



## **16.2 Subject Data Listings**

### **16.2.1 Subject Discontinuation**

[Appendix 16.2.1.1 Subject Discontinuation \(Safety Population\)](#)

[Appendix 16.2.1.2 Subject Discontinuation](#)

## Appendix 16.2.1.1 Subject Discontinuation (Safety Population)

Site	Subject Number	Randomization Number	Randomization Date	Product Group	Completion/ Discontinuation Date	Completed Study?	Reason For Discontinuation	Specify
001	1001	001-036	25JUL2018	VLN non-mentholated	07SEP2018	Yes		
	1002	001-037	25JUL2018	VLN non-mentholated	07SEP2018	Yes		
	1003	001-001	25JUL2018	VLN mentholated	07SEP2018	Yes		
	1007	001-038	25JUL2018	VLN non-mentholated	07SEP2018	Yes		
	1008	001-002	25JUL2018	VLN mentholated	07SEP2018	Yes		
	1010	001-003	25JUL2018	UB mentholated	06SEP2018	Yes		
	1011	001-039	25JUL2018	UB non-mentholated	06SEP2018	Yes		
	1013	001-044	01AUG2018	VLN non-mentholated	14SEP2018	Yes		
	1014	001-007	01AUG2018	VLN mentholated	14SEP2018	Yes		
	1015	001-004	01AUG2018	VLN mentholated	14SEP2018	Yes		
	1016	001-045	01AUG2018	UB non-mentholated	13SEP2018	Yes		
	1017	001-005	01AUG2018	UB mentholated	13SEP2018	Yes		
	1018	001-006	01AUG2018	VLN mentholated	15AUG2018	No	Adverse Event	8-Anxiety
	1019	001-040	01AUG2018	VLN non-mentholated	14SEP2018	Yes		
	1020	001-042	01AUG2018	VLN non-mentholated	14SEP2018	Yes		
	1021	001-041	01AUG2018	UB non-mentholated	13SEP2018	Yes		
	1023	001-043	01AUG2018	VLN non-mentholated	02OCT2018	Yes		
	1029	001-008	28AUG2018	VLN mentholated	11OCT2018	Yes		
	1032	001-010	28AUG2018	VLN mentholated	11OCT2018	Yes		
	1034	001-053	28AUG2018	VLN non-mentholated	10OCT2018	Yes		
	1035	001-048	28AUG2018	VLN non-mentholated	11OCT2018	Yes		
	1036	001-009	28AUG2018	UB mentholated	10OCT2018	Yes		
	1037	001-015	28AUG2018	UB mentholated	10OCT2018	Yes		
	1038	001-050	28AUG2018	VLN non-mentholated	11OCT2018	Yes		
	1042	001-046	28AUG2018	VLN non-mentholated	11OCT2018	Yes		
	1045	001-049	28AUG2018	UB non-mentholated	10OCT2018	Yes		
	1046	001-016	28AUG2018	UB mentholated	10OCT2018	Yes		
	1050	001-052	28AUG2018	VLN non-mentholated	10OCT2018	Yes		
	1051	001-013	28AUG2018	UB mentholated	10OCT2018	Yes		
	1052	001-011	28AUG2018	VLN mentholated	11OCT2018	Yes		
	1053	001-012	28AUG2018	VLN mentholated	11OCT2018	Yes		
	1054	001-054	28AUG2018	UB non-mentholated	10OCT2018	Yes		

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, UDS = Urine Drug Screen

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## Appendix 16.2.1.1 Subject Discontinuation (Safety Population)

