ABSTRACT

Roles of Pharmacopeial Methods, Standards and Regulatory Guidance in Orally Inhaled and Nasal Drug Product (OINDP) Assessments

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The need for standardized testing procedures for OINDP is recognized widely by the stakeholders upstream of the prescribing clinician as the most effective way to assure safety and efficacy of these products when used in accordance with manufacturer instructions. This presentation begins by looking at the regulatory science associated with the laboratory assessment of OINDP products, before identifying key regulatory guidance documents from the FDA, EMA and Health Canada. The presentation then examines the international standard (ISO) forum, paying particular attention to two standards pertinent to OINDP development. ISO-20072:2009 and ISO-27427:2013 that cover OINDP development (excluding nebulizing systems) and the *in vitro* performance evaluation of nebulizers respectively. The role of the United States (USP) and European (PhEur) pharmacopeias in helping assure OINDP product quality is examined. This part of the presentation focuses primarily on the USP, examining the information provided in the most relevant normative chapters: <5> 'General information and producer quality tests'; and <601> 'Inhalation and nasal drug products: Aerosols sprays and powders – performance tests for content uniformity and aerosol aerodynamic particle size distribution (APSD). The role of informative chapters in the greater than 1000 series is also discussed, focusing upon chapter <1601> 'Products/preparations for nebulization' and recently official chapter <1602> 'The evaluation of spacers and valved holding chambers for use with pressurized metered dose inhalers'. The recently introduced monographs covering some GSK inhaler products is mentioned before moving on to discuss likely future directions for the inhaler-related chapters in the pharmacopeias, including the prospects for informative chapters on APSD data analysis and good cascade impactor practice (GCIP). The presentation concludes by looking briefly at the relevant content of the PhEur, focusing on identifying pertinent monographs (chapters) and where there is divergence from the approaches in the USP.

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