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The evaluation of biosimilarity index based on reproducibility probability for assessing biosimilars

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Abstract

When an innovative biological drug product is going off patent, biopharmaceutical companies may file an application for regulatory approval of biosimilar products. Unlike small molecule drug products, biosimilars are not exact copies of their brand-name counterpart, and have greater variability due to their complexity and sensitivity to manufacturing process and environmental factors. Facing these challenges, a biosimilarity index based on reproducibility probability is proposed to assess biosimilarity. We recommend that reference standard is first to be established in an R-R study in which biosimilarity is assessed comparing the reference product with itself. Biosimilarity between test and reference product is then assessed in relative to this reference standard. Biosimilairty index approach has the advantage of allowing us to assess biosimilarity without a well-accepted criterion and to assess the degree of similarity.