Site	Subject Number	Randomization Number	Randomization Date	Product Group	Completion/ Discontinuation Date	Completed Study?	Reason For Discontinuation	Specify
001	1055	001-014	28AUG2018	VLN mentholated	11OCT2018	Yes		
	1056	001-051	28AUG2018	VLN non-mentholated	11OCT2018	Yes		
	1058	001-047	28AUG2018	VLN non-mentholated	11OCT2018	Yes		
	1059	001-055	11SEP2018	UB non-mentholated	24OCT2018	Yes		
	1060	001-019	11SEP2018	VLN mentholated	24OCT2018	Yes		
	1063	001-017	11SEP2018	VLN mentholated	25OCT2018	Yes		
	1064	001-057	11SEP2018	UB non-mentholated	22OCT2018	No	Lost To Follow-Up	
	1066	001-059	11SEP2018	VLN non-mentholated	24OCT2018	Yes		
	1069	001-061	11SEP2018	UB non-mentholated	24OCT2018	Yes		
	1070	001-060	11SEP2018	VLN non-mentholated	24OCT2018	Yes		
	1071	001-056	11SEP2018	VLN non-mentholated	23OCT2018	No	Non-Compliance With Study Procedures	Subject Dropped Due To Having Back Surgery And Not Checking In
	1072	001-018	11SEP2018	VLN mentholated	22OCT2018	No	Withdrawal By Subject	Subject Dropped From Study Due To Moving Out Of State
	1074	001-064	11SEP2018	VLN non-mentholated	24OCT2018	Yes		
	1075	001-065	11SEP2018	UB non-mentholated	24OCT2018	Yes		
	1077	001-063	11SEP2018	VLN non-mentholated	24OCT2018	Yes		
	1078	001-058	11SEP2018	VLN non-mentholated	24OCT2018	Yes		
	1079	001-020	11SEP2018	VLN mentholated	24OCT2018	Yes		
	1082	001-062	11SEP2018	VLN non-mentholated	24OCT2018	Yes		
	1083	001-067	18SEP2018	VLN non-mentholated	31OCT2018	Yes		
	1084	001-068	18SEP2018	VLN non-mentholated	16OCT2018	No	Non-Compliance With Study Procedures	Subject Was Dropped Due To Positive Urine Drug Test
	1086	001-069	18SEP2018	VLN non-mentholated	31OCT2018	Yes		
	1088	001-022	18SEP2018	VLN mentholated	31OCT2018	Yes		
	1089	001-066	18SEP2018	UB non-mentholated	31OCT2018	Yes		
	1092	001-023	18SEP2018	VLN mentholated	31OCT2018	Yes		
	1094	001-021	18SEP2018	VLN mentholated	31OCT2018	Yes		

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
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 UB mentholated = Subjects' UB mentholated filtered cigarettes  
 Site: 001 = Lincoln, 002 = High Point, UDS = Urine Drug Screen

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## Appendix 16.2.1.1 Subject Discontinuation (Safety Population)

Site	Subject Number	Randomization Number	Randomization Date	Product Group	Completion/ Discontinuation Date	Completed Study?	Reason For Discontinuation	Specify
001	1095	001-025	18SEP2018	VLN mentholated	31OCT2018	Yes		
	1096	001-070	18SEP2018	VLN non-mentholated	31OCT2018	Yes		
	1097	001-024	18SEP2018	VLN mentholated	31OCT2018	Yes		
	1098	001-148	04OCT2018	VLN non-mentholated	17NOV2018	Yes		
	1099	001-163	04OCT2018	VLN non-mentholated	16NOV2018	Yes		
	1100	001-149	04OCT2018	VLN non-mentholated	16NOV2018	Yes		
	1101	001-151	04OCT2018	VLN non-mentholated	21NOV2018	Yes		
	1103	001-150	04OCT2018	VLN non-mentholated	16NOV2018	Yes		
	1105	001-164	04OCT2018	VLN non-mentholated	16NOV2018	Yes		
	1106	001-147	04OCT2018	UB non-mentholated	16NOV2018	Yes		
	1107	001-154	04OCT2018	VLN non-mentholated	16NOV2018	Yes		
	1108	001-152	04OCT2018	UB non-mentholated	16NOV2018	Yes		
	1109	001-155	04OCT2018	UB non-mentholated	16NOV2018	Yes		
	1112	001-162	04OCT2018	VLN non-mentholated	16NOV2018	Yes		
	1114	001-165	04OCT2018	UB non-mentholated	16NOV2018	Yes		
	1115	001-146	04OCT2018	VLN non-mentholated	14NOV2018	No	Withdrawal By Subject	Subject Stated He Received A New Job And Cannot Complete The Study
002	2002	002-007	24JUL2018	UB mentholated	12SEP2018	Yes		
	2003	002-033	17JUL2018	VLN mentholated	05SEP2018	Yes		
	2007	002-070	17JUL2018	VLN non-mentholated	05SEP2018	Yes		
	2008	002-006	17JUL2018	VLN mentholated	05SEP2018	Yes		
	2009	002-038	17JUL2018	VLN non-mentholated	14AUG2018	No	Non-Compliance With Study Procedures	Positive UDS
	2010	002-001	17JUL2018	UB mentholated	05SEP2018	Yes		
	2011	002-035	17JUL2018	VLN mentholated	05SEP2018	Yes		
	2014	002-002	17JUL2018	VLN mentholated	05SEP2018	Yes		
	2015	002-032	17JUL2018	UB mentholated	05SEP2018	Yes		
	2016	002-031	17JUL2018	VLN mentholated	10AUG2018	No	Non-Compliance With Study Procedures	Protocol Violation; Positive UDS

