A SIMPLE IMPINGER DEVICE FOR RAPID QUALITY CONTROL OF THE PARTICLE SIZE OF INHALATION AEROSOLS DELIVERED BY PRESSURISED AEROSOLS AND POWDER INHALERS

G.W. Hallworth, D. Clough, T. Newnham and U.G. Andrews, Allen & Hanburys Research Limited, Priory Street, Ware, Hertfordshire, SG12 ODJ

Most of the methods described for particle sizing of inhalation aerosols require complex equipment and/or considerable operation time, (Bell, 1967; Bell and others, 1971; Hallworth and others, 1976 a and b.) For routine assessment of inhalation aerosols for quality control and stability testing purposes, we required a simple but reproducible device for measuring the fine particle (pulmonary) aerosol fraction from either metered pressurised aerosols or powder inhalers. The four-stage Multistage Liquid Impinger (M.L.I.) (see above refs.) has proved useful but necessitates collection of deposited drug from the various chambers and the device is delicate, complex in construction and difficult to reproduce accurately. Our aim was to develop a simple two-stage device collecting two aerosol fractions, a) a coarse particle fraction to simulate the combined deposition in the throat, stages one and two of the M.L.I. and b) a fine fraction to simulate that in stages three and four of the M.L.I. The upper stage is an inlet throat leading to an impingement chamber, with a 1.40cm round jet spaced 0.70cm from a wet glass paper 6cm disc. The lower 'total trap' stage is a liquid swirl impinger, simpler in construction and use than a large membrane filter. The high airflow (60 litre min^{-1}) needed for powder inhalers is achieved at a moderate vacuum (15cm mercury) with twin 0.216cm jets drilled in a nylon block to simplify jet accuracy and correct angling. To simplify assembly, cleaning and drug collection, glass units are used linked by quickfit type joints.

Calibration with methylene blue spheres of known size and density, generated by a spinning disc (O'Connor, 1973), showed the upper stage has a mean cut-off size ($d_{50\%}$) of 6.4µm for unit density spheres, with a satisfactorily steep cut-off curve. Few particles over 10µm can penetrate to the lower stage. The latter is an efficient fine particle trap, with a $d_{50\%}$ below 1µm; it is efficient in retaining finely dispersed salbutamol aerosols. Reproducibility between five models was confirmed with a polydispersed methylene blue suspension type pressurised aerosol. The mean dye deposition in the lower stage was 32.7% and an SD of 0.805%.

Good correlation with the M.L.I. and satisfactory use by various operators has been demonstrated with pressurised aerosols and powder inhalation cartridges of salbutamol and other drugs. The device is suitable for stability testing and quality control.

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