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Analytical Method Development and Validation of Faricimab Injection by RP-HPLC

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Abstract: *A robust and reliable Reverse Phase High-Performance Liquid Chromatography (RP-HPLC) method was developed and validated for the quantitative analysis of Faricimab in Vabysmo injections. Faricimab, an IgG1-based bispecific antibody targeting VEGF-A and Ang-2, is used for treating retinal vascular disorders like age-related macular degeneration and diabetic macular edema. The method development involved the use of an Inertsil C18 column (250 x 4.6 mm, 5 µm) with a mobile phase composed of KH2PO4 (pH 4.6) and methanol in a 1:1 ratio, sonicated for 20 minutes.*

The developed method was evaluated for various validation parameters as per ICH guidelines, including linearity, precision, accuracy, and sensitivity. Linearity was demonstrated within the concentration range of 50-150 µg/ml with a correlation coefficient (R^2) of 0.999. The limit of detection (LOD) and limit of quantitation (LOQ) were found to be 0.050 µg/ml and 0.166 µg/ml, respectively, indicating high sensitivity. Precision, expressed as relative standard deviation (RSD), was below 0.1%, confirming the method's reliability.

Accuracy was assessed, with mean assay values ranging between 97-101%, and RSD below 0.2%, indicating the method's precision. Robustness tests confirmed the method's resilience against slight variations in analytical conditions such as acetonitrile ratio, flow rate, detection wavelength, and pH.

Stability studies showed that Faricimab remains stable under various stress conditions, including exposure to 0.1N HCl, 0.1N NaOH, 30% peroxide, heat, and sunlight, with assay values ranging from 88.93% to 94.07%. The optimized RP-HPLC method ensures good peak shape and resolution, making it suitable for routine quality control of Faricimab in pharmaceutical formulations. The validated method adheres to ICH guidelines, ensuring its reliability for consistent and accurate quantification of Faricimab..

Keywords: Reverse Phase High-Performance Liquid Chromatography.

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