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
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## Appendix 16.2.1.1 Subject Discontinuation (Safety Population)

Site	Subject Number	Randomization Number	Randomization Date	Product Group	Completion/ Discontinuation Date	Completed Study?	Reason For Discontinuation	Specify
002	2017	002-003	17JUL2018	VLN mentholated	05SEP2018	Yes		
	2018	002-034	17JUL2018	UB mentholated	05SEP2018	Yes		
	2020	002-030	17JUL2018	VLN mentholated	05SEP2018	Yes		
	2021	002-004	17JUL2018	VLN mentholated	05SEP2018	Yes		
	2023	002-005	17JUL2018	VLN mentholated	05SEP2018	Yes		
	2024	002-036	17JUL2018	UB non-mentholated	30JUL2018	No	Lost To Follow-Up	
	2025	002-039	17JUL2018	UB non-mentholated	05SEP2018	Yes		
	2028	002-037	17JUL2018	VLN non-mentholated	05SEP2018	Yes		
	2029	002-008	24JUL2018	UB mentholated	12SEP2018	Yes		
	2039	002-029	24JUL2018	VLN mentholated	12SEP2018	Yes		
	2050	002-010	08AUG2018	UB mentholated	27SEP2018	Yes		
	2052	002-011	08AUG2018	VLN mentholated	27SEP2018	Yes		
	2057	002-012	08AUG2018	VLN mentholated	27SEP2018	Yes		
	2058	002-028	08AUG2018	VLN mentholated	27SEP2018	Yes		
	2059	002-025	08AUG2018	UB mentholated	27SEP2018	Yes		
	2060	002-027	08AUG2018	VLN mentholated	27SEP2018	Yes		
	2064	002-013	08AUG2018	VLN mentholated	27SEP2018	Yes		
	2066	002-026	08AUG2018	VLN mentholated	27SEP2018	Yes		
	2067	002-040	08AUG2018	VLN non-mentholated	27SEP2018	Yes		
	2075	002-009	08AUG2018	VLN mentholated	22AUG2018	No	Non-Compliance With Study Procedures	Non Compliant With Study Product
	2076	002-014	01SEP2018	VLN mentholated	21OCT2018	Yes		
	2086	002-041	01SEP2018	VLN non-mentholated	09OCT2018	No	Non-Compliance With Study Procedures	Positive Drug Screen
	2088	002-024	01SEP2018	VLN mentholated	21OCT2018	Yes		
	2092	002-023	01SEP2018	VLN mentholated	21OCT2018	Yes		
	2099	002-042	01SEP2018	VLN non-mentholated	21OCT2018	Yes		
	2100	002-022	01SEP2018	UB mentholated	21OCT2018	Yes		
	2108	002-069	01SEP2018	VLN non-mentholated	21OCT2018	Yes		

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
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 UB mentholated = Subjects' UB mentholated filtered cigarettes  
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## Appendix 16.2.1.1 Subject Discontinuation (Safety Population)

Site	Subject Number	Randomization Number	Randomization Date	Product Group	Completion/ Discontinuation Date	Completed Study?	Reason For Discontinuation	Specify
002	2110	002-021	07SEP2018	UB mentholated	27OCT2018	Yes		
	2113	002-020	07SEP2018	VLN mentholated	22SEP2018	No	Lost To Follow-Up	
	2115	002-019	07SEP2018	VLN mentholated	21SEP2018	No	Non-Compliance With Study Procedures	Positive Drug Test And Lack Of Compliance
	2119	002-017	07SEP2018	VLN mentholated	27OCT2018	Yes		
	2120	002-068	07SEP2018	VLN non-mentholated	27OCT2018	Yes		
	2122	002-043	07SEP2018	UB non-mentholated	27OCT2018	Yes		
	2125	002-015	07SEP2018	UB mentholated	27OCT2018	Yes		
	2126	002-016	07SEP2018	VLN mentholated	27OCT2018	Yes		
	2136	002-044	07SEP2018	VLN non-mentholated	19OCT2018	No	Non-Compliance With Study Procedures	Positive Drug Screen
	2140	002-066	24SEP2018	UB non-mentholated	13NOV2018	Yes		
	2142	002-067	24SEP2018	VLN non-mentholated	08OCT2018	No	Non-Compliance With Study Procedures	Allowed Roommates To Smoke Product
	2143	002-045	24SEP2018	VLN non-mentholated	13NOV2018	Yes		
	2158	002-060	20OCT2018	UB non-mentholated	17NOV2018	No	Lost To Follow-Up	
	2159	002-253	20OCT2018	VLN non-mentholated	09DEC2018	Yes		
	2164	002-059	20OCT2018	VLN non-mentholated	09DEC2018	Yes		
	2168	002-061	20OCT2018	VLN non-mentholated	09DEC2018	Yes		
	2169				20OCT2018	No	Other	Alternate; Not Needed
	2170	002-058	20OCT2018	UB non-mentholated	09DEC2018	Yes		
	2175	002-228	20OCT2018	UB mentholated	09DEC2018	Yes		
	2189	002-018	20OCT2018	VLN mentholated	13NOV2018	No	Non-Compliance With Study Procedures	Did Not Show For End Of Week 2
	2211	002-229	20OCT2018	VLN mentholated	09DEC2018	Yes		
	2212	002-226	20OCT2018	UB mentholated	09DEC2018	Yes		

