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Analytical Method Development and Validation for Quantitative Estimation of Tebentafusp Bulk Dosage by RP-HPLC

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Abstract: *This study evaluates the analytical method for Tebentafusp (TEBN) in Kimmtrak Injection using HPLC with a photodiode array detector. The mobile phase was prepared with a 50% mixture of KH_2PO_4 buffer and methanol, sonicated, and filtered. Standard and sample solutions of TEBN were prepared, and various trials were conducted to optimize the chromatographic conditions. Stability tests were performed under different conditions including 0.1N HCl, 0.1N NaOH, 30% peroxide, sunlight, and 105°C. Trials revealed issues with peak shape and resolution, leading to multiple adjustments in mobile phase composition and column selection. The final optimal conditions were achieved with a KH_2PO_4: Methanol (60:40) mobile phase on a Thermo C18 column at a flow rate of 0.8 ml/min, with acceptable peak shape and system suitability parameters. Validation according to ICH guidelines demonstrated linearity, precision, accuracy, and selectivity. Linearity was confirmed within the range of 25-75 µg/ml with a detection limit of 0.076 µg/ml and quantitation limit of 0.255 µg/ml. Precision was indicated by a low relative standard deviation, and accuracy was confirmed by recovery studies. The method proved robust and suitable for the quantification of TEBN in Kimmtrak Injection, ensuring reliable quality control in pharmaceutical analysis.*

Keywords: Tebentafusp, HPLC, photodiode array detector, Kimmtrak Injection, chromatographic optimization, stability tests, method validation, pharmaceutical analysis

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