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Research Article

RP-HPLC *In-Vitro* Dissolution Method Development and Validation for Determination of Olmesartan Medoxomil, Chlorthalidone and Cilnidipine Drug Combinations

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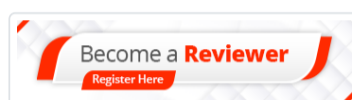
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Abstract

Objective: A simple, sensitive, and accurate in-vitro dissolution method has been developed for Olmesartan Medoxomil (OLM), Chlorthalidone (CHLR) & Cilnidipine (CIL) drug combination according to USP dissolution testing methodologies with different discriminating mediums and validated as per ICH guidelines.

Methods: The in-vitro dissolution profile was obtained using 900 ml of phosphate buffer pH 6.8 with 1.0% SLS at 37 °C ± 0.5 °C as dissolution medium and USP II (paddle) at 75 rpm. The average % in-vitro drug release was above 80% within 45 minutes for the above drug combination. The drug release profile was evaluated by RP-HPLC method. Chromatographic separation was done on Hypersil-BDS C-18 (12.5cm x 4.6mm x 5µm) column using gradient program with initial mobile phase ratio of 55:45 (v/v) mixture of ammonium acetate buffer (pH 5.0) and acetonitrile at a flow rate of 1.0 ml/min with detection wavelength 260 nm.

Results: The method was validated with respect to specificity, linearity, precision, accuracy, and robustness. The method was found to be linear in the range of 7.0-21.0 µg/ml for CHLR ($R^2 = 0.9982$), 22.5-67.5 µg/ml for OLM ($R^2 = 0.9999$) and 5.5 -16.5 µg/ml for CIL ($R^2 = 0.9995$) respectively. The % recovery data were found between 98.3 % to 104.1%. The % RSD for method and intermediate precision of method did not exceed more than 2%.

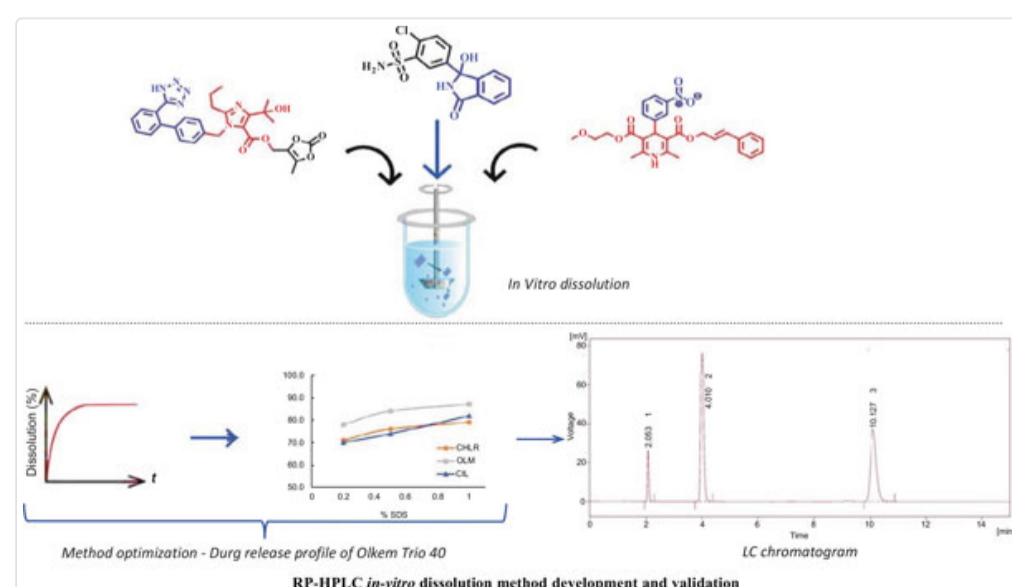
Conclusion: The proposed in-vitro method can be applied successfully for routine quality control analysis to check the quality of above drug combination.

Keywords: [Olmesartan medoxomil](#), [chlorthalidone](#), [cilnidipine](#), [in-vitro drug release](#), [ICH guidelines](#), [dissolution method](#).

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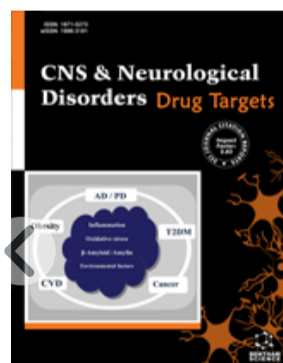
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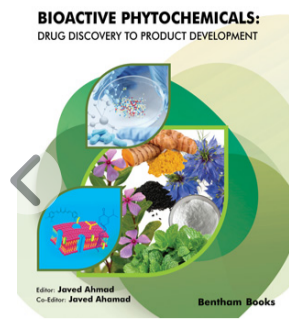
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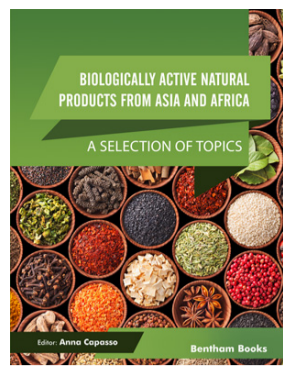
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