CARPAL TUNNEL SYNDROME	1997	1997	NO
					5	CARPAL TUNNEL SYNDROME	1997	1997	NO
1029	YES	Screen	26JUL2018	VLN mentholated	1	ANXIETY, CHRONIC	2014		YES
					2	DEPRESSION, RECURRENT	MAR2012		YES
					3	MILD WHEEZES THAT CHANGE CHARACTER WITH COUGHING	26JUL2018		YES

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
1032	YES	Screen	13AUG2018	VLN mentholated	1	ALLERGY TO PENICILLIN	23SEP1964		YES
					2	TUBAL LIGATION	1998	1998	NO
					3	POSTMENOPAUSAL	NOV2013		YES
					4	GALLSTONES	1993	1993	NO
					5	SURGERY TO REMOVE GALLBLADDER	1993	1993	NO
					6	UTERINE FIBROIDS	2010	2013	NO
					7	ABLATION TO REMOVE UTERINE FIBROIDS	2013	2013	NO
					8	HERNIATED DISC	2012		YES
					9	DEPRESSION, RECURRENT (SITUATIONAL)	06JUN1999		YES
					10	MONONUCLEOSIS	03MAR1980	03MAY1980	NO
					11	SURGERY TO REPAIR ROTATOR CUFF (DUE TO BEING A WRESTLER)	2012	2012	NO
					12	CESAREAN SECTION	23JUN1998	23JUN1998	NO
					13	CESAREAN SECTION	18JUN1988	18JUN1988	NO
					14	TORN ROTATOR CUFF (DUE TO BEING A WRESTLER)	2012	2012	NO
1035	YES	Screen	13AUG2018	VLN non-mentholated	1	LACTOSE INTOLERANCE	24FEB1974		YES
1036	YES	Screen	13AUG2018	UB mentholated	1	ANXIETY, CHRONIC	2008	DEC2017	NO
1037	YES	Screen	13AUG2018	UB mentholated	1	TONSILLITIS	2001	2001	NO
					2	TONSILLECTOMY	2001	2001	NO

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
1038	YES	Screen	13AUG2018	VLN non-mentholated	1	DRUG ABUSE	JAN2003	MAR2005	NO
					2	ALLERGY TO CODEINE	1997		YES
					3	ALLERGY TO SULFA DRUG	1992		YES
					4	ALLERGY TO CONTRAST DYE (IPV OR CT)	1987		YES
					5	TUBAL LIGATION	JAN2008	JAN2008	NO
					6	DEPRESSION	JUN2005	JUN2005	NO
					7	CORNEAL ABRASION	29JUL2018	30NOV2018	NO
1042	YES	Screen	13AUG2018	VLN non-mentholated	1	SURGERY TO INSERT PINS FOR REPAIR OF BROKEN ANKLE	NOV2008	NOV2008	NO
					2	SURGERY TO REMOVE PINS FROM ANKLE	JAN2009	JAN2009	NO
					3	SURGERY TO REPAIR DISLOCATED SHOULDER	1988	1988	NO
					4	BROKEN ANKLE	NOV2008	NOV2008	NO
					5	DISLOCATED SHOULDER	1988	1988	NO
1045	YES	Screen	14AUG2018	UB non-mentholated	1	DRUG ABUSE	JAN1979	JUN1994	NO
					2	ALCOHOL ABUSE	14JUN1994	13JUL1994	NO
					3	SURGERY TO INSERT PINS, SCREW AND PLATES FOR REPAIR OF BROKEN BONE IN HIP	13MAY1977	13MAY1977	NO
					4	SURGERY TO REMOVE PINS, SCREW AND PLATES FROM HIP	AUG1978	AUG1978	NO
					5	BROKEN BONE IN HIP	13MAY1977	13MAY1977	NO

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
1046	YES	Screen	14AUG2018	UB mentholated	1	GALLSTONES	2002	07APR2003	NO
					2	SURGERY TO REMOVE GALLBLADDER	07APR2003	07APR2003	NO
					3	HEADACHE (ABOUT ONCE A MONTH)	09AUG2018		YES
1050	YES	Screen	14AUG2018	VLN non-mentholated	1	HAYFEVER	1993		YES
					2	ALLERGY TO PENICILLIN	JUN1992		YES
					3	TUBAL LIGATION	2008	2008	NO
					4	OVARIAN CYST (BENIGN)	FEB1998	OCT1998	NO
					5	SLEEP DISORDER	APR2004		YES
1051	YES	Screen	14AUG2018	UB mentholated	1	TUBAL LIGATION	2004	2004	NO
					2	MENSTRUAL BLEEDING, ABNORMAL	2009		YES
1055	YES	Screen	14AUG2018	VLN mentholated	1	TUBAL LIGATION	2006	2006	NO
					2	OVARIAN CYST (BENIGN)	2009	17MAR2009	NO
					3	SURGERY TO REMOVE BENIGN OVARIAN CYST	17MAR2009	17MAR2009	NO
1059	YES	Screen	27AUG2018	UB non-mentholated	1	VASECTOMY	2017	2017	NO
					2	APPECTOMY (UNKNOWN REASON FOR SURGERY)	2006	2006	NO
					3	EDENTULOUS	2014		YES

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
1060	YES	Screen	27AUG2018	VLN mentholated	1	ABDOMINAL EXPLORATORY SURGERY FOR STAB WOUND	1988	1988	NO
					2	SURGERY TO INSERT PINS AND PLATE INTO BROKEN FOREARM FOR REPAIR	1988	1988	NO
					3	SURGERY TO REMOVE PINS AND PLATE FROM FOREARM	1988	1988	NO
					4	BROKEN FOREARM	1988	1988	NO
					5	PIGMENTED LESIONS ON TONGUE	27AUG2018		YES
1064	YES	Screen	27AUG2018	UB non-mentholated	1	TONSILLITIS	2000	2000	NO
					2	TONSILLECTOMY	2000	2000	NO
					3	SURGERY TO REPAIR LEFT HAND TENDONS AND NERVES DUE TO DOG BITE	2016	2016	NO
					4	GENERALIZED BODY ACHES	MAR2015		YES
					5	DOG BITE	2016	2016	NO
1066	YES	Screen	27AUG2018	VLN non-mentholated	1	TONSILLITIS	1963	1963	NO
					2	TONSILLECTOMY	1963	1963	NO
					3	TRIGEMINAL NEURALGIA	SEP2017	NOV2017	NO
1069	YES	Screen	28AUG2018	UB non-mentholated	1	TUBAL LIGATION	1999	1999	NO
					2	GALLSTONES	2001	2001	NO

