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NOTE

Spectrophotometric Determination of Famciclovir and Racecodotril

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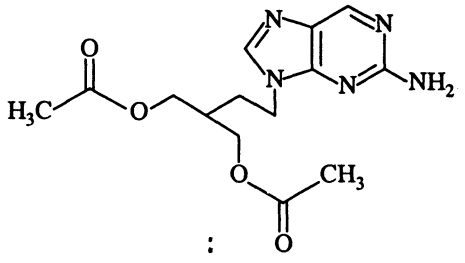
Simple and sensitive UV spectrophotometric methods have been developed for the determination of famciclovir and racecodotril in pure and pharmaceutical dosage forms. These methods obey Beer's law in the concentration range of 10–60 and 20–100 μg/mL exhibiting absorption maximum at 305 and 211 nm respectively. These methods are extended to pharmaceutical preparations and there is no interference from any common pharmaceutical additives and diluents. The methods have been statistically evaluated and are found to be precise and accurate.

Key Words: UV Spectrophotometric determination, Famciclovir, Racecodotril.

Famciclovir (FCV)[1, 2] is an antiviral drug and is chemically 2-[2-(2-amino-9H-purin-9-yl) ethyl]-1,3-propanediol, diacetate (m.f. $C_{14}H_{19}N_5O_4$). Racecodotril (RCD) is an anti-platelet agent and chemically it is, N-[2-[(acetyl thio) methyl]-1-oxo-3-phenyl propyl]-phenyl methyl glycine. Literature survey reveals that no visible and UV methods are reported for the estimation of FCV and an HPLC method is reported for RCD[3]. The present investigation has been undertaken to develop two simple, accurate and reliable UV spectrophotometric methods for the estimation of FCV and RCD in pure as well as in pharmaceutical dosage forms.



Famciclovir

Spectral and absorbance measurements were made on Systronics UV-Visible spectrophotometer-117 with 10 mm matched quartz cells.

Accurately weighed 100 mg of FCV was dissolved in 100 mL of distilled water and the solutions were diluted quantitatively with distilled water to obtain a final concentration of 100 μg/mL. Accurately weighed 100 mg of RCD was dissolved in 100 mL of methanol and then diluted stepwise with methanol to obtain working standard solution of 40 μg/mL concentration.

Preparation of Sample Solutions

An accurately weighed tablet powder of FCV equivalent to 100 mg was dissolved in 100 mL of distilled water and filtered. This solution was further diluted with distilled water so as to obtain a concentration of 100 μg/mL.

An accurately weighed tablet powder of RCD equivalent to 100 mg was dissolved in 100 mL of methanol and filtered. This solution was further diluted with methanol so as to obtain a concentration of 40 μg/mL.

Assay Procedure for FCV and RCD

Aliquots of solution 1.0 to 6.0 mL (100 μg/mL for FCV) and 0.5 to 2.5 mL (40 μg/mL for RCD) were transferred into a series of 10 mL volumetric flasks and the volume was brought up to 10 mL with distilled water for FCV or with methanol for RCD. The absorbance was measured at 305 nm for FCV or 211 nm for RCD against a reagent blank. The amount of FCV and RCD present in the sample solution was computed from its calibration curve.

The Beer's law limits, Sandell's sensitivity, molar extinction coefficient, per cent relative standard deviation (calculated from the eight measurements containing 3/4th of the amount of the upper Beer's law limits), regression equation, correlation coefficients, % range of error (0.05 and 0.01 confidence limits) obtained are summarized in Table-1.

Pharmaceutical formulations of Famcilovir and Racecodotril were successfully analyzed by the proposed methods. The results obtained by the proposed methods are presented in Table-2. To evaluate validity and reproducibility of the methods, known amounts of pure drug were added to previous pharmaceutical preparations and the mixtures were analyzed by the proposed methods and the results are presented in Table-2. Interference studies revealed that the common excipients and other additives usually present in the dosage form did not interfere in the proposed methods.

In conclusion the proposed methods are most economic, simple, sensitive and accurate and can be used for the determination of FCV and RCD in bulk as well as in its pharmaceutical preparations.

TABLE-1
OPTICAL CHARACTERISTICS AND PRECISION OF THE PROPOSED METHODS

Parameter	FCV	RCD
λ_{max} (nm)	305	211
Beer's law limit (μg/mL)	10–60	20–100
Sandell's sensitivity (μg cm^{-2}/0.001 absorbance unit)	0.101	0.142
Molar absorptivity (L mol^{-1} cm^{-1})	3.159×10^4	2.698×10^4
Regression equation (Y = a + bC)		
Slope (b)	0.01	0.007
Intercept (a)	0.005	–0.005
Correlation coefficient (r)	0.9998	0.9999
Relative standard deviation (%)*	0.2759	0.5923
% Range of error (confidence limits)*		
0.05 level	0.230	0.495
0.01 level	0.341	0.732

*Average of eight determinations.

TABLE-2
ESTIMATION OF FCV AND RCD IN PHARMACEUTICAL FORMULATIONS

Sample	Labelled amount (mg)	Amount found (mg) Proposed method	Recovery (%)*
Famciclovir			
Tablet I	60	59.99	99.98
Tablet II	60	59.97	99.95
Racecodotril			
Tablet I	10	10.03	100.30
Tablet II	10	9.98	99.80

*Recovery amount was the average of five determinations.

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