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NOTE

Spectrophotometric Determination of Valacyclovir in Pharmaceutical Formulation

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A Simple, sensitive, spectrophotometric method in UV region has been developed for the determination of valacyclovir in bulk and tablet dosage forms. Valacyclovir is a new antiviral drug, which shows maximum absorbance at 274 nm with apparent molar absorpitivity of 2.69167×10^4 L/molcm. Beer's law was obeyed in the concentration range of 5-50 μg/mL. Results of the analysis were validated statistically and by recovery studies.

Key Words: Valacyclovir, UV spectrophotometry.

Valacyclovir is used for the treatment of the herpes simplex viruses and the varicella zoster virus[1,2]. Few methods for the assay of valacyclovir from the biological samples have been reported[3-5].

Valacyclovir reference standard was kindly supplied by Cipla laboratories Ltd. (India). Pharmaceutical dosage forms (Valcivir®) containing valacyclovir was obtained commercially. Ultra pure water was obtained from a Milli-Q® UF-Plus apparatus (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 274 nm using 1.0 cm quartz cells. Spectra treats software was used for all absorbance measurements.

Preparation of the standard solutions: 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 5, 10, 20, 30, 40 and 50 μg/mL were made in 10 mL volumetric flasks and volume was adjusted with distilled water.

Preparation of valacyclovir samples from valcivir tablets: About 20 tablets of valcivir (each tablet contains 250 mg of valacyclovir as API) were weighed and thoroughly powdered. 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 ultra-

sonic bath for 15 min. The solution was then cooled and diluted to volume with the same solvent. The solution was filtered though a 0.45 µm filter and then the filtrate were used to prepare sample solutions of different concentrations.

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

Limit of detection (LOD) and limit of quantitation: The parameters LOD and LOQ were determined on the basis of response and slope of the regression equation.

The spectrum of a 10 µg/mL valacyclovir standard solution in water (against a blank of the same) is shown in Fig. 1. Two intense absorbance bands in the UV region, with maxima at 227 and 274 nm, are apparent. Good linearity was obtained on standard solutions over the 5-50 µg/mL concentration range (Table-1). The linearity equation was Y = -0.04213x-0.0213 (r = 0.9998), where *x* is the valacyclovir concentration (expressed as µg/mL) and Y is the response. Precision assessed on standard solutions was satisfactory: RSD% values of 1.242% (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 16 µg/mL and the LOD 4.5 µg/mL, according to ICH guidelines[6].

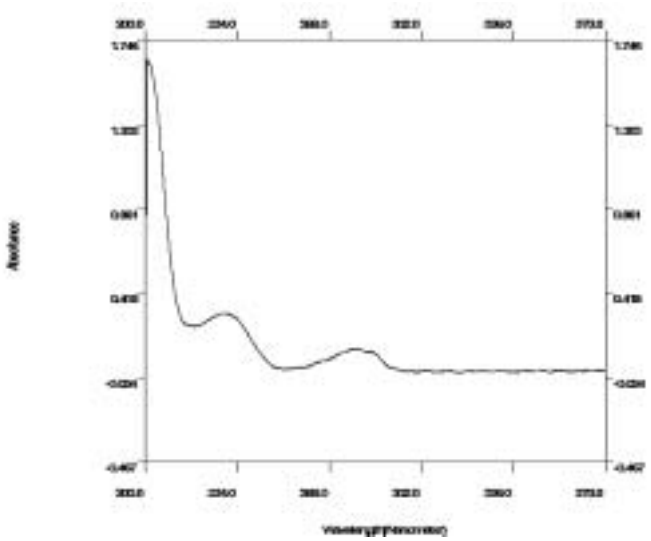

Fig. 1. Ultraviolet spectrum of valacyclovir standard solution (10 µg/mL)

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)	5-50
Regression equation	Y = 0.00213x - 0.021320
Correlation coefficient (r)	0.99989
Stand error on estimation (S_e)	0.01571
Standard deviation on slope (S_b)	0.00022
Standard deviation on intercept (S_a)	0.01
Limit of detection (μg/mL)	4.5
Limit of quantification (μg/mL)	16

TABLE-2
PERCENTAGE RECOVERY VALCIVIR[a]

Taken (μg/mL)	Found (μg/mL)	Recovery (%)
25	24.45	98.30
50	49.15	98.51
75	75.93	101.24
100	99.45	99.45

[a]Mean of three determinations.

Conclusion

The UV specrophotometric method has been used in the quality control of drugs because of its simplicity, rapid, economical and allows the determination of drugs with sufficient reliability. The present work reports the development of UV method for the estimation of valacyclovir in tablets.

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