Note: VLN non-mentholated = Non-mentholated VLN cigarettes  
 VLN mentholated = Mentholated VLN cigarettes  
 UB non-mentholated = Subjects' UB non-mentholated filtered cigarettes  
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## Appendix 16.2.1.1 Subject Discontinuation (Safety Population)

Site	Subject Number	Randomization Number	Randomization Date	Product Group	Completion/ Discontinuation Date	Completed Study?	Reason For Discontinuation	Specify
002	2213	002-227	20OCT2018	VLN mentholated	09DEC2018	Yes	Other	Alternate; Not Needed
	2214				20OCT2018	No		
	2215	002-230	20OCT2018	UB mentholated	09DEC2018	Yes		
	2220	002-056	20OCT2018	VLN non-mentholated	09DEC2018	Yes		
	2224				20OCT2018	No	Other	Alternate;not Needed
	2235	002-231	03NOV2018	VLN mentholated	23DEC2018	Yes		
	2244	002-057	03NOV2018	VLN non-mentholated	23DEC2018	Yes		
	2247	002-232	07DEC2018	VLN mentholated	04JAN2019	No		
							Non-Compliance With Study Procedures	Did Not Complete Diary. Stopped Product And Was Smoking UB
	2251	002-336	07DEC2018	UB non-mentholated	26JAN2019	Yes		
	2257	002-360	07DEC2018	UB non-mentholated	28JAN2019	Yes		
	2259	002-234	07DEC2018	UB mentholated	26JAN2019	Yes		
	2269	002-235	07DEC2018	VLN mentholated	26JAN2019	Yes		
	2272	002-233	07DEC2018	VLN mentholated	26JAN2019	Yes		

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  
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## Appendix 16.2.1.2 Subject Discontinuation

Site	Subject Number	Discontinuation Date	Reason For Discontinuation	Specify
001	1001	07SEP2018		
	1002	07SEP2018		
	1003	07SEP2018		
	1004	03JUL2018	Screen Failure	
	1005	03JUL2018	Screen Failure	
	1006	12JUL2018	Screen Failure	
	1007	07SEP2018		
	1008	07SEP2018		
	1009	13JUL2018	Screen Failure	
	1010	06SEP2018		
	1011	06SEP2018		
	1012	16JUL2018	Screen Failure	
	1013	14SEP2018		
	1014	14SEP2018		
	1015	14SEP2018		
	1016	13SEP2018		
	1017	13SEP2018		
	1018	15AUG2018	Adverse Event	8-Anxiety
	1019	14SEP2018		
	1020	14SEP2018		
	1021	13SEP2018		
	1022	17JUL2018	Screen Failure	
	1023	02OCT2018		
	1024	23JUL2018	Screen Failure	
	1025	30JUL2018	Screen Failure	
	1026	02AUG2018	Screen Failure	
	1027	23JUL2018	Screen Failure	
	1028	26JUL2018	Screen Failure	
	1029	11OCT2018		
	1030	26JUL2018	Screen Failure	
	1031	26JUL2018	Screen Failure	
	1032	11OCT2018		
	1033	13AUG2018	Screen Failure	
	1034	10OCT2018		
	1035	11OCT2018		
	1036	10OCT2018		
	1037	10OCT2018		

Note: Site: 001 = Lincoln, 002 = High Point, UDS = Urine Drug Screen

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## Appendix 16.2.1.2 Subject Discontinuation

