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Improvement of physicochemical characteristics of biosimilar mAb to the innovator by high-resolution mass spectrometry

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Physicochemical and functional characteristics of mAbs are vital to defining critical quality attributes which affect safety, efficacy and quality of drugs. For head to the head comparison; mass spectrometry, capillary electrophoresis and SPR technology were used. The mirror plot images of deconvoluted mass spectrum for intact and reduced masses (heavy and light chain) of innovator mAb and its biosimilar candidate were significantly similar. MS/MS experiments have revealed that the amino acid sequence of the biosimilar is identical to the innovator and comparison of UV chromatograms of trypsin-digested samples is also identical. The relative percentages of post-translational modifications are also comparable with minor changes both in small scale (3L) and large-scale (200L). To increase the similarity of N-glycan profiles, different sugar supplements such as galactose was added to the culture media and the effect of these supplements on the glycosylation level was evaluated by MS during the upstream development. Capillary electrophoresis data revealed the similarity of impurity and purity profiles of both drugs. Additionally, both acidic and basic charge variants were comparable as a result of upstream and downstream process optimization. The functional similarity was proven by SPR technology based on the binding kinetics, similarity score and also apoptosis inhibition assay. As a result; state of art instruments becomes an important tool to enhance biosimilarity to the innovator in order to diminish clinical efforts.

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