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Biosimilars: Comparative evaluation of Regulatory requirements of selected countries

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Abstract

In recent few years, there are many classic Biological products are going off patent which has generated an abridged route for the Biosimilars products which relies on the extensive comparability testing against Reference Biological Products (RBP). A biosimilar demonstrates similarity to the reference biotherapeutics product in terms of quality, safety and efficacy. Biosimilars are product similar to biologics but not identical. The generic approach (demonstration of bioequivalence with a reference medicinal product by appropriate BABE studies) which used for most small molecule drugs is in principle not appropriate to biological/biotechnology derived products due to their complexity. For approval of a biosimilar product, guidelines in various countries provide abbreviated approval pathway involving step-wise comparability exercise of a biosimilar with reference biological product which requires the generation of comparative analytical, non-clinical and clinical data. Analytical and non-clinical data requirement are similar across countries. Since local participation is required in all countries, so Phase III trial should be global and multi-centric. There is a need to develop a robust post-marketing surveillance plan to allay safety/immunogenicity concerns promising therapeutic approach for liver fibrosis.

Biography:

Dr. Priti Mehta, Professor of Pharmaceutical Analysis at Institute of Pharmacy, Nirma University, has more than 20 years of teaching, Research and industrial experience. She is pioneer in getting interdisciplinary research grants at Nirma University. Currently Dr Mehta is working on many government funded research projects worth of more than 10 million She is mentor of Women Scientist under WOS-A scheme of DST.

Speaker Publications:

1. "Raw Data Management and Data Integrity in Pharmaceutical Product development"; 2020.
2. "Bamboo a Supplement to Human Health: A Comprehensive Review on its Ethnopharmacology, Phytochemistry, and Pharmacological activity"; 2020.
3. "Knowledged -aided assessment & structured application (KASA): US-FDA's new initiative evolution of submission"; 2019.
4. "Correction to: Stability Indicating RP-HPLC Method Development and Validation for Simultaneous Quantification of 15 Organic Impurities of Olmesartan Medoxomil, Amlodipine and Hydrochlorothiazide in Combined Dosage Form"; 2019; Chromatographia: Vol 82(9).
5. "Simulated space radiation: Investigating ionizing radiation effects on the stability of amlodipine besylate API and tablets"; European Journal of Pharmaceutical Sciences; 2012, Vol 5137:104982.

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