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Analytical biosimilarity: Strategies and challenges

Shalini Sharma
Intas Pharmaceuticals Ltd., India

Unlike small molecules, biological medicinal products are complex in nature. Despite the guidance from regulatory agencies like EMA and US-FDA, establishing analytical biosimilarity of a biological product with the reference product remains a challenge for analytical scientists, owing to the complex nature of biological medicinal products. Analytical similarity has gained more importance in recent years, since the analytical characterization data-package directly impacts the extent of clinical studies required to establish biosimilarity. The recent US-FDA draft guidance on establishing biosimilarity states the impact of the outcome of analytical similarity studies on biosimilar product development programme, wherein, based on the analytical biosimilarity results, the biosimilar product under development can be categorized as non-similar, similar, highly-similar and highly-similar with fingerprint like similarity. It further states that "The outcome of the comparative analytical characterization should inform the next steps in the demonstration of biosimilarity". Considering these facts, demonstration of analytical biosimilarity becomes one of the most important aspects of biosimilar product development. An accurate and reliable analytical biosimilarity evaluation requires not only state-of-the art methods, but also an in-depth assessment of capability of analytical methodologies to detect minor differences between the biosimilar product and reference product. Employing methods like LC-MS, peptide-mass fingerprinting, circular dichroism, differential scanning calorimetry is imperative for structural evaluation during biosimilarity demonstration. Comparison of product related impurities in biosimilar product with the reference product can be particularly challenging, and needs to be evaluated using routine methods like reverse phase chromatography, SDS-PAGE etc, along with orthogonal high-end techniques like Analytical ultracentrifugation, SEC-MALS, CE-SDS etc. Identifying these impurities through LC-MS analysis, and comparing stability behaviors of both the products is also equally important. Choosing a set of right and useful analytical techniques is the key to successful demonstration of analytical biosimilarity, which can sufficiently support an abridged clinical trial, thus decreasing the cost of biosimilar development.

Biography

Shalini Sharma is microbiology Postgraduate from Maharaja Sayajirao University (MSU), Baroda. She is a Principal Scientist in Analytical Development Lab (Global Development) with the Biotech division of Intas Pharmaceuticals Ltd., and has more than 10 years of experience in the field of analytical method development and validation for biological drug products, which includes liquid chromatography methods, electrophoresis, ELISA and LC-MS. She has played key role in developing analytical methodologies and strategies, for establishing biosimilarity for EU and US registrations.

shalini_sharma@intaspharma.com