

16.2.3 Subjects Excluded From the Analysis

The following subjects were included in the PP and/or ITT Population:

Subject Number	
PP Population (n=71)	ITT population (n=142)
1007, 1010, 1011, 1015, 1016, 1017, 1018, 1021, 1032, 1036, 1037, 1045, 1046, 1051, 1054, 1059, 1063, 1064, 1066, 1069, 1070, 1072, 1075, 1077, 1079, 1089, 1098, 1106, 1108, 1109, 1114, 1115, 2002, 2007, 2008, 2009, 2010, 2015, 2016, 2018, 2021, 2023, 2024, 2025, 2028, 2029, 2050, 2052, 2059, 2100, 2110, 2113, 2115, 2119, 2120, 2122, 2125, 2140, 2143, 2158, 2164, 2170, 2175, 2189, 2212, 2215, 2247, 2251, 2257, 2259	1001, 1002, 1003, 1007, 1008, 1010, 1011, 1013, 1014, 1015, 1016, 1017, 1018, 1019, 1020, 1021, 1023, 1029, 1032, 1034, 1035, 1036, 1037, 1038, 1042, 1045, 1046, 1050, 1051, 1052, 1053, 1054, 1055, 1056, 1058, 1059, 1060, 1063, 1064, 1066, 1069, 1070, 1071, 1072, 1074, 1075, 1077, 1078, 1079, 1082, 1083, 1084, 1086, 1088, 1089, 1092, 1094, 1095, 1096, 1097, 1098, 1099, 1100, 1101, 1103, 1105, 1106, 1107, 1108, 1109, 1112, 1114, 1115, 2002, 2003, 2007, 2008, 2009, 2010, 2011, 2014, 2015, 2016, 2017, 2018, 2020, 2021, 2023, 2024, 2025, 2028, 2029, 2039, 2050, 2052, 2057, 2058, 2059, 2060, 2064, 2066, 2067, 2075, 2076, 2086, 2088, 2092, 2099, 2100, 2108, 2110, 2113, 2115, 2119, 2120, 2122, 2125, 2126, 2136, 2140, 2142, 2143, 2158, 2159, 2164, 2168, 2170, 2175, 2189, 2211, 2212, 2213, 2215, 2220, 2235, 2244, 2247, 2251, 2257, 2259, 2269, 2272

In addition, the following subjects were partially excluded from their respective population analyses:

Subject	Analysis	Excluded Data	Reason
1008	Urine	Week 6	The pooling jugs were discarded in error.
1010	Urine	Week 6	The pooling jugs were discarded in error.
1011	Urine	Week 6	The pooling jugs were discarded in error.
1013	Urine	Week 2	Subject 1013's urine was pooled into subject 1014's 24-hour pooling container in error
1014	Urine	Week 2	Subject 1013's urine was pooled into subject 1014's 24-hour pooling container in error
1018	All	Weeks 2 and 6	Subject dropped at end of Week 2 due to an AE (Week 2 available product use data included)
1021	Urine	Week -1	Subject's urine was spilled in error on Week -1

Subject	Analysis	Excluded Data	Reason
1038	Topography	Week 2	This subject smoked two cigarettes using the topography device during the topography session. Upon completion of this event the topography data from the first cigarette smoked was able to be retrieved from the topography device however there was no data available for the second cigarette
1071	All	Week 6	Subject did not check in on Week 6 due to back surgery
1072	Urine, blood, topography, questionnaires	Week 6	Subject withdrew on Week 6 due to personal reasons (Available product use data included)
1078	Topography	Week 2	Subject's Sodim device was started after the administration of the first cigarette during ad libitum conditions in error
1084	All	Week 6	Subject was dropped on Week 4 (Day 28) due to a positive urine drug screen (UDS)
1095	Urine	Week 2	Subject spilled urine collection container
1099	Urine	Week -1	Subject voided urine into the toilet on Week-1
1115	Urine, blood, questionnaires	Week 6	Subject withdrew on Week 6 due to personal reasons (Available product use data included)
2009	All	Week 6	Subject was dropped on Week 4 due to a positive UDS
2016	Urine, blood, questionnaires	Weeks 2 and 6	Subject was dropped on Week 3 due to a positive UDS (Week 2 available product use data excluded)
2024	Urine, blood, questionnaires	Weeks 2 and 6	Subjects was lost to follow-up after Week 2 (Week 2 product use data available)
2075	All	Weeks 2 and 6	Subject was dropped on Week 2 (Day 14) due to lack of compliance with study product (Week 2 available product use data excluded)
2086	All	Week 6	Subject was dropped on Week 4 due to a positive UDS
2113	All	Week 6	Subject 2113 was lost to follow-up after Week 2
2115	Urine, blood, questionnaires	Weeks 2 and 6	Subject was dropped on Week 2 (Day 14) due to a positive UDS and non-compliance to study procedures (Week 2 product use data available)
2136	Urine, blood	Week 6	Subject was dropped on Week 6 due to a positive UDS (Available product use data excluded)
2142	All	Weeks 2 and 6	Subject was dropped on Week 2 because they allowed their roommate to smoke the product (Week 2 available product use data excluded)

Subject	Analysis	Excluded Data	Reason
2158	Urine, blood, questionnaires	Week 6	Subject was lost to follow-up after Week 2
2168	Urine	Week 6	Subject 2170 had a 24-hour urine void placed in the collection container for Subject 2168
2170	Urine	Week 6	Subject 2170 had a 24-hour urine void placed in the collection container for Subject 2168
2189	Urine, blood, questionnaires	Weeks 2 and 6	Subject was discontinued as they failed to show at the end of Week 2 (Week 2 product use data available)
2247	All	Week 6	Subject was dropped after Week 4 as they did not complete their diary, stopped the product, and were smoking their UB