7.1 Executive Summary: Product Characterization studies

The reports provided in this section are composed of data generated to meet regulatory and internal requirements for product characterization. This consists of both aerosol and physical characterization of the product. The following product analyses were performed:

Droplet Size Distribution

The Droplet Size Distribution (DSD) is a measurement to assess whether an aerosol is in the respirable range. This assay is used to determine the DSD of the aerosol generated from the THS product, and to ensure a DSD in the respirable range.

Characterization of Tobacco and Tobacco Smoke

The THS aerosol was analyzed, using ISO and Health Canada Intense smoking regimes, to determine the levels of 18 Harmful and Potentially Harmful Constituents identified in the FDA abbreviated list of HPHCs in cigarette smoke. The THS tobacco was analyzed to determine the levels of 6 HPHCs identified on the FDA abbreviated list for cigarette filler.

Comparison to Combustible Reference Product

There are 58 analytes (PMI-58) assessed to characterize the THS aerosol. This analysis is used for interpretation of the reduction of HPHCs versus reference products. PMI-58 are comprised of the main aerosol deliveries and a set of 54 Harmful or Potentially Harmful Constituents (HPHCs). Selection is based upon measured ISO standards in smoke, priority toxicants in smoke according to numerous regulatory agencies, constituents with established biomarkers of exposure and product specific analytes. Further details on the constituents measured and the rationales can be found in Appendix A3.2.1-12.

Determination of ISO Parameters Under ISO Smoking Regime

ISO standards prescribe methods for the quantification of certain analytes and constituents in conventional cigarette smoke, such as nicotine, carbon monoxide (CO) and nicotine-free dry particulate matter (NFDPM). These tests were performed on the mainstream aerosol of THS.

The list of studies is provided in 7.1 TabIndex_Product Char.

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