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
1069	YES	Screen	28AUG2018	UB non-mentholated	3	SURGERY TO REMOVE GALLBLADDER	2001	2001	NO
1070	YES	Screen	28AUG2018	VLN non-mentholated	1	DENTURES UPPER FULL SET			YES
1071	YES	Screen	28AUG2018	VLN non-mentholated	1	HERNIATED DISC IN NECK	2017		YES
					2	SURGERY TO REMOVE BONE FROM KNEE	2008	2008	NO
					3	GALLSTONES	2011	2011	NO
					4	SURGERY TO REMOVE GALLBLADDER	2011	2011	NO
					5	SURGERY FOR CERVICAL INTERVERTEBRAL DISC REPLACEMENT	APR2018	APR2018	NO
1072	YES	Screen	28AUG2018	VLN mentholated	1	SURGERY TO INSERT SCREW FOR RIGHT SHOULDER ROTATOR CUFF REPAIR	28MAR2018	28MAR2018	NO
					2	SURGERY TO INSERT SCREW FOR RIGHT SHOULDER ROTATOR CUFF REPAIR	1998	1998	NO
					3	TORN ROTATOR CUFF RIGHT SHOULDER	28MAR2018	28MAR2018	NO
					4	TORN ROTATOR CUFF RIGHT SHOULDER	1998	1998	NO

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
1074	YES	Screen	28AUG2018	VLN non-mentholated	1	MISSING TEETH, POOR DENTITION	2013		YES
1075	YES	Screen	28AUG2018	UB non-mentholated	1	TUBAL LIGATION	AUG2015	AUG2015	NO
					2	GALLSTONES	2012	2012	NO
					3	SURGERY TO REMOVE GALLBLADDER	2012	2012	NO
1077	YES	Screen	28AUG2018	VLN non-mentholated	1	HAYFEVER	12AUG1969		YES
					2	ALLERGY, ENVIRONMENTAL	12AUG1969		YES
					3	POSTMENOPAUSAL	2014		YES
					4	TONSILLITIS	1974	1974	NO
					5	TONSILLECTOMY	1974	1974	NO
					6	HEART MURMUR	1969	1970	NO
					7	POST TRAUMATIC STRESS DISORDER	1991	1992	NO
					8	LAPAROSCOPY FOR PERSISTENT UPSET STOMACH	1988	1988	NO
					9	UPSET STOMACH	1988	1988	NO
1078	YES	Screen	28AUG2018	VLN non-mentholated	1	ALLERGY TO CODEINE	1975		YES
					2	POSTMENOPAUSAL	2014		YES
					3	APPENDICITIS	1979	1979	NO
					4	APPENDECTOMY	1979	1979	NO
1079	YES	Screen	28AUG2018	VLN mentholated	1	DRUG ABUSE	01MAY2006	01DEC2006	NO
1083	YES	Screen	04SEP2018	VLN non-mentholated	1	HAYFEVER	APR2009		YES
					2	POSTMENOPAUSAL	AUG2013		YES

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
1083	YES	Screen	04SEP2018	VLN non-mentholated	3	HYSTERECTOMY	2006	2006	NO
					4	PAIN IN UTERUS	2005	2006	NO
					5	HERNIATED DISC	2005	2005	NO
					6	CERVICAL FUSION TO REPAIR HERNIATED DISC	2005	2005	NO
					7	TOE INFECTION	JUN2014	JUN2014	NO
1084	YES	Screen	04SEP2018	VLN non-mentholated	1	ALLERGY TO LAWN TREATMENT CHEMICAL (UNSPECIFIED)	1988		YES
1086	YES	Screen	04SEP2018	VLN non-mentholated	1	HERNIATED DISC	2010	24SEP2010	NO
					2	SURGERY TO REPAIR HERNIATED DISC	24SEP2010	24SEP2010	NO
					3	SURGERY TO REPAIR PUNCTURED EAR DRUM	MAY2013	MAY2013	NO
					4	SURGERY TO INSERT SCREWS INTO RIGHT FOOT FOR REPAIR	23SEP2011	23SEP2011	NO
					5	PUNCTURED EAR DRUM	MAY2013	MAY2013	NO
					6	CRUSHED FOOT DUE TO CAR ACCIDENT	23SEP2011	23SEP2011	NO
					7	EDENTULOUS UPPER AND JAW	2010		YES
1088	YES	Screen	04SEP2018	VLN mentholated	1	ALCOHOL ABUSE	JUN2006	DEC2006	NO
					2	ALLERGY TO ADDERALL	1999		YES
					3	TONSILLECTOMY (DOCTOR RECOMMENDED)	1997	1997	NO

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 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-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
1088	YES	Screen	04SEP2018	VLN mentholated	4	ADENOIDECTOMY (DOCTOR RECOMMENDED)	1997	1997	NO
					5	CARPAL TUNNEL SYNDROME	2005	2008	NO
					6	TENDONITIS IN KNEE	2004		YES
					7	ATTENTION DEFICIT DISORDER	1999	2008	NO
					8	SURGERY TO REPAIR SHATTERED ARTERIES LEFT FOOT DUE TO SHOT GUN INJURY	31JUL2016	31JUL2016	NO
					9	SURGERY TO REPAIR TORN MENISCUS	2007	2007	NO
					10	SHOT GUN INJURY	31JUL2016	31JUL2016	NO
					11	TORN MENISCUS	2007	2007	NO
1089	YES	Screen	04SEP2018	UB non-mentholated	1	HYSTERECTOMY	1980	1980	NO
					2	CESAREAN SECTION	20MAR1978	20MAR1978	NO
					3	ABDOMINAL ADHESION (RESOLVED WITH HYSTERECTOMY)	20MAR1978	1980	NO
					4	ABDOMINAL PAIN FROM CESAREAN SECTION (RESOLVED WITH HYSTERECTOMY)	20MAR1978	1980	NO
1092	YES	Screen	05SEP2018	VLN mentholated	1	BACK PROBLEM/PAIN	1994	OCT2002	NO
					2	BREAST REDUCTION SURGERY	OCT2002	OCT2002	NO
1094	YES	Screen	05SEP2018	VLN mentholated	1	ULCER	08SEP1988	09SEP1988	NO