Site	Subject Number	Discontinuation Date	Reason For Discontinuation	Specify
001	1038	11OCT2018		
	1039	22AUG2018	Screen Failure	
	1040	22AUG2018	Screen Failure	
	1041	13AUG2018	Screen Failure	
	1042	11OCT2018		
	1043	13AUG2018	Screen Failure	
	1044	14AUG2018	Screen Failure	
	1045	10OCT2018		
	1046	10OCT2018		
	1047	14AUG2018	Screen Failure	
	1048	14AUG2018	Screen Failure	
	1049	14AUG2018	Screen Failure	
	1050	10OCT2018		
	1051	10OCT2018		
	1052	11OCT2018		
	1053	11OCT2018		
	1054	10OCT2018		
	1055	11OCT2018		
	1056	11OCT2018		
	1058	11OCT2018		
	1059	24OCT2018		
	1060	24OCT2018		
	1061	27AUG2018	Screen Failure	
	1062	05SEP2018	Screen Failure	
	1063	25OCT2018		
	1064	22OCT2018	Lost To Follow-Up	
	1065	31AUG2018	Screen Failure	
	1066	24OCT2018		
	1067	27AUG2018	Screen Failure	
	1068	28AUG2018	Screen Failure	
	1069	24OCT2018		
	1070	24OCT2018		

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## Appendix 16.2.1.2 Subject Discontinuation

Site	Subject Number	Discontinuation Date	Reason For Discontinuation	Specify	
001	1071	23OCT2018	Non-Compliance With Study Procedures	Subject Dropped Due To Having Back Surgery And Not Checking In	
	1072	22OCT2018	Withdrawal By Subject		
	1073	07SEP2018	Screen Failure		Subject Was Dropped Due To Positive Urine Drug Test
	1074	24OCT2018			
	1075	24OCT2018			
	1077	24OCT2018			
	1078	24OCT2018			
	1079	24OCT2018	Screen Failure		
	1080	05SEP2018			
	1081	28AUG2018			
	1082	24OCT2018	Screen Failure		
	1083	31OCT2018			
	1084	16OCT2018	Non-Compliance With Study Procedures		
	1085	04SEP2018	Screen Failure		
	1086	31OCT2018	Screen Failure		
	1087	10SEP2018			
	1088	31OCT2018			
	1089	31OCT2018	Screen Failure		
	1090	05SEP2018			
	1091	05SEP2018	Screen Failure		
	1092	31OCT2018			
	1094	31OCT2018	Screen Failure		
	1095	31OCT2018			
	1096	31OCT2018			
	1097	31OCT2018			
	1098	17NOV2018			

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## Appendix 16.2.1.2 Subject Discontinuation

Site	Subject Number	Discontinuation Date	Reason For Discontinuation	Specify
001	1099	16NOV2018		
	1100	16NOV2018		
	1101	21NOV2018		
	1102	18SEP2018	Screen Failure	
	1103	16NOV2018		
	1104	21SEP2018	Screen Failure	
	1105	16NOV2018		
	1106	16NOV2018		
	1107	16NOV2018		
	1108	16NOV2018		
	1109	16NOV2018		
	1110	21SEP2018	Screen Failure	
	1111	03OCT2018	Screen Failure	
	1112	16NOV2018		
	1113	21SEP2018	Screen Failure	
	1114	16NOV2018		
	1115	14NOV2018	Withdrawal By Subject	Subject Stated He Received A New Job And Cannot Complete The Study
002	1116	24SEP2018	Screen Failure	
	2001	13JUL2018	Screen Failure	
	2002	12SEP2018		
	2003	05SEP2018		
	2004	16JUL2018	Screen Failure	
	2005	29JUN2018	Screen Failure	
	2006	29JUN2018	Screen Failure	
	2007	05SEP2018		
	2008	05SEP2018		
	2009	14AUG2018	Non-Compliance With Study Procedures	Positive UDS
	2010	05SEP2018		
	2011	05SEP2018		
	2012	16JUL2018	Screen Failure	

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## Appendix 16.2.1.2 Subject Discontinuation

