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DRUG DISSOLUTION STUDIES AND ANALYSIS OF DEFLAZACORT IN PHARMACEUTICALS, BIOLOGICAL SAMPLES BY RP-HPLC

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Deflazacort, a prednisolone derivative with lower lipid solubility, has been suggested to have lesser effects on bone, carbohydrate and lipid metabolism than does prednisolone. The corticosteroids are used in pharmacological doses for their anti-inflammatory and immunosuppressant glucocorticoid properties, which suppress the clinical manifestations of disease in a wide range of disorders.

A novel, rapid, sensitive, simple, accurate and fully validated RP-HPLC method developed to determine deflazacort in pharmaceutical dosage forms and human serum. The proposed method was conducted using a reverse phase technique, UV monitoring at 244 nm and etodolac as an internal standard. Chromatography was carried out on a Waters C18 column (5 μm ODS1; 4.6×250 mm) using a mixture of methanol: acetonitrile: 0.067 M KH₂PO₄ (20:27:53; v/v/v) adjusted to pH 6.5 with 3 M NaOH at a flow rate 1.5 ml·min⁻¹. Linearity was obtained in the concentration range of 10 – 30,000 ng·ml⁻¹ with a slope of 5.86×10⁻⁴, intercept of −3.36×10⁻². Validation of the method showed it to be precise, accurate and linear over the concentration range of analysis with limit of detection of 2.05 ng·ml⁻¹ and limit of quantification 6.83 ng·ml⁻¹.

The proposed method was successfully applied without any interferences to the determination of deflazacort in biological samples and pharmaceutical dosage forms. This method was also applied without any interference from the excipients for the determination of this compound in drug dissolution studies.