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 six key aspects involving: (1) simulation of delayed inhalation when testing valved holding chambers used with pressurized metered dose inhalers; (2) the advantages of replacing the compendial right-angle bend induction port with either an age-appropriate anatomically correct or idealized inlet; (3) the use of breathing simulation as the normative approach for evaluating total delivered dose; (4) breathing simulation in conjunction with the cascade impactor for aerodynamic particle size distribution determinations; (5) testing the patient interface (mouthpiece or facemask) appropriately; (6) simulation of aerosol medication delivery to the mechanically ventilated patient.

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