Note: VLN non-mentholated = Non-mentholated VLN cigarettes
 VLN mentholated = Mentholated VLN cigarettes
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 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
1094	YES	Screen	05SEP2018	VLN mentholated	2	SURGERY TO REPAIR ULCER	09SEP1988	09SEP1988	NO
					3	TWO SMALL KELOIDS RIGHT ANTECUBITAL FOSSA	05SEP2018		YES
1095	YES	Screen	07SEP2018	VLN mentholated	1	POSTMENOPAUSAL	2015		YES
					2	ADENOIDECTOMY	1973	1973	NO
					3	TONSILLECTOMY	1973	1973	NO
					4	TONSILLITIS	1973	1973	NO
					5	GALLSTONES	1986	1986	NO
					6	SURGERY TO REMOVE GALLBLADDER	1986	1986	NO
1096	YES	Screen	07SEP2018	VLN non-mentholated	1	HAYFEVER	SEP2003		YES
					2	RINGING IN THE EARS	OCT1998	SEP2003	NO
					3	BRONCHITIS	11FEB2010	21FEB2010	NO
					4	KIDNEY INFECTION	1984	1984	NO
					5	CESAREAN SECTION	15SEP2001	15SEP2001	NO
					6	KIDNEY INFECTION	1985	1985	NO
					7	KIDNEY INFECTION	1986	1986	NO
1098	YES	Screen	18SEP2018	VLN non-mentholated	1	ALCOHOL ABUSE	JUL1983	JUL1990	NO
					2	ALLERGY TO PENICILLIN	JUN1980		YES
					3	RHEUMATIC FEVER	1960	1960	NO
					4	PNEUMONIA	SEP1991	SEP1991	NO
					5	PNEUMONIA	12AUG2014	12AUG2014	NO
					6	BACK PAIN	JUL1978	MAR1997	NO
1099	YES	Screen	18SEP2018	VLN non-mentholated	1	TONSILLITIS	1976	1976	NO

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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

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
1099	YES	Screen	18SEP2018	VLN non-mentholated	2	TONSILLECTOMY	1976	1976	NO
					3	GALLSTONES	2002	2002	NO
					4	SURGERY TO REMOVE GALLBLADDER	2002	2002	NO
					5	APPENDICITIS	1982	1982	NO
					6	APPECTOMY	1982	1982	NO
					7	CESAREAN SECTION	16AUG2011	16AUG2011	NO
					8	TUBAL LIGATION	2011	2011	NO
1100	YES	Screen	18SEP2018	VLN non-mentholated	1	SURGERY TO INSERT PINS AND SCREWS INTO BROKEN RIGHT LEG FOR REPAIR	2007	2007	NO
					2	SURGERY TO REPAIR BROKEN LEFT WRIST	2004	2004	NO
					3	SURGERY TO REPAIR BROKEN LEFT WRIST	1999	1999	NO
					4	DENTAL CARIES AND MISSING TEETH	2009		YES
					5	BROKEN RIGHT LEG	2007	2007	NO
					6	BROKEN LEFT WRIST	2004	2004	NO
					7	BROKEN LEFT WRIST	1999	1999	NO
					8	MISSING TEETH, POOR DENTITION	2009		YES
1103	YES	Screen	18SEP2018	VLN non-mentholated	1	ATTENTION DEFICIT DISORDER	2008		YES
1105	YES	Screen	19SEP2018	VLN non-mentholated	1	GALLSTONES	20AUG2017	20AUG2017	NO
					2	SURGERY TO REMOVE GALLBLADDER	20AUG2017	20AUG2017	NO

Note: 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-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
1106	YES	Screen	19SEP2018	UB non-mentholated	1	POOR DENTITION. DENTURE ON TOP. NO ACTIVE DISEASE	2014		YES
1107	YES	Screen	21SEP2018	VLN non-mentholated	1	BURNED LUNGS DUE TO INHALATION OF INDUSTRIAL BLEACH WITH AMMONIA	FEB1988	FEB1988	NO
					2	INGUINAL HERNIA (NO REPAIR)	AUG1987	DEC1987	NO
1108	YES	Screen	21SEP2018	UB non-mentholated	1	ALLERGY TO PENICILLIN	1969		YES
					2	HEARTBURN	2010		YES
					3	GALLSTONES	1996	1996	NO
					4	SURGERY TO REMOVE GALLBLADDER	1996	1996	NO
					5	TORN MUSCLES IN LEFT SHOULDER	10JUL1998	10JUL1998	NO
					6	SURGERY TO REMOVE L5 IN BACK DUE TO INJURY	2010	2010	NO
					7	SURGERY TO INSERT PINS INTO BROKEN KNEE	1975	1975	NO
					8	SURGERY TO REPAIR GLASS CUTS TO BACK DUE TO INJURY	1981	1981	NO
					9	BACK INJURY	2010	2010	NO
					10	BROKEN KNEE	1975	1975	NO

Note: 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-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
1108	YES	Screen	21SEP2018	UB non-mentholated	11	GLASS CUTS TO BACK INJURY	1981	1981	NO
1112	YES	Screen	21SEP2018	VLN non-mentholated	1	POST MENOPAUSAL	JUL2009		YES
					2	SURGERY TO INSERT WIRES INTO BROKEN CLAVICLE FOR REPAIR	NOV2005	NOV2005	NO
					3	SURGERY TO INSERT SCREWS INTO BROKEN ANKLE FOR REPAIR	JUN1981	JUN1981	NO
					4	SURGERY TO REMOVE SCREWS FROM ANKLE	1982	1982	NO
					5	BROKEN CLAVICLE	NOV2005	NOV2005	NO
					6	BROKEN ANKLE	JUN1981	JUN1981	NO
1115	YES	Screen	24SEP2018	VLN non-mentholated	1	SURGERY TO REMOVE VOCAL NODULES	2000	2000	NO
					2	VOCAL NODULES	2000	2000	NO
2003	YES	Screen	29JUN2018	VLN mentholated	1	SEASONAL ALLERGIES	1989		YES
					2	TUBAL LIGATION	2009	2009	NO
2011	YES	Screen	29JUN2018	VLN mentholated	1	ALLERGY TO RED DYE # 2	1994		YES
2014	YES	Screen	02JUL2018	VLN mentholated	1	HEARTBURN	2017		YES
2015	YES	Screen	02JUL2018	UB mentholated	1	LATEX ALLERGY	1987		YES
2016	YES	Screen	02JUL2018	VLN mentholated	1	BACTERIAL INFECTION OF L OVARY	1983	1983	NO