Site	Subject Number	Discontinuation Date	Reason For Discontinuation	Specify
002	2013	25JUL2018	Screen Failure	
	2014	05SEP2018		
	2015	05SEP2018		
	2016	10AUG2018	Non-Compliance With Study Procedures	Protocol Violation; Positive UDS
	2017	05SEP2018		
	2018	05SEP2018		
	2019	05JUL2018	Screen Failure	
	2020	05SEP2018		
	2021	05SEP2018		
	2022	02JUL2018	Screen Failure	
	2023	05SEP2018		
	2024	30JUL2018	Lost To Follow-Up	
	2025	05SEP2018		
	2026	10JUL2018	Screen Failure	
	2027	17JUL2018	Screen Failure	
	2028	05SEP2018		
	2029	12SEP2018		
	2030	01AUG2018	Screen Failure	
	2031	09JUL2018	Screen Failure	
	2032	01AUG2018	Screen Failure	
	2033	09JUL2018	Screen Failure	
	2034	17JUL2018	Screen Failure	
	2035	23JUL2018	Screen Failure	
	2036	18JUL2018	Screen Failure	
	2037	02AUG2018	Screen Failure	
	2038	23JUL2018	Screen Failure	
	2039	12SEP2018		
	2040	02AUG2018	Screen Failure	
	2041	13JUL2018	Screen Failure	
	2042	13JUL2018	Screen Failure	
	2043	23JUL2018	Screen Failure	
	2044	13JUL2018	Screen Failure	
	2045	16JUL2018	Screen Failure	
	2046	23JUL2018	Screen Failure	

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## Appendix 16.2.1.2 Subject Discontinuation

Site	Subject Number	Discontinuation Date	Reason For Discontinuation	Specify
002	2047	13JUL2018	Screen Failure	
	2048	06AUG2018	Screen Failure	
	2049	08AUG2018	Screen Failure	
	2050	27SEP2018		
	2051	24JUL2018	Screen Failure	
	2052	27SEP2018		
	2053	20JUL2018	Screen Failure	
	2054	20JUL2018	Screen Failure	
	2055	07AUG2018	Screen Failure	
	2056	20JUL2018	Screen Failure	
	2057	27SEP2018		
	2058	27SEP2018		
	2059	27SEP2018		
	2060	27SEP2018		
	2061	26JUL2018	Screen Failure	
	2062	26JUL2018	Screen Failure	
	2063	23JUL2018	Screen Failure	
	2064	27SEP2018		
	2065	24JUL2018	Screen Failure	
	2066	27SEP2018		
	2067	27SEP2018		
	2068	08AUG2018	Screen Failure	
	2069	10AUG2018	Screen Failure	
	2070	31JUL2018	Screen Failure	
	2071	31JUL2018	Screen Failure	
	2072	30JUL2018	Screen Failure	
	2073	30JUL2018	Screen Failure	
	2074	30JUL2018	Screen Failure	
	2075	22AUG2018	Non-Compliance With Study Procedures	Non Compliant With Study Product
	2076	21OCT2018		
	2077	12SEP2018	Screen Failure	
	2078	03AUG2018	Screen Failure	
	2079	03AUG2018	Screen Failure	
	2080	31AUG2018	Screen Failure	
	2081	03AUG2018	Screen Failure	

Note: Site: 001 = Lincoln, 002 = High Point, UDS = Urine Drug Screen

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## Appendix 16.2.1.2 Subject Discontinuation

Site	Subject Number	Discontinuation Date	Reason For Discontinuation	Specify
002	2082	03AUG2018	Screen Failure	Positive Drug Screen
	2083	18AUG2018	Screen Failure	
	2084	06AUG2018	Screen Failure	
	2085	03AUG2018	Screen Failure	
	2086	09OCT2018	Non-Compliance With Study Procedures	
	2087	03AUG2018	Screen Failure	
	2088	21OCT2018		
	2089	29AUG2018	Screen Failure	
	2090	10AUG2018	Screen Failure	
	2091	06AUG2018	Screen Failure	
	2092	21OCT2018		
	2093	07AUG2018	Screen Failure	
	2094	06AUG2018	Screen Failure	
	2095	19AUG2018	Screen Failure	
	2096	06AUG2018	Screen Failure	
	2097	06AUG2018	Screen Failure	
	2098	06AUG2018	Screen Failure	
	2099	21OCT2018		
	2100	21OCT2018		
	2101	17AUG2018	Screen Failure	
	2102	22AUG2018	Screen Failure	
	2103	10AUG2018	Screen Failure	
	2104	10AUG2018	Screen Failure	
	2105	31AUG2018	Screen Failure	
	2106	10AUG2018	Screen Failure	
	2107	31AUG2018	Screen Failure	
	2108	21OCT2018		
	2109	06SEP2018	Screen Failure	
	2110	27OCT2018		
	2111	13AUG2018	Screen Failure	
	2112	15AUG2018	Screen Failure	
	2113	22SEP2018	Lost To Follow-Up	
	2114	15AUG2018	Screen Failure	

