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BIOSIMILARS: Concept and Regulatory Requirements

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ABSTRACTS

Biological on Biopharmaceutical are drugs produced from living cells through the biological process. Biosimilars are copy drugs similar to biological drugs that have already been authorised as the biological reference medicine so similar but not identical .Biosimilars are a growing drugs class designed to be used interchangeably with biologics. Although biosimilars have been part of clinical practice for more than a decade, healthcare professional do not fully accept them .This article reviewed the literature on biosimilars drugs that cover the therapeutic status. This article also focuses regarding regulatory guides.

KEYWORD: Biosimilars, Development process for biosimilars, synthesis of biosimilars, Regulatory required biosimilars.

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