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New Validated RP-HPLC Method for the Determination of Eflornithine Hydrochloride

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Abstract : Objective: A Newer highly sensitive, accurate, precise and specific RP-HPLC method of Eflornithine hydrochloride (2-difluoromethyl-DL-ornithine; DFMO) was developed and validated as per ICH guidelines.
Method: The developed method is not only eligible of identifying and quantifying the impurities but also can be capable for the assay of Eflornithine hydrochloride in marketed parenteral formulations. The separation was performed using BDS Hypersil 5µ C18 (150 × 4.6 mm) column at room temperature by using methanol and water, 60:40 v/v as mobile phase at the flow rate 1 ml/min with UV detection at 254 nm.
Results: The retention time of DFMO was 4.8 min. The method was linear over concentration range of 5-15 ng/ml for DFMO. The accuracy of the proposed method was determined by recovery studies and was found 98.4% for DFMO. The developed method was validated as per ICH guidelines for linearity, accuracy, precision, limit of detection, limit of quantification, ruggedness, robustness and system suitability for Eflornithine hydrochloride and its impurities. This method can be successfully used for quantitative analysis of DFMO in parenteral formulation.
Keywords : RP-HPLC, Eflornithine hydrochloride (DFMO), Validation, ICH guidelines.

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