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## Appendix 16.2.1.2 Subject Discontinuation

Site	Subject Number	Discontinuation Date	Reason For Discontinuation	Specify
002	2115	21SEP2018	Non-Compliance With Study Procedures	Positive Drug Test And Lack Of Compliance
	2116	17AUG2018	Screen Failure	
	2117	31AUG2018	Screen Failure	
	2118	01SEP2018	Screen Failure	
	2119	27OCT2018		
	2120	27OCT2018		
	2121	31AUG2018	Screen Failure	
	2122	27OCT2018		
	2123	13SEP2018	Screen Failure	
	2124	13SEP2018	Screen Failure	
	2125	27OCT2018		
	2126	27OCT2018		
	2127	21AUG2018	Screen Failure	
	2128	30AUG2018	Screen Failure	
	2129	25SEP2018	Screen Failure	
	2130	23AUG2018	Screen Failure	
	2131	29AUG2018	Screen Failure	
	2132	24AUG2018	Screen Failure	
	2133	24AUG2018	Screen Failure	
	2134	21SEP2018	Screen Failure	
	2135	29AUG2018	Screen Failure	
	2136	19OCT2018	Non-Compliance With Study Procedures	Positive Drug Screen
	2137	27AUG2018	Screen Failure	
	2138	25SEP2018	Screen Failure	
	2139	25SEP2018	Screen Failure	
	2140	13NOV2018		Allowed Roommates To Smoke Product
	2141	30AUG2018	Screen Failure	
	2142	08OCT2018	Non-Compliance With Study Procedures	
	2143	13NOV2018		
	2144	04SEP2018	Screen Failure	
	2145	04SEP2018	Screen Failure	

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## Appendix 16.2.1.2 Subject Discontinuation

Site	Subject Number	Discontinuation Date	Reason For Discontinuation	Specify
002	2146	04SEP2018	Screen Failure	
	2147	04SEP2018	Screen Failure	
	2148	04SEP2018	Screen Failure	
	2149	04SEP2018	Screen Failure	
	2150	05SEP2018	Screen Failure	
	2151	12SEP2018	Screen Failure	
	2152	18SEP2018	Screen Failure	
	2153	10SEP2018	Screen Failure	
	2154	14SEP2018	Screen Failure	
	2155	28SEP2018	Screen Failure	
	2156	20SEP2018	Screen Failure	
	2157	18SEP2018	Screen Failure	
	2158	17NOV2018	Lost To Follow-Up	
	2159	09DEC2018		
	2160	13OCT2018	Screen Failure	
	2161	24SEP2018	Screen Failure	
	2162	14OCT2018	Screen Failure	
	2163	26SEP2018	Screen Failure	
	2164	09DEC2018		
	2165	27SEP2018	Screen Failure	
	2166	27SEP2018	Screen Failure	
	2167	02OCT2018	Screen Failure	
	2168	09DEC2018		
	2169	20OCT2018	Other	Alternate; Not Needed
	2170	09DEC2018		
	2171	28SEP2018	Screen Failure	
	2172	01OCT2018	Screen Failure	
	2173	28SEP2018	Screen Failure	
	2174	01OCT2018	Screen Failure	
	2175	09DEC2018		
	2176	01OCT2018	Screen Failure	
	2177	01OCT2018	Screen Failure	
	2178	02OCT2018	Screen Failure	
	2179	04OCT2018	Screen Failure	
	2180	02OCT2018	Screen Failure	

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## Appendix 16.2.1.2 Subject Discontinuation