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 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
2016	YES	Screen	02JUL2018	VLN mentholated	2	OOPHERECTOMY LEFT	1983	1983	NO
2017	YES	Screen	02JUL2018	VLN mentholated	1	GUN SHOT WOUND	01JAN2006	01JAN2006	NO
					2	RIGHT UPPER CHEST	01JAN2006	01JAN2006	NO
					3	BULLET REMOVAL			
2018	YES	Screen	02JUL2018	UB mentholated	1	ALLERGY TO ASPIRIN	1994		YES
					2	ECZEMA	1993		YES
2020	YES	Screen	02JUL2018	VLN mentholated	1	TUBAL LIGATION	2013	2013	NO
					2	HIGH CHOLESTEROL	2016		YES
					3	HYSTERECTOMY	16NOV2017	16NOV2017	NO
					4	ALLERGY TO TAPE	2008		YES
					5	ALLERGY TO FLAGYL	2008		YES
2023	YES	Screen	02JUL2018	VLN mentholated	1	ALLERGY TO MORPHINE	2008		YES
					1	ALLERGY TO SHELLFISH	1987		YES
2028	YES	Screen	06JUL2018	VLN non-mentholated	1	ALLERGY TO SUNFLOWER	2006		YES
					2	ALLERGY TO AMOXICILLIN	2017		YES
2029	YES	Screen	09JUL2018	UB mentholated	1	ACID REFLUX	2008		YES
					2	ARTHRITIS	2010	2012	NO
					3	HEADACHE	2013		YES
					4	RIGHT SHOULDER REPLACED	2012	2012	NO
2039	YES	Screen	13JUL2018	VLN mentholated	1	LOWER BACK PAIN	2000		YES

Note: VLN non-mentholated = Non-mentholated VLN cigarettes
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 UB mentholated = Subjects' UB mentholated filtered cigarettes

Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
2050	YES	Screen	20JUL2018	UB mentholated	1	BACK PAIN LUMBAR	2016		YES
					2	GLAUCOMA	01JAN2000		YES
					3	DIABETES TYPE 2	FEB2018		YES
2052	YES	Screen	20JUL2018	VLN mentholated	1	HAIR LOSS; OCCIPITAL AREA	JUN2018		YES
2057	YES	Screen	23JUL2018	VLN mentholated	1	HIGH BLOOD PRESSURE	01JAN2008		YES
2059	YES	Screen	23JUL2018	UB mentholated	1	HYPERLIPIDEMIA	2015		YES
					2	HYSTERECTOMY	2003	2003	NO
2060	YES	Screen	23JUL2018	VLN mentholated	1	TUBAL LIGATION	JUL2015	JUL2015	NO
2064	YES	Screen	23JUL2018	VLN mentholated	1	HIGH CHOLESTEROL	1981		YES
2067	YES	Screen	23JUL2018	VLN non-mentholated	1	HIGH BLOOD PRESSURE	2016		YES
					2	RIGHT KNEE PAIN	2015		YES
2076	YES	Screen	30JUL2018	VLN mentholated	1	RECURRENT HEART BURN	2013		YES
2088	YES	Screen	03AUG2018	VLN mentholated	1	INSOMNIA	2003		YES
					2	ALLERGY TO CODEINE	2005		YES
					3	TUBAL LIGATION	2010	2010	NO
2092	YES	Screen	06AUG2018	VLN mentholated	1	MIGRAINES	1993		YES
					2	HEAVY MENSTRAL BLEEDING	1988	2014	NO
					3	KIDNEY STONES	2014	2014	NO
					4	ALLERGY TO ULTRAM	2007		YES
					5	UTERINE ABLASION	APR2014	APR2014	NO

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
2099	YES	Screen	09AUG2018	VLN non-mentholated	1	LOW IRON LEVELS UNKNOWN CAUSE	APR2018		YES
					2	UMBILICAL HERNIA	2001	20APR2018	NO
					3	UMBILICAL HERNIA REPAIR	20APR2018	20APR2018	NO
					4	HERNIATED DISC L4 L5	28MAY2017	JUN2017	NO
					5	SURGERY TO REPAIR HERNIATED DISC	JUN2017	JUN2017	NO
					6	HERNIATED DISC L4 L5	AUG2017	OCT2017	NO
					7	SURGERY TO REPAIR HERNIATED DISC	OCT2017	OCT2017	NO
2100	YES	Screen	09AUG2018	UB mentholated	1	HIGH BLOOD PRESSURE	2002		YES
2108	YES	Screen	13AUG2018	VLN non-mentholated	1	HIGH BLOOD PRESSURE	1998		YES
					2	ENVIROMENTAL ALLERGIES	1975		YES
					3	SEASONAL ALLERGIES	1975		YES
2113	YES	Screen	15AUG2018	VLN mentholated	1	PENICILLIN ALLERGY	1988		YES
					2	HEART BURN	2014		YES
2115	YES	Screen	15AUG2018	VLN mentholated	1	GASTRO ESOPHAGEAL REFLUX	2000		YES
					2	BILATERAL LEG PAIN	JUL2018		YES
					3	TUBAL LIGATION	14APR1996	14APR1996	NO
2119	YES	Screen	20AUG2018	VLN mentholated	1	LEFT KNEE AND ANKLE INFLAMMATION	MAY1995		YES
					2	LEFT TIBIA / FIBULA FRACTURE	MAY1995		YES

