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Original Research Article

DEVELOPMENT AND VALIDATION OF UV SPECTROPHOTOMETRIC METHOD FOR THE ESTIMATION OF DEFLAZACORT

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ABSTRACT

UV spectrophotometric method have been developed for the estimation of Deflazacort in pure and its pharmaceutical formulations. In UV method Deflazacort showed absorption maximum at 242.8nm in methanol medium and it obeyes Beers law in the concentration range of 5-25µg/ml.

Key words: Deflazacort, UV spectrophotometry, methanol.

INTRODUCTION

Deflazacort[1] is a cortico steroid with mainly glucocorticoid activity. It is used for its anti inflammatory and immuno suppressant properties in conditions responsive to cortico steroid therapy.Deflazacort[2] is chemically 11β,21-dihydroxy 2 ′-methyl-5′Bh-pregna-1,4-dieno[17,16d]oxazole -3,20 dione 21-acetate.It is practically insoluble in water ,soluble in ethanol and methanol. Two spectrophotometric methods were reported[3].First method reported was UV using ethanol and second method colorimetric method based on redox reaction with tetrazolium in alkaline medium was reported.Hence,it was thought worthwhile to develop UV spectrophotometric[7] method using different solvents .The present study illustrates a simple,accurate,economical and reproducible procedure for UV spectrophotometric estimation of Deflazacort in pure and its pharmaceutical formulations.

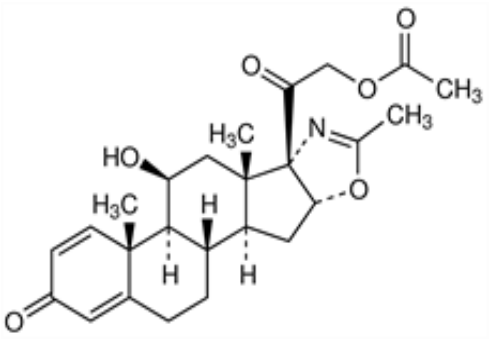

Fig.1.Structure of Deflazacort

MATERIALS AND METHODS

Instrument

All spectral measurements were done on Shimadzu 1800 with 1cm matched quartz cells.

Materials

Pure sample was obtained from Lupin pharma Ltd,Mumbai,Maharashtra.Indian and commercial formulations were procured from local market.All the chemicals used were of analytical grade.

Chemicals : methanol

Preparation of standard and sample solutions[5]

Deflazacort (pure or formulation) 50mg was accurately weighed and dissolved in methanol and transferred to standard 50ml volumetric flask .The volume was made upto mark with methanol(1mg/ml).Final concentration was brought upto 100µg/ml with methanol.In case of formulation ,20 tablets of Deflazacort each containing 6mg were accurately weighed and powdered.50mg of drug equivalent was taken or the study.

Assay

Aliquots of Deflazacort ranging from 5-25 µg/ml (1ml=100µg/ml) were transferred into a series of 10ml volumetric flasks .The volume were made upto mark with methanol .The absorbance of the solutions was measured at 242.8nm against reagent

blank. The amount of drug was computed from calibration curve.

RESULTS

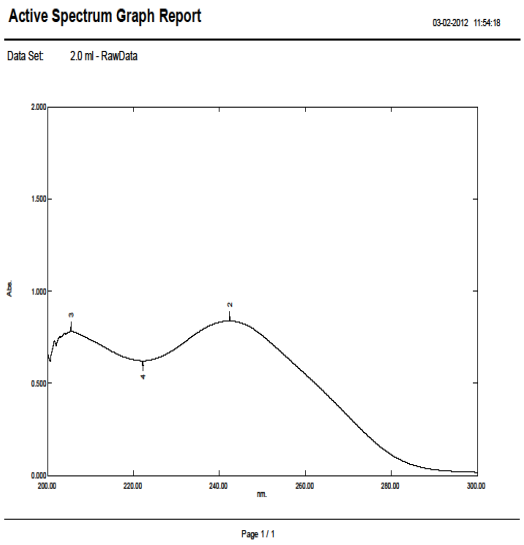

Fig.2.Absorption spectra for Deflazacort in methanol (20µg/mL, λmax 242.8nm)

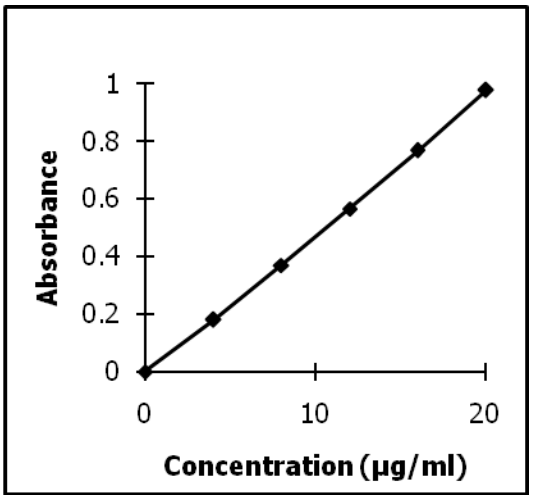

Fig.3.Calibration curve for Deflazacort at 242.8nm with methanol

Table.1.Optical characteristics and precision by UV spectroscopy

Parameter	**UV**
λmax (nm)	242.8
Beer's law limits (µg/ml) (c)	5-25
Molar absorptivity (lit. mol^{-1} cm^{-1})	1.7034×10^4
Limit of Detection (LOD/ $mcgml^{-1}$)	0.112391
Limit of Quantification (LOQ/ $mcgml^{-1}$)	0.3405762
Regression equation (Y*) Slope (b)	 0.03714
Intercept (a)	0.0175
Standard error of estimation (Se)	0.0012
Correlation coefficient (r)	0.9998
% RSD	0.2342
Range of Errors** Confidence limits with 0.05 level Confidence limits with 0.01 level	 0.00106 0.00156
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*Y=bC+a, where C is the concentration of Deflazacort in µg/ml and Y is the absorbance at the respective maximum absorbancy, **Average of eight determinations.

Table.2.Assay results of Deflazacort in Pharmaceutical dosage form (tablet) by UV Method (Reference method)

Sample	Labelled amount (mg)	Amount found by the Proposed method*±SD (mg)	% recovery by the proposed method ± SD
C_1	250	249.86 ± 0.270	99.96 ± 0.448
C_2	250	248.74 ± 0.638	99.52 ± 0.345

C_1 and C_2 are tablets from different manufactures, *Average ± SD of five determinations.

DISCUSSIONS

The optical characteristics such as absorption maxima ,Beers law limits,molar absorptivity are presented in Table.2 The regression[6] analysis using the method of least squares was made for the slope (b),intercept(a) and correlation coefficient (r) obtained from different concentrations and the results are summarised in Table 2.The % relative standard deviation and % range of errors (0.05 and 0.01 level of confidence limits)calculated from the eight measurements ,3/4 of the upper Beers law limits of Deflazacort are given in Table 2.The results showed that method has reasonable precision.Comparision was also made with the proposed and UV methods for dosage forms (Table 3) which confirms the suitability of these methods for pharmaceutical dosage forms .In order to justify the reliability and suitability of the proposed methods ,known quantities of pure Deflazacort was added to its various pre-analysed formulations and the mixtures were analysed by the proposed methods. The results of recovery experiments are also summarised in Table 3.The other active ingredients and excipients usually present in pharmaceutical dosage forms did not interfere.The proposed methods are found to be simple,sensitive,selective,accurate,precise and economical .It can be used in the determination of Deflazacort in bulk drug and its pharmaceutical formulation in a routine manner.

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