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NOTE

UV-Spectrophotometric Determination of Famciclovir in Pharmaceutical Formulations

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A simple, sensitive, spectrophotometric method in UV region has been developed for the determination of famciclovir in bulk and tablet dosage forms. Famciclovir shows maximum absorbance at 304 nm with apparent molar absorptivity of 5.8892×10^3 Lmol⁻¹cm⁻¹. Beer's law was obeyed in the concentration range of 10-50 µg/mL. Results of the analysis were validated statistically and by recovery studies.

Key Words: Famciclovir, UV spectrophotometry.

Chemically, famciclovir (FCV) is known as 2-[2-(2-amino-9H-purin-9-yl)ethyl]-1,3-propanediol diacetate. It is a novel antiviral drug, which is highly efficient in the treatment of acute uncomplicated herpes zoster¹ and ophthalmic zoster². FCV is synthetic guanine derivative, which is metabolized to the potent antiviral compound penciclovir. Famciclovir is absorbed rapidly and extensively after oral administration and total systemic availability of penciclovir³ is 77%, which is about four times higher than that of acyclovir⁴.

The present work reports the development of UV method for the estimation of famciclovir in tablets.

Famciclovir reference standard was kindly supplied by Cipla Laboratories Ltd. (India). Pharmaceutical dosage forms (famtrex[®], varovir[®]) containing famciclovir was obtained commercially. Ultra pure water was obtained from a Milli-Q[®] UF-Plus appratus (Millipore) and was used to prepare all solutions for the UV method. All solutions were prepared daily. The UV method was performed on a UV-visible spectrophotometer model 164 (Elico, India) at 304 nm using 1 cm quartz cells. Spectra treats software was used for all absorbance measurements.

Preparation of standard solution: Accurately weighed 100 mg of reference standard was transferred to 100 mL volumetric flask and

dissolved in distilled water (final concentration of 1 mg/mL). From this solution, concentrations of 10, 20, 30, 40 and 50 μ g/mL were made in 10 mL volumetric flasks and volume was adjusted with distilled water.

Preparation of famciclovir samples from accolate tablets: About 20 tablets of famtrex (each tablet contains 250 mg of famciclovir as API) were weighed and throughly powdred. The amount of powder equivalent to about 100 mg was placed in a 100 mL volumetric flask. To it around 90 mL of solvent (water) was added and the flask was placed in an ultrasonic bath for 15 min. The solutions were then cooled and diluted to volume with the same solvent. The solutions were filtered though a 0.45 μ m filter and then the filtrate were used to prepare sample solutions of different concentrations.

Measurement of spectra: For famciclovir solutions, the spectra were recorded in the wavelength range 200-400 nm using water as reference. The instrument settings were optimized to produce a spectrum with about 80% ful-scale deflection and acceptable noise level. Each spectrum was recorded in triplicate. For each replicate measurement the cell was refilled with fresh solution.

The spectrum of a 10 µg/mL famciclovir standard solution in water (against a blank of the same) observed the two intense absorbance bands in the UV region, with maxima at 221 and 304 nm. Good linearity was obtained on standard solutions over the 10-50 µg/mL concentraton range (Table-1). The linearity equation was Y = -0.0213x - 0.0193 (r = 0.9968), where x is the famciclovir concentration and Y is the response. Precision assessed on standard solutions was satisfactory: RSD values of 1.32 % (repeatability) was found for five replicates at a concentration of 100 µg/mL. Recovery studies were tabulated (Table-2). The spectra of formulation sample solution are morphologically identical to those of standard solutions. The LOQ was 28 µg/mL and the LOD 8.5 µg/mL, according to ICH guidelines⁵.

TABLE-1 RESULTS OF THE ANALYSIS OF THE DATA FOR THE QUANTITATIVE DETERMINATION OF FAMCICLOVIR BY THE PROPOSED METHOD

Statistical parameter	UV
Concentration range (µg/mL)	10-100
Regression equation	0.00469x - 0.01820
Correlation coefficient (r)	0.99679
Stand error on estimations (S _e)	0.01571
Standard deviation on slope (S_b)	0.00022
Standard deviation on intercept (S _a)	0.01321
Limit of detection (μ g/mL)	8.53
Limit of quantification (µg/mL)	28

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Famtrex 250 ^a		
Taken (µg/mL)	Found (µg/mL)	Recovery (%)
25	24.45	97.80
50	49.15	98.34
75	75.93	101.24
100	99.13	99.13
125	124.16	99.23

TABLE-2 PERCENTAGE RECOVERY

^amean of three determinations

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