J Bioanal Biomed 2019, Volume 11
DOI: 10.4172/1948-593X-C1-048



## Biosimilars: Stability and quality considerations

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**Statement of the Problem**: Biosimilars are biological medicinal products that contain a version of the active substance of an already authorized original biological medicinal product (reference medicinal products). They shall demonstrate similarity to the reference medicinal products in terms of quality characteristics, biological activity, safety, efficacy and stability.

**Aim**: The aim of this review is to discuss the relevant analytical reports that are concerned with the assessment of proposed products and reference products biosimilarity.

**Findings**: The approval of biosimilars is a highly regulated, complicated and detailed process. The European Medicines Agency (EMA), The United States (US) Food and Drug Administration (FDA) guidance documents stipulate that biosimilar manufacturers shall perform a series of extensive similarity assessments to demonstrate biosimilarity to the reference product, and ultimately gain regulatory approval or licensure.

**Conclusion & Significance**: Establishment of biosimilarity shall be based on the totality of evidence, through non-clinical and clinical studies. An increased awareness is needed to confirm that not only clinical studies can be used as an important tool in the development of biosimilars but also the analytical and stability evaluation is more sensitive in similarity assessment.

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