Measurements of Aerosol Size Distribution and Particle Number Concentration from a Novel Heated Tobacco Capsule (HTC) Prototype

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Abstract

Heated Tobacco Products (HTP) contain a tobacco substrate that is heated to low temperatures (below 350°C), resulting in an inhalable nicotine-containing aerosol. For HTP, test data on aerosol design parameters, such as count medium diameter and particle number concentration are required for regulatory submissions as per the Premarket Tobacco Product Applications and Recordkeeping Requirements Final Rule issued by the Food and Drug Administration in 2021. Currently, there is no defined standardized methodology for HTP aerosol characterization. The objectives of this work are 1) to present the measurement methodology we developed, and 2) to compare the results from the analysis of a novel heated tobacco capsule (HTC) prototype to those from the analysis of other HTPs. The HTC prototype consists of a hand-held battery-operated device (BVR 3.2) and a disposable tobacco-containing capsule that is inserted into the device. HTP aerosol was generated under an intense puffing regime (ISO 27088, 55 cc puff volume, 2 s puff duration, 30 s puff interval, and bell-shaped puff profile). Due to the high concentration of HTP aerosol, two dilution systems were designed. A scanning mobility particle sizer was used downstream to measure the count medium diameter, while a condensation particle counter was used as the detector for measuring the particle number concentration. The results show the aerosols from different HTPs have count medium diameters in the range of 100 to 200 nm; and particle number concentrations around 10^9 particles/cm^3. Additionally, we developed a low-flow cascade impactor method coupled with a pressure-feedback loop interface for aerosol size measurement. The impactor sampling system was designed to control humidity to minimize aerosol evaporation.

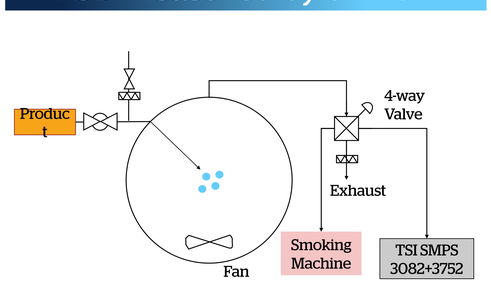
Objective

- Develop methodologies to determine aerosol count median diameter (CMD) and aerosol particle number concentration (PNC) in aerosol emissions generated from Heated Tobacco Products (HTPs) using a novel heated tobacco capsule (HTC) prototype and comparator HTPs that use heated tobacco sticks (HTS).
- Compare the measurement results with different methodologies.

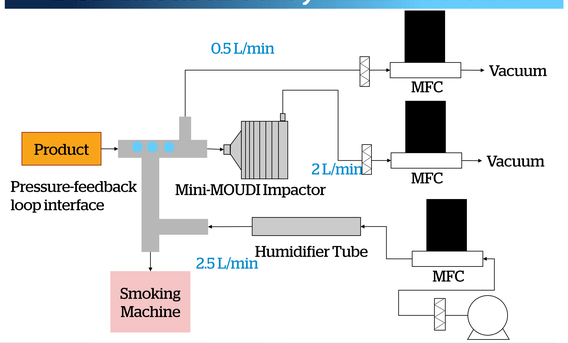
Method Principle

Aerosol emissions from HTPs are generated under an intense puffing regime (ISO 20778) which is a 2 s bell-shaped puff profile with a 55 ml puff volume giving one puff every 30 seconds. Particle size distribution (PSD) was measured using a scanning mobility particle sizer (SMPS) and a Mini-MOUDI Impactor. To avoid saturation of the detector due to the highly concentrated HTP aerosol, HTP aerosol was diluted in a ball chamber at a dilution factor of 430 and then introduced to SMPS to determine CMD. On the other hand, a pressure-feedback loop interface[1] has been developed in tandem with a low-flow Mini-MOUDI impactor to minimize the dilution ratio at 1.2 and to allow bell-shaped puffing from products. Mass mean aerodynamic diameter (MMAD) was measured and calculated using the Probit method[2]. CMD was estimated from MMAD using the Hatch-Choate equation. Furthermore, a new dilution system has been developed in tandem with a condensation particle counter (CPC) to provide puff-by-puff number concentrations.

