Assessment of Fugitive Aerosol Emission During Actuation of a Breath-actuated Mesh Nebuliser

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Introduction

- Fugitive aerosol involves two major aspects, the aerosol that is exhaled by a patient receiving inhalation treatment and the aerosol that is directly release into the environment before reaching the respiratory airways.
- It has been reported that up to half of the aerosol generated by continuous mode nebulisers may escape through the orifices of the device, these being on the mask, mouthpiece, or the reservoir's ventholes.
- In order to mitigate fugitive aerosol emission, the addition of several solutions has been implemented, such as the incorporation of filters and face masks with a scavenger that could successfully reduce fugitive aerosol.
- Breath actuation has arisen as an approach to inhibit fugitive aerosol emission. It relies on a mechanism that allows the generation of aerosol during a period of the inhalation phase only.
- In this study, the smart breath-actuated mesh nebuliser, AdheResp® (Figure 1), was used to assess fugitive aerosol emission. A breath simulator was employed to quantitate the delivered dose under three different setups, nebulising the bronchodilator terbutaline sulphate.

Figure 1. AdheResp® Vibrating Mesh Nebuliser

Method

Fugitive Aerosol Emission Assessment

- **Device:** Standard AdheResp® Breath-actuated Mesh Nebuliser (HCmed Innovations Co. Ltd., Taiwan).
- **Formulation:** 2mL terbutaline sulphate (Bricanyl Respules®; 2.5 mg/mL; AstraZeneca, UK).
- **Equipment Set Up for Fugitive Aerosol Assessment:**

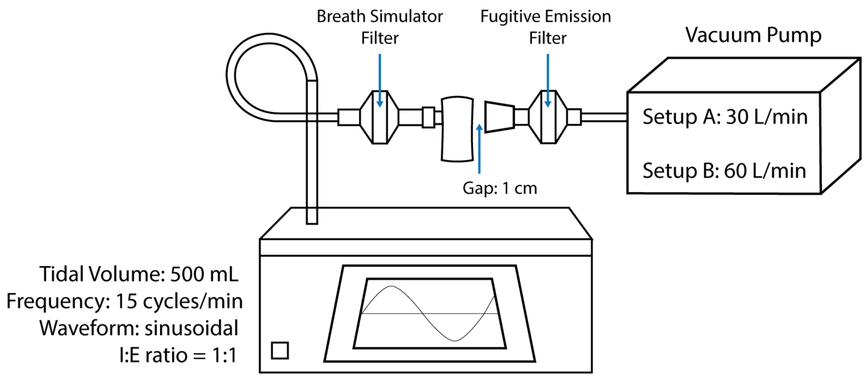

Figure 2. Equipment configuration for Setups A and B

- A breath simulator (BRS 200i, Copley Scientific, UK), operating according to the configuration described in the USP <1601> for the adult breathing pattern (volume: 500 mL; frequency: 15 cycles/min; waveform: sinusoidal; I:E = 1:1).
- A vacuum pump connected to a filter holder and an adaptor in proximity to the ventholes of the nebuliser with a gap of 1 cm between the adaptor and the nebuliser. The pump was either off or operated under two setups: 30 and 60 L/min (Figure 2).
- API was collected from the breath simulator filter, reservoir, vacuum pump filter, and adaptor. Fugitive aerosol emission was calculated as the addition of API in the vacuum pump filter and adaptor.

- **Quantification:**
  - 0.9% saline was used to rinse and extract API, which was quantified with a UV-Vis spectrometer (Lambda 365, Perkin Elmer, US) at wavelength 276 mm.
- **Aerosol Characterisation:**
  - Aerosol characterisation values (DV10, DV50, DV90, FPF, GSD) were assessed with a laser diffraction particle size analyser (Spraytec; Malvern, UK).

Results

Fugitive Aerosol Assessment (Table 1)

- The control group served as a base to understand the influence of the vacuum pump for collection of fugitive aerosol.
- Mean percentage of fugitive aerosol under Setup A and B was 2.1% and 1.7%, respectively.
- Total recovered API from the 3 groups was between 102.6% and 107.6% of the labelled dose.

Aerosol Characterisation (Table 2)

- The aerosol characterisation values obtained from the laser diffraction particle size analyser were collected for the control group only. It was assumed that the elements to collect fugitive aerosol would not influence the performance.

Table 1. Data collected from breath simulation study (n=3)

Equipment Setup	Measures	Treatment Time (m:s)	Delivered Dose (µg)	Residue (µg)	Fugitive Aerosol (µg)	API Recovery (%)
Control	Mean	11:18	4022	1136	NA	103.2
	SD	00:09	34	193	NA	3.9
Setup A	Mean	11:11	3987	1280	111	107.6
	SD	00:12	168	149	19	2.0
Setup B	Mean	11:36	3804	1236	87	102.6
	SD	00:18	133	283	9	5.1

Table 2. Aerosol characterisation conducted with laser diffraction particle size analyser (n=3)

Measures	DV10 (µm)	DV50 (µm)	DV90 (µm)	FPF (%)	GSD
Mean	2.00	4.54	9.18	56.38	1.76
SD	0.02	0.08	0.20	1.24	0.01

Discussion

- The results demonstrated that the breath-actuated function could keep the emission of fugitive aerosol as low as 1.6% of the loaded dose.
- For the setup A, the recorded delivered dose and residue provided a firm correlation for comparison to the control setup, supporting the findings about fugitive aerosol.
- It is hypothesised that a combination of the variations in loaded dose and a higher suction rate influenced the aerosol movement towards the fugitive emission filter and API recovery.
- Aerosol characterisation showed a DV50 value of 4.54 µm, which falls within the respirable range, indicating a theoretically higher and deeper lung deposition with a GSD of 1.76.

Conclusion

- The incorporation of breath actuation in newly developed nebuliser has introduced an important tool to achieve reduction of fugitive aerosol emission.
- This study demonstrated that fugitive aerosol could be reduced to below 2.1%, when the it is expected to be around 50% with continuous output mode nebulisers.

References

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