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UV-Visible Spectroscopic Method for Estimation of Famciclovir

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Abstract: *A novel simple, rapid, sensitive and accurate method was developed for the estimation of Famciclovir in pharmaceutical formulation. The method is carried out at 223 nm. The method was statistically validated in terms of linearity, accuracy, precision, LOD and LOQ in accordance with ICH guidelines. Linear regression analysis data for the calibration plot showed that there was a linear relationship between response and concentration in the range of 2-10 µg/mL and the correlation coefficient is 0.998. The developed method was validated as per international conference on Harmonization (ICH) guidelines with respect to validation parameter.*

Keywords: Validation, UV-Visible Spectroscopic Method, Famciclovir, Linearity, Estimation, etc.

I. INTRODUCTION

2-Amino-9-[4-acetoxy-3-(acetoxymethyl) but-1-yl] purine is the chemical name for famciclovir. C14H19N5O4 is the chemical formula, and the molecular weight is 321.332 g/mol. Figure 1 shows the chemical structure of famciclovir. Famciclovir (FCV) is used to treat immune-competent patients with VZV-caused acute herpes zoster (shingles) [1-2]. FCV is a nucleoside analogue, which is a type of medicine that mimics one of DNA's building blocks. It prevents the herpes virus from spreading throughout the body by blocking the replication of viral DNA, which is required for viruses to reproduce [3]. FCV can also be utilised to treat ophthalmic zoster [4]. Famvir [5] is a brand of famciclovir that comes in 125 mg, 250 mg, and 500 mg tablets for oral use.

Figure 1: Structure of Famciclovir

The literature survey reveals that analytical methods for the estimation of FCV was found to be simple, precision, accurate, rapid and reproducible for the estimation of FCV. In literature, few analytical methods have been reported for the quantification of impurities and assay of famciclovir [6-15]. An ion pair RP-HPLC method development, validation and stability indicating assay for famciclovir [6]. Stability indicating LC method was developed and validated [7]. UV-Spectrophotometric method for determination of Famciclovir [8]. RP-HPLC method developed for the estimation of famciclovir in tablet dosage form [9]. Development and validation of a stability-indicating RP-LC [10]. Development and validation of spectrophotometric method for the determination of famciclovir in its dosage forms based on redox followed by complex formation with potassium ferricynide-Fe (III) reagent and oxidation followed by complex formation with 2,2-Bipyridyl-Fe (III) to form bluish green colored chromogen exhibiting absorption maximum at 500 nm [11].
Validated spectrophotometric estimation of famciclovir in tablet dosage form based on the condensation reaction of famciclovir with carbonyl reagent such as p-dimethylaminocinnamaldehyde (PDCA) in acidic condition to form orange

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red colored chromogen with absorption maxima at 510 nm [12]. Development and validation of RP-HPLC method [13]. Validated spectrophotometric estimation of famciclovir in tablet dosage form based on the condensation reaction of famciclovir with carbonyl reagent such as p-dimethylaminocinnamaldehyde (PDAB) and vanillin in acidic condition to form orange yellow colored chromogen with absorption maxima at 480 and 470 nm respectively [14].
Spectrophotometric estimation of antiviral drugs (valacyclovir and famciclovir) in bulk and pharmaceutical dosage forms based on extraction with Tpooo analytical reagent [15]. Subsequently, an alternative simple, sensitive UV-visible spectroscopic method was developed and optimized to determine the assay of famciclovir in famciclovir drug substance.

II. METHODOLOGY

Instrumentations:
Scimadzu (UV-1800) double beam UV- visible Spectrometer with 1 cm Quartz cells and UV- probe 2.34 Software connected to a personal computer. Over the wavelength range of 200-400nm, zero order absorption spectra were observed.

Materials:
The Ajanta Pharmaceutical Laboratories, Vapi, Gujrat provided the Famciclovir. FDA Ltd. Produced Famciclovir 250 mg tablet (Virovir 250 mg). The capsules were purchased at a nearby market. Throughout the experimental, ethanol was used.

