ABSTRACT:

Clinically Appropriate Methods for Performance Testing of Orally Inhaled Products (OIPs)

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Although the compendial methods describe robust techniques for the determination of unit dose uniformity and particle size distribution of aerosols from medical inhalers, there are other factors that need to be considered if the intention is to go further than assess product quality to bridge the gap between the laboratory and the clinic. This presentation begins by asking the fundamental question: What is the purpose of the measurements that are being made? Beyond quality control, the closer realization of clinically relevant testing methods is a highly desirable goal, if the intent is to derive information in support of clinical batches or to develop a deeper understanding of possible *in vitro-in vivo* correlations (IVIVCs) for a given medication and inhaler class (pMDI, DPI etc.) as well as to serve patient needs better. The presentation then looks at the following aspects involving:

(1) the selection of anatomically correct or idealized inlet (throat) as entry to a cascade impactor used for determining aerodynamic particle size distribution (APSD) as a measure of the potential for lung deposition;
(2) the use of breathing simulation as the normative approach for evaluating total delivered dose;
(3) the use of breathing simulation in conjunction with the cascade impactor for APSD determinations
(4) the simulation of delayed inhalation when testing valved holding chambers used with pressurized metered dose inhalers;
(5) testing of the patient interface (mouthpiece or facemask) appropriately;
(6) simulation of aerosol medication delivery to the mechanically ventilated patient.

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