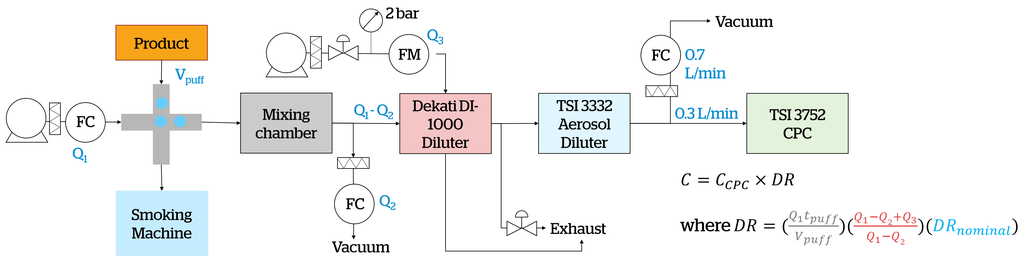
PSD Measured by SMPS



PSD Measured by Mini-MOUDI



PNC Measured by CPC with a Dilution System

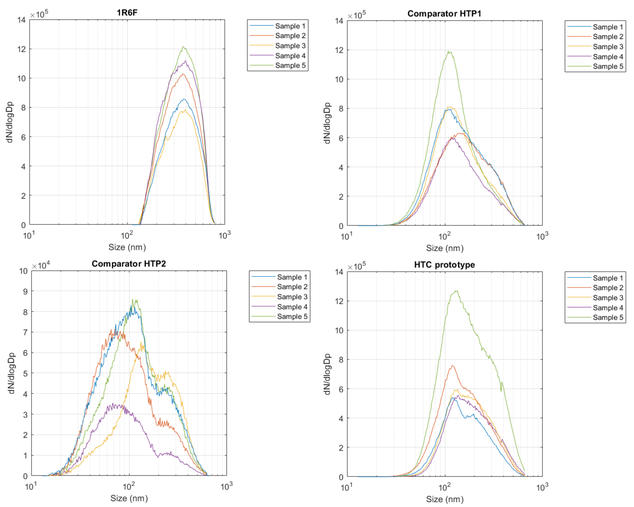


$$C = C_{CPC} \times DR$$

where $DR = \left(\frac{Q_1 t_{puff}}{V_{puff}}\right)\left(\frac{Q_1 - Q_2 + Q_3}{Q_1 - Q_2}\right)(DR_{nominal})$

Methods have been developed to quantitate the count median diameter (CMD) and particle number concentration (PNC) of aerosols generated from HTPs.

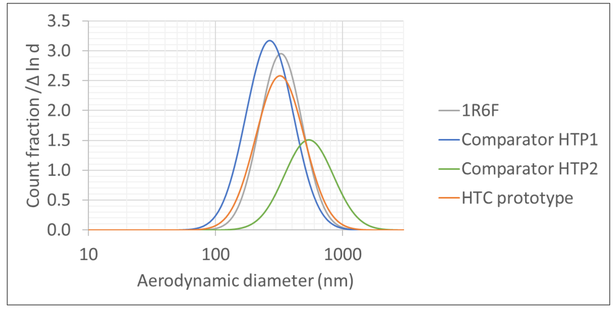
Results* – PSD Measured by SMPS



*All HTP Comparator products tested use heated tobacco sticks (HTS).

At high dilution ratios, SMPS measurements indicate that the CMDs for HTPs are smaller than CMD of 1R6F.

Results* – PSD Measured by Mini-MOUDI



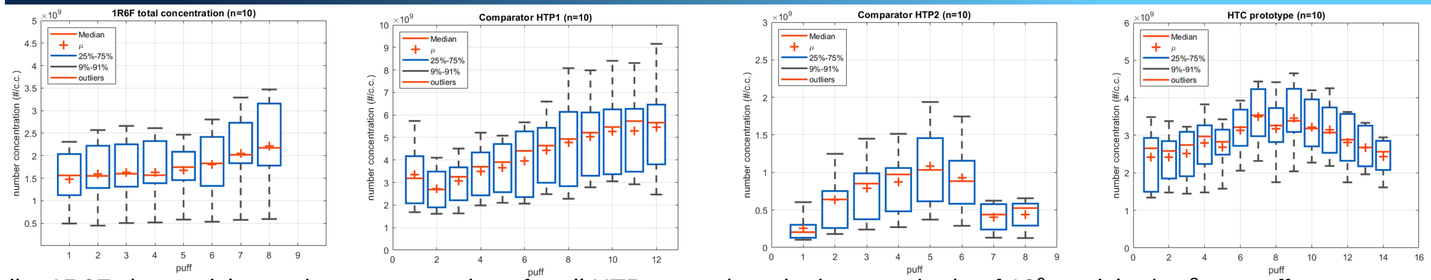
Comparison of Two PSD Methods

Methods		1R6F	Comparator HTP1	Comparator HTP2	HTC Prototype
SMPS	CMD (nm)	348	134	107	162
	GSD*	1.45	1.75	1.95	1.69
Mini-MOUDI	CMD (nm)	380	320	660	390
	GSD	1.47	1.54	1.56	1.55

Results of Low flow impactor measurements with minimum dilution show that the HTC prototype's CMD is similar to the CMD of 1R6F.

*GSD stands for geometric standard deviation

Results* – PNC Measurements



Like 1R6F, the particle number concentrations for all HTPs tested are in the magnitude of 10^9 particles/cm^3 per puff.

*All HTP Comparator products tested use heated tobacco sticks (HTS).

Conclusions

- Two methods have been developed to measure CMD for HTPs. We recommend the low-flow impactor method, as dilution with the SMPS method can lead to a biased impact on HTP measurements due to the high water content in HTP aerosols compared to cigarette smoke.
- A puff-by-puff measurement system has been developed to measure the PNC of cigarette smoke and aerosols generated from HTPs.

References

1. Nadarassan, D. K., Assi, K. H., & Chrystyn, H. (2010). Aerodynamic characteristics of a dry powder inhaler at low inhalation flows using a mixing inlet with an Andersen Cascade Impactor. *Eur J Pharm Sci*, 39(5), 348-354.
2. Oldham, M. J., Zhang, J., Rusyniak, M. J., Kane, D. B., & Gardner, W. P. (2018). Particle size distribution of selected electronic nicotine delivery system products. *Food Chem Toxicol*, 113, 236-240.

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