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Downstream processing of Monoclonal Antibodies (MAbs): Challenges and troubleshooting

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Recent advances in mammalian cell culture technology has resulted in significant increases in upstream productivity, with antibody titers >5 g/L. Such increases, leading to higher levels of product-related heterogeneous proteins like aggregates, degraded products, processing variants and cell-derived impurities such as host cell protein and DNA. Hence, the development of efficient downstream process is desired to control the impurities as well as to meet the innovator specifications. The entire purification process must be validated by demonstrating a 12 to 20 log reduction of viral load using at least four different model viruses.

Biography

Prasad have been working as Senior Executive in Purification Lab; Biologics Division at Hetero drugs Ltd, Hyderabad, India. At present, He is working on process development of glycosylated proteins and Monoclonal antibodies. Prior, he served for Dr Reddys Laboratories, Intas Biopharmaceutical Ltd and Zenotech Labs in India. Prasad had extensive experience in development of downstream processing, virus clearance studies, scale-up, and process characterization using design of experiments (DOE).

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