

**Title: Biologics [3-0-0-3]**

**Content :**

Introduction to Biosimilars, Development and its role in Therapeutics, Cell Line Development and Upstream Bioprocessing, cell culture methods, clone selection and optimization, Bioreactors, Scale-up optimization

Critical Quality Attributes for Biologics and Bio-similars, Glycosylation, De-amidation, Charge Variant analysis, Analytical Methods to measure Glycosylation, De-amidation, Charge Variant (AUC, CE, Mass spectrometry)

Biophysical and analytical Characterization of Biologics products, Primary, secondary and tertiary structural analysis by various Biophysics Methods, Protein aggregation principle and analysis by DLS and SE-HPLC, Thermodynamic stability by DSC, ITC

Downstream Purification for Biologics, Regulatory Approach for Biosimilars, Globalization of Biosimilars

**Texts / References:**

- Introduction to Biologic and Biosimilar Product Development and Analysis, Nagel, Karen M. Springer, 2018
- Biosimilars: Regulatory, Clinical, and Biopharmaceutical Development Editors: Gutka, Hiten J., Yang, Harry, Kakar, Shefali (Eds.) Springer, 2018