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
2120	YES	Screen	20AUG2018	VLN non-mentholated	1	HIGH BLOOD PRESSURE	FEB2018		YES
					2	HIGH CHOLESTEROL	FEB2018		YES
					3	ARTHRITIS -LEFT HEEL	2013		YES
					4	BASAL CELL CARCINOMA	JUN2018	17JUL2018	NO
					5	REMOVAL OF BASAL CELL CARCINOMA - RIGHT UPPER NOSE	17JUL2018	17JUL2018	NO
					6	TUBAL LIGATION	2003	2003	NO
2122	YES	Screen	20AUG2018	UB non-mentholated	1	GALLSTONES	2008	2008	NO
					2	KIDNEY STONES	2008	2008	NO
					3	CHOLECYSTECTOMY	2008	2008	NO
2125	YES	Screen	21AUG2018	UB mentholated	1	PERIODIC MUSCLE SPASMS	01NOV2009		YES
					2	SURGERY LEFT ANKLE	2012	2012	NO
					3	LEFT ANKLE FRACTURE	2012	2012	NO
2126	YES	Screen	21AUG2018	VLN mentholated	1	DEVIATED NASAL SEPTUM	01SEP2000	01OCT2000	NO
					2	RHINOPLASTY	01OCT2000	01OCT2000	NO
2136	YES	Screen	27AUG2018	VLN non-mentholated	1	HIGH BLOOD PRESSURE	JUL2017		YES
					2	ACID REFLUX	JUL2016		YES
					3	OSTEOARTHRITIS- BILATERAL HANDS	JUL2013		YES
					4	DIFFICULTY SLEEPING	JUN2018		YES
2140	YES	Screen	30AUG2018	UB non-mentholated	1	HIGH BLOOD PRESURE	2012		YES
					2	HYSTERECTOMY	JAN2018	JAN2018	NO

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 VLN mentholated = Mentholated VLN cigarettes
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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
2142	YES	Screen	31AUG2018	VLN non-mentholated	1	ACID REFLUX	2016		YES
					2	HEADACHE			YES
2158	YES	Screen	18SEP2018	UB non-mentholated	1	HYPOTHYROID	2015	2016	NO
					2	DEPRESSION	1994		YES
					3	CONTROLLED HEADACHES	2016		YES
2159	YES	Screen	19SEP2018	VLN non-mentholated	1	CHOLECYSTECTOMY	2013	2013	NO
					2	CHOLECYSTITIS	2013	2013	NO
					3	HEADACHES DUE TO SINUS CONGESTION	2015		YES
2168	YES	Screen	28SEP2018	VLN non-mentholated	1	PENICILLIN ALLERGY	2002		YES
2170	YES	Screen	28SEP2018	UB non-mentholated	1	PARTIAL HYSTERECTOMY	2003	2003	NO
					2	SEASONAL ALLERGIES	2014		YES
					3	HEMATURIA	1985		YES
2175	YES	Screen	01OCT2018	UB mentholated	1	TUBAL LIGATION	2012	2012	NO
2215	YES	Screen	10OCT2018	UB mentholated	1	HIGH BLOOD PRESSURE	2016		YES
					2	HIGH CHOLESTEROL	2016		YES
					3	HEADACHES	2017		YES
2220	YES	Screen	11OCT2018	VLN non-mentholated	1	MIGRAINES	1991		YES
2244	YES	Screen	25OCT2018	VLN non-mentholated	1	DIVERTICULITIS	JAN2017	JUN2017	NO
					2	ANXIETY	2010		YES
					3	ACID REFLUX	2010		YES
					4	PENICILLIN ALLERY	1987		YES

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.3 Medical History (Safety Population)

Subject Number	Any History?	Visit		Product Date Group	MH Number	Reported Term	Date		Ongoing?
		Name					Start	End	
2251	YES	Screen	09NOV2018	UB non-mentholated	1	HEADACHE	2000		YES
2257	YES	Screen	14NOV2018	UB non-mentholated	1	SCOLIOSIS	27OCT1963		YES
					2	R FOOT LATERAL PLANTAR WART	JUL2018	16JAN2019	NO
2269	YES	Screen	26NOV2018	VLN mentholated	1	SHELL FISH ALLERGY	1979		YES
					2	HEADACHE	2013		YES

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Program: /CA24914/sas_prg/stsas/sdtm-lis/SDTM-LIS-MH.SAS 18JUN2019 11:10

Appendix 16.2.4.4 Tobacco/Nicotine Use History (Safety Population)

Subject Number	Visit		Product Group	Duration of Cigarette Use (years)	Typical Number of CPD	Cigarette		
	Name	Date				Brand-Style	Flavor	Size
1001	Screen	02JUL2018	VLN non-mentholated	48	20	MARLBORO - RED	NON-MENTHOL	KING
1002	Screen	02JUL2018	VLN non-mentholated	18	10	EAGLE 20S - RED	NON-MENTHOL	KING
1003	Screen	03JUL2018	VLN mentholated	18	10	CAMEL - CRUSH SILVER (POPPED)	MENTHOL	KING
1007	Screen	12JUL2018	VLN non-mentholated	25	14	EAGLE 20S - RED	NON-MENTHOL	KING
1008	Screen	12JUL2018	VLN mentholated	16	20	NEWPORT - GREEN	MENTHOL	KING
1010	Screen	13JUL2018	UB mentholated	14	20	PALL MALL - SILVER	MENTHOL	KING
1011	Screen	13JUL2018	UB non-mentholated	21	20	EAGLE 20S - RED	NON-MENTHOL	KING
1013	Screen	16JUL2018	VLN non-mentholated	20	20	NEWPORT - RED	NON-MENTHOL	KING
1014	Screen	16JUL2018	VLN mentholated	18	17	NEWPORT - GREEN	MENTHOL	KING
1015	Screen	16JUL2018	VLN mentholated	33	12	CAMEL - CRUSH SILVER (POPPED)	MENTHOL	KING
1016	Screen	16JUL2018	UB non-mentholated	30	20	MARLBORO - RED	NON-MENTHOL	KING
1017	Screen	17JUL2018	UB mentholated	15	20	MARLBORO - GOLD	MENTHOL	KING
1018	Screen	17JUL2018	VLN mentholated	18	17	PALL MALL - GREEN	MENTHOL	KING
1019	Screen	17JUL2018	VLN non-mentholated	16	20	EAGLE 20S - RED	NON-MENTHOL	KING

Note: CPD = Cigarette smoked per day
 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-SU.SAS 18JUN2019 11:10

Appendix 16.2.4.4 Tobacco/Nicotine Use History (Safety Population)

