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Development and Validation of Stability Indicating RP-HPLC (PDA) Method for Estimation of Rifaximin and Ornidazole in Bulk and Combined Tablet Dosage Formulation

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Abstract:An isocratic stability indicating RP-HPLC(PDA) method was developed and validated for the determination of Rifaximin and Ornidazole in pharmaceutical dosage form. Isocratic elution was performed using the mobile phase Ammoniumformatebuffer(pH 7.2) and Acetonitirile (55:45 v/v).Linearity was observed in the concentration range of 50-150µg ml⁻¹ (0.999) for Rifaximin and 62.5 -875.5µg ml⁻¹(0.999) for Ornidazole.Rifaximin and Ornidazole were subjected to stress conditions of degradation such as acidic,alkaline,oxidation,photolytic and thermal degradation. The drug combination was found to be more sensitive towards acidic degradation. The method was validated as per ICH Guidelines. The recovery was in good agreement with the labeled amount in the pharmaceutical formulation. Theproposed method is simple,precise,specific, accurate and robust for the determination of Rifaximin and Ornidazolein pharmaceutical dosage form.

Key words: RP-HPLC, Rifaximin, Ornidazole, Stability indicating, Validation, Quantification.

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