Evaluation of assay and in-vitro dissolution profile of certain fixed-dose combination using green analytical method

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Abstract

Objectives: The pharmaceutical industry and the National Regulatory Authorities (NRAs) are now focusing on the dissolution of multi-component drugs for quality control testing and predicting in vivo results to further consolidation of the biowaiver concept. The mixed formulation of Ciprofloxacin hydrochloride (CIP) and Metronidazole (MET) have been used as a model for simultaneous determination and obtaining in vitro dissolution profiles by using green analysis method namely (UV-CWT(Db4, a=490)). Material and methods: The proposed method (UV-CWT(Db4, a=490)) includes UV detection combined with Continuous Wavelet Transform (CWT) with Daubechies family and the order of fourth at the scaling factor (a=490) has been used and validated for analyzing and obtaining the dissolution profiles of the fixed-dose combination (CIP-MET). Results: The proposed method (UV-CWT(Db4, a=490)) has been validated effectively in accordance with ICH rules, regarding linearity, specificity, rigor, and preciseness of the working range (3.0ï16.0 εg/mL) for both (CIP) and (MET), respectively. As well as figures of merit were concluded. The dissolution profiles of CIP-MET tablets were acquired by the proposed (UV-CWT (Db4, a=490)) and HPLC reported methods were conveniently compared using the indicators f1 and f2 ("difference" and "similarity") the results ensured that there were no statistically differences between the methods. In addition, the green assessment tool, namely analytical eco-scale, evaluated and compared the greenness of the suggested method (UV-CWT (Db4, a=490)) and HPLC reported one. Conclusion: the suggested process (UV-CWT(Db4, a=490)) was considered as an excellent green, rapid, accurate, economical and minimum-steps method for simultaneously resolve and construct the dissolution curves of a fixed-dose combination drug (CIP-MET) in a short time and without the use of organic solvents, enabling significant labor and resource savings.

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