Subject Number	Visit		Product Group	Duration of Cigarette Use (years)	Typical Number of CPD	Cigarette		
	Name	Date				Brand-Style	Flavor	Size
1020	Screen	17JUL2018	VLN non-mentholated	21	35	MARLBORO - GOLD	NON-MENTHOL	KING
1021	Screen	17JUL2018	UB non-mentholated	40	23	MARLBORO - GOLD	NON-MENTHOL	KING
1023	Screen	17JUL2018	VLN non-mentholated	28	20	MARLBORO - GOLD	NON-MENTHOL	KING
1029	Screen	26JUL2018	VLN mentholated	17	15	MARLBORO - SILVER	MENTHOL	KING
1032	Screen	13AUG2018	VLN mentholated	15	14	PALL MALL - GREEN	MENTHOL	KING
1034	Screen	13AUG2018	VLN non-mentholated	32	17	WILDHORSE - RED	NON-MENTHOL	KING
1035	Screen	13AUG2018	VLN non-mentholated	23	17	PARLIAMENT - BLUE	NON-MENTHOL	KING
1036	Screen	13AUG2018	UB mentholated	23	11	SALEM - GREEN	MENTHOL	KING
1037	Screen	13AUG2018	UB mentholated	5	18	PALL MALL - GREEN	MENTHOL	KING
1038	Screen	13AUG2018	VLN non-mentholated	21	19	WILDHORSE - RED	NON-MENTHOL	KING
1042	Screen	13AUG2018	VLN non-mentholated	8	20	MARLBORO - RED	NON-MENTHOL	KING
1045	Screen	14AUG2018	UB non-mentholated	40	17	USA GOLD - GOLD	NON-MENTHOL	KING
1046	Screen	14AUG2018	UB mentholated	28	17	MARLBORO - SMOOTH	MENTHOL	KING
1050	Screen	14AUG2018	VLN non-mentholated	23	20	EAGLE 20S - RED	NON-MENTHOL	KING
1051	Screen	14AUG2018	UB mentholated	15	14	NEWPORT - GREEN	MENTHOL	KING

Note: CPD = Cigarette smoked per day
 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-SU.SAS 18JUN2019 11:10

Appendix 16.2.4.4 Tobacco/Nicotine Use History (Safety Population)

Subject Number	Visit		Product Group	Duration of Cigarette Use (years)	Typical Number of CPD	Cigarette		
	Name	Date				Brand-Style	Flavor	Size
1052	Screen	14AUG2018	VLN mentholated	13	15	NEWPORT - GREEN	MENTHOL	KING
1053	Screen	14AUG2018	VLN mentholated	22	10	NEWPORT - GREEN	MENTHOL	KING
1054	Screen	14AUG2018	UB non-mentholated	8	12	MARLBORO - SPECIAL SELECT RED	NON-MENTHOL	KING
1055	Screen	14AUG2018	VLN mentholated	5	15	PALL MALL - BLACK	MENTHOL	KING
1056	Screen	14AUG2018	VLN non-mentholated	20	16	MARLBORO - BLACK	NON-MENTHOL	KING
1058	Screen	15AUG2018	VLN non-mentholated	9	18	MARLBORO - GOLD	NON-MENTHOL	KING
1059	Screen	27AUG2018	UB non-mentholated	25	15	MARLBORO - BLACK	NON-MENTHOL	KING
1060	Screen	27AUG2018	VLN mentholated	42	10	NEWPORT - GREEN	MENTHOL	KING
1063	Screen	27AUG2018	VLN mentholated	13	36	CAMEL - CRUSH SILVER (POPPED)	MENTHOL	KING
1064	Screen	27AUG2018	UB non-mentholated	19	25	CAMEL - FILTERS	NON-MENTHOL	KING
1066	Screen	27AUG2018	VLN non-mentholated	45	15	WILDHORSE - GOLD	NON-MENTHOL	KING
1069	Screen	28AUG2018	UB non-mentholated	28	19	MARLBORO - BLACK	NON-MENTHOL	KING
1070	Screen	28AUG2018	VLN non-mentholated	36	12	MARLBORO - BLACK	NON-MENTHOL	KING
1071	Screen	28AUG2018	VLN non-mentholated	27	30	MARLBORO - RED	NON-MENTHOL	KING

Note: CPD = Cigarette smoked per day
 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-SU.SAS 18JUN2019 11:10

Appendix 16.2.4.4 Tobacco/Nicotine Use History (Safety Population)

Subject Number	Visit		Product Group	Duration of Cigarette Use (years)	Typical Number of CPD	Cigarette		
	Name	Date				Brand-Style	Flavor	Size
1072	Screen	28AUG2018	VLN mentholated	18	12	PALL MALL - GREEN	MENTHOL	KING
1074	Screen	28AUG2018	VLN non-mentholated	18	14	MARLBORO - EIGHTY-THREES	NON-MENTHOL	KING
1075	Screen	28AUG2018	UB non-mentholated	11	20	EAGLE 20S - RED	NON-MENTHOL	KING
1077	Screen	28AUG2018	VLN non-mentholated	32	17	TIMELESS - SILVER	NON-MENTHOL	KING
1078	Screen	28AUG2018	VLN non-mentholated	30	20	PYRAMID - BLUE	NON-MENTHOL	KING
1079	Screen	28AUG2018	VLN mentholated	7	14	L&M - GREEN	MENTHOL	KING
1082	Screen	30AUG2018	VLN non-mentholated	18	15	MARLBORO - GOLD	NON-MENTHOL	KING
1083	Screen	04SEP2018	VLN non-mentholated	36	28	MARLBORO - SPECIAL SELECT RED	NON-MENTHOL	KING
1084	Screen	04SEP2018	VLN non-mentholated	26	15	PYRAMID - BLUE	NON-MENTHOL	KING
1086	Screen	04SEP2018	VLN non-mentholated	45	40	USA GOLD - RED	NON-MENTHOL	KING
1088	Screen	04SEP2018	VLN mentholated	12	10	MARLBORO - GREEN	MENTHOL	KING
1089	Screen	04SEP2018	UB non-mentholated	43	10	MARLBORO - SPECIAL SELECT RED	NON-MENTHOL	KING
1092	Screen	05SEP2018	VLN mentholated	10	18	NEWPORT - GREEN	MENTHOL	KING
1094	Screen	05SEP2018	VLN mentholated	22	10	NEWPORT - GREEN	MENTHOL	KING

Note: CPD = Cigarette smoked per day
 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-SU.SAS 18JUN2019 11:10

Appendix 16.2.4.4 Tobacco/Nicotine Use History (Safety Population)

