Fraunhofer Institute
Toxicology and
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Pharmaceutical Research
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More measurements on the aerosol release from a PROP.SET® Inhalator

Manufacturer's note: Trade name: salivent® AEROSOL INHALATOR

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Introduction

The function of inhalators depends on both the aerosol mass concentration and the aerosol particle size distribution. The latter determines where the aerosol is deposited. While very large particles are preferably deposited in the nose-pharynx, smaller particles reach the trachea-bronchial tract while the smallest ones can infiltrate into the alveoli.

We had already done studies in January 1997 to determine the droplet mass size distribution and their concentration [1]. The quantity of aerosol emission was identified as needing improvement. In the meantime, modifications have been made on the suction tube and the sponge and this report characterises the now current device.

Test record

For reasons of comparison with the previous study, the same measurement technology was used. This is why collection was done size-resolved using a Berner impactor again because the size of the aerosol particles determines their availability to the lungs and deposition site. The separating sizes of this impactor are at 0.065, 0.125, 0.25, 0.5, 1, 2, 4, 8 and 16 µm. With the analysis of the mass size distribution, the mass media diameter d50 and the geometric standard deviation σ_g is determined. They determine the mean diameter and the width of the distribution.

Due to the design, the most aerosol is created immediately after the use of the air flow because the fluid film in the sponge cavities is torn by the air flow. When this happens, the production rate goes down greatly. If the air flow is interrupted, as the patient does for physiological reasons, the sponge soaks itself full again and the initial situation is restored. The inhalation by the patient was reproduced by a simulated breathing sequence (and the exhalation by a pausing of the volume flow).

A greater benefit of the device lies in the fact that it can be operated without a power source. For comparison, the measurements were not only done at higher temperature (45ºC), but also at room temperature.

The trial preparation was done as follows: After cleaning the inhalator, the sponge was moistened in normal water and then squeezed out. Then 3g salt was dissolved in 20 ml water, the over-saturated solution was drizzled over the sponge and the sponge was placed on the intake pipe. Finally, the device was screwed together.

The volume flow through (heated or unheated) the inhalator and impactor was 28.75 litre per minute in every case and it was either aspirated continually or via a clock generator in a specified cycle/pause ratio. In all cases, the aerosol was supplied to the impactor using a heated graphite tube which reliably evaporated the remaining droplets allowing for an objective determination of the salt particle size.

Results

Trial 1 was done under continual operation with an unheated inhalator;
91 µg resulted from a total of 1 m³ distributed salt quantity. The repetition of the trials 2 and 2a with a total volume of 3.45 m³ each resulted in a distributed salt quantity of 87 µg and 103 µg: Apparently the inhalator dried out rather quickly during continual operation and did not produce any more particles.

The next series of trials were to gather (also during continual operation) information on the relationship from inhalable to respirable aerosol. For this purpose the preliminary stage using the impactor was also evaluated at which particles >16 µm were collected. While without this, 303 µg and 402 µg respectively were collected in the trials 3 and 4, with the preliminary steps in the trials 3a and 4a were 11950 µg and 5,200 µg respectively collected. Taking the error propagation in quotients of random variables, the following results

$$\frac{d<16}{d>16} = 0.041 +/- 0.024.$$

Trials 5 to 8 were done at room temperature (25°C) and timed volume flow (Tab. 1)

Trial	Cycle/pause	Total mass (µg)	Cycles	Mg/cycle
5	12/33	48	80	0.60
6	12/33	129	147	0.88
7	5/35	204	180	1.13
8	25/35	68	90	0.76

Tab.1: Timed test at room temperature

The distribution is fairly large and a clear dependence on the cycle time cannot be detected. The average and standard deviation are at 0.84 µg/cycle or at 0.22 µg/cycle at room temperature measurements.

In contrast, at an inhalator temperature of 45ºC, the following values resulted (Tab.2.):

Trial	Cycle/pause	Total mass (µg)	Cycles	Mg/cycle
9	12/33	103	133	0.77
10	12/33	78	113	0.69
11	12/33	148	187	0.79
12	6/33	65	323	0.20
13	6/33	65	185	0.35

Tab.2: Timed test with heated inhalator

Average and standard deviation are at 0.56µg/cycle or at 0.27µg/cycle and there is a significant difference to the room temperature values.

If the mass emission of all values of the timed experiments are averaged, an average value of 0.69 µg/cycle with a standard deviation of 0.28µg/cycle results for the respiratory fine fraction is given. If you apply this mass emission to the tidal volume of 1 litre [2], there is a therapy-relevant respiratory concentration of 690 µg/m³.

Summary

The salivent® device creates a respirable fine aerosol with a mass median between 1 and 2 µm. With intermittent use as well as the inhalation done, the dispersion is more effective and there was an average therapy-relevant respirable saline concentration of 690 µg/m³.

Literature

[1] Holländer, W. & P. Langer; Aerosolfreisetzung aus einem PROP.SET® Inhalator [Aerosol release from a PROP.SET® Inhalator]; January 1997

[2] Lotz, P.; E. Siegel & D. Spilker; Grundbegriffe der Beatmung [Basic terms for breathing]; GIT Verlag, Darmstadt, 1984