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SPECTROPHOTOMETRIC DETERMINATION OF FAMCICLOVIR IN PHARMACEUTICAL PREPARATIONS MD. S. MAQSOOD AHMED^{*}, J. SUDHAKAR REDDY and I. E. CHAKRAVARTHI^a

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ABSTRACT

A simple, sensitive and highly accurate UV spectrophotometric method has been developed for the determination of famiclovir in bulk and tablet dosage form. The proposed method was based on the the charge transfer reactions of famiclovir as *n*-electron donor with acceptor, 2,3-dichloro-5,6-dicyano-p-benzoquinone. The absorbance of the highly intensive coloured solution was measured at 415 nm against reagent blank treated similarly The method was validated by determining its sensitivity, accuracy and precision, which proves suitability of the developed method for the routine estimation of famiclovir in bulk and solid dosage form.

Key words: Ultraviolet-visible spectrophotometry, Famiclovir, 2,3-Dichloro-5,6-dicyano-p-benzoquinone, Assay.

INTRODUCTION

Famciclovir, chemically 2-[2-(2-amino-9H-purin-9-yl)ethyl]trimethylene diacetate^{1,2} is an acyclic guanine nucleoside analog. It is a new generation antiviral drug, which is active *in vitro* and *in vivo* against herpes simplex virus types 1 and 2 and against varicella-zoster virus³⁻⁶. It is not official in any Pharmacopoeia. A few analytical methods have been reported for its quantitative estimation in pharmaceutical formulations e.g. HPLC⁷ and spectrophotometric method^{9,10}. The objective of the work is to develop new spectrophotometric methods for its estimation in bulk and tablet dosage form with good accuracy, simplicity, precision and economy. The proposed was based on the the charge transfer reactions of famiclovir as *n*-electron donor with acceptor, 2,3-dichloro-5,6-dicyano-p-benzoquinone. The absorbance of the highly intensive coloured solution was measured at wavelength of maximum absorbance.

EXPERIMENTAL

Materials and methods

Instrument and materials

All absorbance measurements were made on a Spectronic 1001 plus spectrophotometer (Milton Roy Company, USA) with 1 cm matched quartz cells.

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All the solutions were freshly prepared. All solvent and other chemicals used through this study were of analytical grade. 2,3-dichloro-5,6-dicyano-p-benzoquinone (DDQ; Merck) solution (0.1%) was prepared in methanol and it was prepared afresh daily.

Preparation of standard solution

A standard stock solution containing 1 mg/mL was prepared by dissolving 50 mg of famiclovir in 50 mL of distilled water. From this, a working standard solution containing 100 µg/mL was prepared.

Assay procedure

Various aliquots of standard solution of famiclovir ranging from 0.2-1.0 mL were transferred into 10 mL calibrated flasks. To each flask 1.0 mL of the acceptor solution (DDQ) was added, and the reaction was allowed to proceed at room temperature ($25 \pm 5^{\circ}$ C). The reaction was completed instantaneously. The solutions were diluted to desired volume with distilled water. The absorbance of the resulting solutions was measured at the wavelengths of maximum absorption, 415 nm, against reagent blanks treated similarly. The amount of drug present in sample is read from the calibration graph and calibration graph is shown in Fig. 2. Beer's law is obeyed in the concentration of 20-100 µg/mL of famiclovir.

Parameters	Proposed method		
λ_{max} (nm)	445		
Beer's law limit (µg/mL)	20-100		
Molar absorptivity (L mole ⁻¹ cm ⁻¹)	$1.7 \ge 10^3$		
Sandell's sensitivity ($\mu g \text{ cm}^{-2} / 0.001$ absorbance unit)	0.1785		
Regression equation $(Y = a + bC)$	Y = 0.055x + 0.044		
Slope (b)	0.055		
Intercept (a)	0.044		
Correlation coefficient (r)	0.9993		
*Y = a+bX, where Y is the absorbance and X concentration in	µg/mL		

Table 1: Optical characteristics of proposed method

 S_a = Standard deviation of intercept.

 S_{b} = Standard deviation of slope.

Pharmaceutical preparations

Twenty tablets containing famiclovir were weighed and finely powdered. An accurately weighed portion of the powder equivalent to 50 mg of famiclovir was dissolved in a 25 mL of methanol and mixed for about 5 minutes and then filtered. Then the volume was diluted to 50 mL with methanol and analyzed as given under the assay procedures for bulk samples. The results are represented in Table 2. To ensure the accuracy and reproducibility of the results obtained, known amounts of pure drug was added to the previously analysed formulated samples and these samples were reanalyzed by the proposed methods and were recovery experiments also performed. The percentage recoveries thus obtained were given in Table 2.

RESULTS AND DISCUSSION

Famiclovir forms charge transfer complex with acceptor, 2,3-dichloro-5,6-dicyano-p-benzoquinone. The absorption spectra of the charge transfer complex are shown in Fig. 1. The colorless reagent blanks under similar conditions showed no absorption. The optimum conditions were established by varying one parameter at a time and keeping the others fixed and observing the effect on absorbance of chromogen for the proposed method. Recovery studies were close to 100% that indicates good accuracy of the method. The optical characteristics such as absorption maxima, Beer's law limits, molar absorptivity and Sandell's sensitivity are presented in Table 1. The regression analysis using method of least squares was made for the slope (b), intercept (a) and correlation (r) and results are summarized in Table 1. The high molar absorptivities of the resulting colored complexes indicate the high sensitivity of the methods. The percent relative standard deviation, standard deviation and student's 't' test values were calculated from the five measurements of famiclovir are presented in Table 2.

Sample	Labeled amount (mg/tab)	*Amount found ± S.D	% Recovery	% RSD [*]	[*] t _{cal}
Penvir	500	500.08 ± 0.46	100.24	0.0931	0.3840
Famtrex	500	500.2 ± 0.55	100.38	0.1103	0.8101

Table 2: A	Assay of	famicl	ovir i	in tal	blets
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*Average of five determination based on the label claim

0.3 0.2 0.1 0

375

Absorbnance



425



Wavelength

525

575

625

475





Fig. 2: Calibration graph of famciclovir

Relative standard deviation values and standard deviation were low that indicates the reproducibility of the proposed methods. In the student's 't' tests, no significant differences were found between the calculated and theoretical values of both the proposed methods at 95% confidence level. This indicated similar precision and accuracy in the analysis of famiclovir in its tablets. The additives and excipients usually present in pharmaceutical preparations did not interfere.

CONCLUSION

Thus, the proposed method is simple, sensitive, accurate and reproducible and can be used for the routine analysis of Famciclovir in bulk and in pharmaceutical dosage forms.

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