Subject Number	Visit		Product Group	Duration of Cigarette Use (years)	Typical Number of CPD	Cigarette		
	Name	Date				Brand-Style	Flavor	Size
1095	Screen	07SEP2018	VLN mentholated	18	18	PYRAMID - GOLD	MENTHOL	KING
1096	Screen	07SEP2018	VLN non-mentholated	27	15	MARLBORO - GOLD	NON-MENTHOL	KING
1097	Screen	07SEP2018	VLN mentholated	12	20	NEWPORT - GREEN	MENTHOL	KING
1098	Screen	18SEP2018	VLN non-mentholated	50	20	EDGEFIELD - RED	NON-MENTHOL	KING
1099	Screen	18SEP2018	VLN non-mentholated	34	20	MARLBORO - BLACK	NON-MENTHOL	KING
1100	Screen	18SEP2018	VLN non-mentholated	44	15	OLD GOLD - RED	NON-MENTHOL	KING
1101	Screen	18SEP2018	VLN non-mentholated	24	20	MARLBORO - GOLD	NON-MENTHOL	KING
1103	Screen	18SEP2018	VLN non-mentholated	5	20	MARLBORO - GOLD	NON-MENTHOL	KING
1105	Screen	19SEP2018	VLN non-mentholated	33	20	WAVE - BLUE	NON-MENTHOL	KING
1106	Screen	19SEP2018	UB non-mentholated	28	20	MARLBORO - RED	NON-MENTHOL	KING
1107	Screen	21SEP2018	VLN non-mentholated	30	19	L&M - RED	NON-MENTHOL	KING
1108	Screen	21SEP2018	UB non-mentholated	41	20	WILDHORSE - RED	NON-MENTHOL	KING
1109	Screen	21SEP2018	UB non-mentholated	45	19	NEWPORT - RED	NON-MENTHOL	KING
1112	Screen	21SEP2018	VLN non-mentholated	35	14	PALL MALL - RED	NON-MENTHOL	KING
1114	Screen	24SEP2018	UB non-mentholated	16	15	MARLBORO - SPECIAL SELECT RED	NON-MENTHOL	KING

Note: CPD = Cigarette smoked per day
 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-SU.SAS 18JUN2019 11:10

Appendix 16.2.4.4 Tobacco/Nicotine Use History (Safety Population)

Subject Number	Visit		Product Group	Duration of Cigarette Use (years)	Typical Number of CPD	Cigarette		
	Name	Date				Brand-Style	Flavor	Size
1115	Screen	24SEP2018	VLN non-mentholated	10	20	MARLBORO - RED	NON-MENTHOL	KING
2002	Screen	29JUN2018	UB mentholated	30	30	NEWPORT - GREEN	MENTHOL	KING
2003	Screen	29JUN2018	VLN mentholated	25	20	MARLBORO - BLACK	MENTHOL	KING
2007	Screen	29JUN2018	VLN non-mentholated	35	20	PALL MALL - ORANGE	NON-MENTHOL	KING
2008	Screen	06JUL2018	VLN mentholated	25	12	NATURAL AMERICAN SPIRIT - GREEN	MENTHOL	KING
2009	Screen	29JUN2018	VLN non-mentholated	20	20	NATURAL AMERICAN SPIRIT - TURQUIOSE	NON-MENTHOL	KING
2010	Screen	29JUN2018	UB mentholated	10	20	NEWPORT - GREEN	MENTHOL	KING
2011	Screen	29JUN2018	VLN mentholated	13	13	NEWPORT - GREEN	MENTHOL	KING
2014	Screen	02JUL2018	VLN mentholated	15	16	NEWPORT - GREEN	MENTHOL	KING
2015	Screen	02JUL2018	UB mentholated	41	15	NEWPORT - GREEN	MENTHOL	KING
2016	Screen	02JUL2018	VLN mentholated	14	15	NEWPORT - GREEN	MENTHOL	KING
2017	Screen	02JUL2018	VLN mentholated	15	15	NEWPORT - GREEN	MENTHOL	KING
2018	Screen	02JUL2018	UB mentholated	11	14	NEWPORT - GREEN	MENTHOL	KING
2020	Screen	02JUL2018	VLN mentholated	13	20	SALEM - GOLD	MENTHOL	KING

Note: CPD = Cigarette smoked per day
 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-SU.SAS 18JUN2019 11:10

Appendix 16.2.4.4 Tobacco/Nicotine Use History (Safety Population)

Subject Number	Visit		Product Group	Duration of Cigarette Use (years)	Typical Number of CPD	Cigarette		
	Name	Date				Brand-Style	Flavor	Size
2021	Screen	02JUL2018	VLN mentholated	6	12	NEWPORT - GREEN	MENTHOL	KING
2023	Screen	02JUL2018	VLN mentholated	16	10	NEWPORT - GREEN	MENTHOL	KING
2024	Screen	03JUL2018	UB non-mentholated	10	20	CAMEL - FILTERS	NON-MENTHOL	KING
2025	Screen	03JUL2018	UB non-mentholated	40	25	PALL MALL - ORANGE	NON-MENTHOL	KING
2028	Screen	06JUL2018	VLN non-mentholated	7.5	10	MARLBORO - GOLD	NON-MENTHOL	KING
2029	Screen	09JUL2018	UB mentholated	35	25	CAMEL - CRUSH SILVER (POPPED)	MENTHOL	KING
2039	Screen	13JUL2018	VLN mentholated	20	16	NEWPORT - GREEN	MENTHOL	KING
2050	Screen	20JUL2018	UB mentholated	40	30	NEWPORT - GREEN	MENTHOL	KING
2052	Screen	20JUL2018	VLN mentholated	40	15	MARLBORO - ICE	MENTHOL	KING
2057	Screen	23JUL2018	VLN mentholated	25	10	NEWPORT - GREEN	MENTHOL	KING
2058	Screen	23JUL2018	VLN mentholated	15	10	PALL MALL - GREEN	MENTHOL	KING
2059	Screen	23JUL2018	UB mentholated	10	10	NEWPORT - GREEN	MENTHOL	KING
2060	Screen	23JUL2018	VLN mentholated	20	10	NEWPORT - GREEN	MENTHOL	KING
2064	Screen	23JUL2018	VLN mentholated	37	30	PALL MALL - GREEN	MENTHOL	KING
2066	Screen	23JUL2018	VLN mentholated	6	10	NEWPORT - GREEN	MENTHOL	KING

