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Analytical Similarity Assessment of Bevacizumab Biosimilar Candidate MB02 Using Multiple State-of-the-Art Assays

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Abstract : MB02 (Alymsys®) is a candidate biosimilar to bevacizumab, which was developed against the reference product (RP) Avastin® sourced from both the European Union (EU) and United States (US). MB02 has been extensively characterized comparatively to Avastin® at a physicochemical and biological level using sensitive orthogonal state-of-the-art analytical methods. MB02 has been demonstrated similar to the RP with regard to its primary and higher-order structure, post- and co-translational profiles such as glycosylation, charge, and size variants. Specific focus has been put on the characterization of Fab-related activities, such as binding to VEGF A 165, which directly reflect the bevacizumab mechanism of action. Fc-related functionality was also investigated, including binding to FcRn, which is indicative of antibodies' half-life. The data generated during the analytical similarity assessment demonstrate the high analytical similarity of MB02 to its RP.

Keywords : analytical similarity, bevacizumab, biosimilar, MB02
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