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Assessment of bioequivalence of respiratory dosage forms

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Statement of the Problem: Respiratory dosage forms are at the forefront of asthma and chronic obstructive pulmonary disease treatments, two diseases that afflict worldwide populations. The global sales data estimates for asthma is approximately $15.9 billion. The US itself contributes 64% of the sales mainly due to much higher prices and lack of generic inhalers in the market. Introduction of generics is essential as pricing is barrier to patient care. However, regulatory approvals of these products by different agencies are demanding and are not harmonized.

Methodology & Theoretical Orientation: Current topic will cover US and EU requirement of bioequivalence and *in-vitro* performance studies and understanding various study designs and challenges. Presentation will also cover current practice and precautions to be taken during the conduct of bioequivalence studies.

Conclusion & Significance: This presentation will critically review requirement and present future directions for clinicians, scientists, and regulators to consider optimizing the development and approval of drug products for respiratory dosage forms.

Biography

Ashish Mungantiwar is a Pharmacologist by profession. He is working as President Medical Services in Macleods Pharmaceuticals Limited. He heads various departments like Bioequivalence, Clinical trial and Pharmacovigilance. As Head of Bioequivalence he has served as Study Director for more than 2000 bioequivalence studies. He has successfully handled more than 25 regulatory inspections from USFDA, WHO, EU and ANVISA. He has attended meeting with regulators of WHO and EU during approval process of the product. His passion for respiratory drug is seen from the fact that he has been awarded patent on device of dry powder inhaler. In order to keep his academic temperament alive, he works as PhD guide in industry and has already guided five PhD students. He is invited speaker in various international conferences.

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