Note: CPD = Cigarette smoked per day
 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-SU.SAS 18JUN2019 11:10

Appendix 16.2.4.4 Tobacco/Nicotine Use History (Safety Population)

Subject Number	Visit		Product Group	Duration of Cigarette Use (years)	Typical Number of CPD	Cigarette		
	Name	Date				Brand-Style	Flavor	Size
2067	Screen	23JUL2018	VLN non-mentholated	12	15	L&M - RED	NON-MENTHOL	KING
2075	Screen	30JUL2018	VLN mentholated	10	15	PALL MALL - BLACK	MENTHOL	KING
2076	Screen	30JUL2018	VLN mentholated	20	10	CAMEL - CRUSH (POPPED)	MENTHOL	KING
2086	Screen	03AUG2018	VLN non-mentholated	15	25	MARLBORO - SPECIAL BLEND RED	NON-MENTHOL	KING
2088	Screen	03AUG2018	VLN mentholated	20	15	NEWPORT - GREEN	MENTHOL	KING
2092	Screen	06AUG2018	VLN mentholated	20	10	MARLBORO - GREEN	MENTHOL	KING
2099	Screen	09AUG2018	VLN non-mentholated	35	25	MARLBORO - RED	NON-MENTHOL	KING
2100	Screen	09AUG2018	UB mentholated	20	20	L&M - GREEN	MENTHOL	KING
2108	Screen	13AUG2018	VLN non-mentholated	40	30	PALL MALL - ORANGE	NON-MENTHOL	KING
2110	Screen	13AUG2018	UB mentholated	7	10	NEWPORT - GREEN	MENTHOL	KING
2113	Screen	15AUG2018	VLN mentholated	20	15	MAVERICK - FULL FLAVOR	MENTHOL	KING
2115	Screen	15AUG2018	VLN mentholated	20	12	NEWPORT - GREEN	MENTHOL	KING
2119	Screen	20AUG2018	VLN mentholated	11	15	PALL MALL - GREEN	MENTHOL	KING
2120	Screen	20AUG2018	VLN non-mentholated	40	15	MARLBORO - SPECIAL BLEND GOLD	NON-MENTHOL	KING

Note: CPD = Cigarette smoked per day
 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-SU.SAS 18JUN2019 11:10

Appendix 16.2.4.4 Tobacco/Nicotine Use History (Safety Population)

Subject Number	Visit		Product Group	Duration of Cigarette Use (years)	Typical Number of CPD	Cigarette		
	Name	Date				Brand-Style	Flavor	Size
2122	Screen	20AUG2018	UB non-mentholated	50	20	MARLBORO - SILVER	NON-MENTHOL	KING
2125	Screen	21AUG2018	UB mentholated	10	10	NEWPORT - GREEN	MENTHOL	KING
2126	Screen	21AUG2018	VLN mentholated	16	20	KOOL - BLUE	MENTHOL	KING
2136	Screen	27AUG2018	VLN non-mentholated	50	20	CAMEL - FILTERS	NON-MENTHOL	KING
2140	Screen	30AUG2018	UB non-mentholated	30	15	DORAL - SILVER	NON-MENTHOL	KING
2142	Screen	31AUG2018	VLN non-mentholated	17	30	EAGLE 20S - RED	NON-MENTHOL	KING
2143	Screen	04SEP2018	VLN non-mentholated	40	30	CROWNS - GOLD	NON-MENTHOL	KING
2158	Screen	18SEP2018	UB non-mentholated	28	15	KAMEL RED - GENUINE ORIGINAL	NON-MENTHOL	KING
2159	Screen	19SEP2018	VLN non-mentholated	14	40	LD - RED	NON-MENTHOL	KING
2164	Screen	27SEP2018	VLN non-mentholated	48	10	NEWPORT - RED	NON-MENTHOL	KING
2168	Screen	28SEP2018	VLN non-mentholated	16	20	MARLBORO - GOLD	NON-MENTHOL	KING
2170	Screen	28SEP2018	UB non-mentholated	34	15	MARLBORO - RED	NON-MENTHOL	KING
2175	Screen	01OCT2018	UB mentholated	30	15	NEWPORT - GREEN	MENTHOL	KING
2189	Screen	04OCT2018	VLN mentholated	10	20	NEWPORT - GREEN	MENTHOL	KING
2211	Screen	10OCT2018	VLN mentholated	15	20	NEWPORT - GREEN	MENTHOL	KING

Note: CPD = Cigarette smoked per day
 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-SU.SAS 18JUN2019 11:10

Appendix 16.2.4.4 Tobacco/Nicotine Use History (Safety Population)

Subject Number	Visit		Product Group	Duration of Cigarette Use (years)	Typical Number of CPD	Cigarette		
	Name	Date				Brand-Style	Flavor	Size
2212	Screen	10OCT2018	UB mentholated	12	20	NEWPORT - GREEN	MENTHOL	KING
2213	Screen	10OCT2018	VLN mentholated	10	40	MARLBORO - ICE	MENTHOL	KING
2215	Screen	10OCT2018	UB mentholated	20	10	NEWPORT - GREEN	MENTHOL	KING
2220	Screen	11OCT2018	VLN non-mentholated	17	10	NEWPORT - RED	NON-MENTHOL	KING
2235	Screen	19OCT2018	VLN mentholated	6	13	NEWPORT - GREEN	MENTHOL	KING
2244	Screen	25OCT2018	VLN non-mentholated	18	16	CAMEL - BLUE	NON-MENTHOL	KING
2247	Screen	06NOV2018	VLN mentholated	10	12	NEWPORT - GREEN	MENTHOL	KING
2251	Screen	09NOV2018	UB non-mentholated	10	20	MARLBORO - BLACK	NON-MENTHOL	KING
2257	Screen	14NOV2018	UB non-mentholated	39	15	MARLBORO - SPECIAL SELECT	NON-MENTHOL	KING
2259	Screen	14NOV2018	UB mentholated	21	13	NEWPORT - GREEN	MENTHOL	KING
2269	Screen	26NOV2018	VLN mentholated	20	15	NEWPORT - GREEN	MENTHOL	KING
2272	Screen	28NOV2018	VLN mentholated	20	10	NEWPORT - GREEN	MENTHOL	KING

Note: CPD = Cigarette smoked per day
 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-SU.SAS 18JUN2019 11:10