

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

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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 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 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 high analytical similarity of MB02 to its RP.

Biography

Marie-Elise Beydon is a biochemist from Nice University, France with an MSc in International Drug Development and Registration from Paris XI university. She has over 15 years experience in the pharmaceutical industry with over 10 working with biosimilars. She is currently R&D CMC Team Leader at mAbxience in Spain where she leads the extended characterization activities for their biosimilar portfolio, including demonstration of analytical similarity.