Site	Subject Number	Discontinuation Date	Reason For Discontinuation	Specify
002	2181	02OCT2018	Screen Failure	
	2182	02OCT2018	Screen Failure	
	2183	14OCT2018	Screen Failure	
	2184	11OCT2018	Screen Failure	
	2185	04OCT2018	Screen Failure	
	2186	04OCT2018	Screen Failure	
	2187	04OCT2018	Screen Failure	
	2188	04OCT2018	Screen Failure	
	2189	13NOV2018	Non-Compliance With Study Procedures	Did Not Show For End Of Week 2
	2190	29OCT2018	Screen Failure	
	2191	05OCT2018	Screen Failure	
	2192	05OCT2018	Screen Failure	
	2193	05OCT2018	Screen Failure	
	2194	05OCT2018	Screen Failure	
	2195	08OCT2018	Screen Failure	
	2196	07OCT2018	Screen Failure	
	2197	07OCT2018	Screen Failure	
	2198	07OCT2018	Screen Failure	
	2199	14OCT2018	Screen Failure	
	2200	14OCT2018	Screen Failure	
	2201	07OCT2018	Screen Failure	
	2202	14OCT2018	Screen Failure	
	2203	20OCT2018	Other	Alternate; Not Needed
	2204	09OCT2018	Screen Failure	
	2205	09OCT2018	Screen Failure	
	2206	09OCT2018	Screen Failure	
	2207	09OCT2018	Screen Failure	
	2208	11OCT2018	Screen Failure	
	2209	10OCT2018	Screen Failure	
	2210	20OCT2018	Screen Failure	
	2211	09DEC2018		
	2212	09DEC2018		
	2213	09DEC2018		

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## Appendix 16.2.1.2 Subject Discontinuation

Site	Subject Number	Discontinuation Date	Reason For Discontinuation	Specify
002	2214	20OCT2018	Other	Alternate; Not Needed
	2215	09DEC2018		
	2216	10OCT2018	Screen Failure	
	2217	11OCT2018	Screen Failure	
	2218	10OCT2018	Screen Failure	
	2219	11OCT2018	Screen Failure	
	2220	09DEC2018		
	2221	12OCT2018	Screen Failure	
	2222	11OCT2018	Screen Failure	
	2223	14OCT2018	Screen Failure	
	2224	20OCT2018	Other	Alternate;not Needed
	2225	11OCT2018	Screen Failure	
	2226	12OCT2018	Screen Failure	
	2227	26OCT2018	Screen Failure	
	2228	14OCT2018	Screen Failure	
	2229	29OCT2018	Screen Failure	
	2230	25OCT2018	Screen Failure	
	2231	18OCT2018	Screen Failure	
	2232	18OCT2018	Screen Failure	
	2233	18OCT2018	Screen Failure	
	2234	19OCT2018	Screen Failure	
	2235	23DEC2018		
	2236	28OCT2018	Screen Failure	
	2237	19OCT2018	Screen Failure	
	2238	23OCT2018	Screen Failure	
	2239	23OCT2018	Screen Failure	
	2240	25OCT2018	Screen Failure	
	2241	15NOV2018	Screen Failure	
	2242	24OCT2018	Screen Failure	
	2243	24OCT2018	Screen Failure	
	2244	23DEC2018		
	2245	28DEC2018	Screen Failure	
	2246	05NOV2018	Screen Failure	

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## Appendix 16.2.1.2 Subject Discontinuation

Site	Subject Number	Discontinuation Date	Reason For Discontinuation	Specify
002	2247	04JAN2019	Non-Compliance With Study Procedures	Did Not Complete Diary. Stopped Product And Was Smoking UB
	2248	06NOV2018	Screen Failure	
	2249	01DEC2018	Screen Failure	
	2250	08NOV2018	Screen Failure	
	2251	26JAN2019		
	2252	01DEC2018	Screen Failure	
	2253	20NOV2018	Screen Failure	
	2254	01DEC2018	Screen Failure	
	2255	13NOV2018	Screen Failure	
	2256	01DEC2018	Screen Failure	
	2257	28JAN2019		
	2258	06DEC2018	Screen Failure	
	2259	26JAN2019		
	2260	25NOV2018	Screen Failure	
	2261	01DEC2018	Screen Failure	
	2262	14NOV2018	Screen Failure	
	2263	06DEC2018	Screen Failure	
	2264	19NOV2018	Screen Failure	
	2265	19NOV2018	Screen Failure	
	2266	16NOV2018	Screen Failure	
	2267	19NOV2018	Screen Failure	
	2268	21NOV2018	Screen Failure	
	2269	26JAN2019		
	2270	27NOV2018	Screen Failure	
	2271	27NOV2018	Screen Failure	
	2272	26JAN2019		
	2273	03DEC2018	Screen Failure	
	2274	28DEC2018	Screen Failure	
	2275	09JAN2019	Study Terminated By Sponsor	

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## Appendix 16.2.1.2 Subject Discontinuation

Site	Subject Number	Discontinuation Date	Reason For Discontinuation	Specify
002	2276	09JAN2019	Study Terminated By Sponsor	
	2277	31DEC2018	Screen Failure	
	2278	04JAN2019	Screen Failure	
	2279	04JAN2019	Screen Failure	

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