Preparation of Standard Solutions:
Accurately weighed 10 mg of Famciclovir was transferred to separate 10 mL volumetric flask and dissolved in 100 mL ethanol. The flasks were shaken and volume was made up to the mark with methanol to give solutions containing 100 µg/mL Famciclovir.

UV-Visible spectroscopic Method:

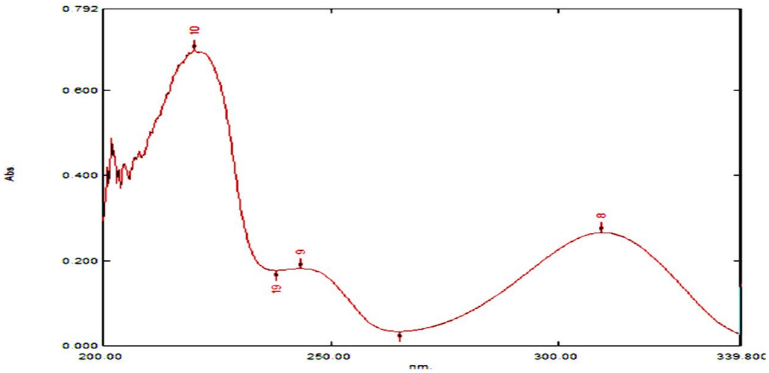

Figure 2: UV- Spectra of Famciclovir

Application to Marketed Formulation:
After twenty tablets, the average weight was calculated. The tablet was ground and blended well. Weighing and dissolving a powdered tablet containing 5 mg of FCV in 10 mL methanol After 15 minutes of sonication, the solution was filtered. Appropriate dilutions of the produced solution were made to prepare its working solution, which comprises 50g/Ml.

III. METHOD VALIDATION

1. Linearity
Adequate dilution of standard stock solutions was analysed for each medication using the described procedures. The Beer- Lambert concentration range for FCV was discovered to be 2-10 µg/mL. The method's linearity data is shown in Table 1.

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Table 1: Linearity Data for Famciclovir

Sr. No.	Concentration (µg/mL)	Absorbance
1.	2	0.134
2.	4	0.264
3.	6	0.421
4.	8	0.533
5.	10	0.681

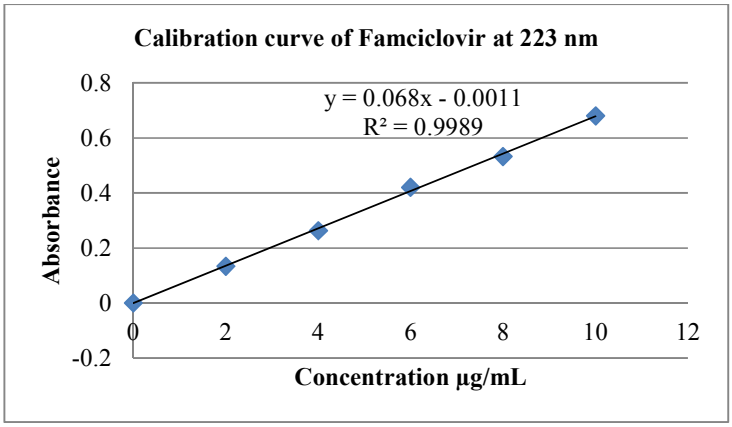

Figure 2: Calibration Curve of Famciclovir

2. Limit of Detection

The detection limit is determined by analyzing sample with known analyte concentration and determining the lowest concentration at which the analyte can be consistently identified.

LOD= 3.3×σ/S

Where σ is the error of y-intercept and S is the slope of calibration curve.

3. Limit of Quantitation

The quantitation limit is usually determined by analyzing sample with known concentrations and determining the lowest level at which the analye can be determined with acceptable accuracy and precision. Table 2 shows the result. LOQ= 10×σ/S

Where σ is the error of y-intercept and S is the slope of calibration curve.

Table 2: Optical Characteristics of Famciclovir

Parameter	Famciclovir
Linearity range (µg/mL)	2-10
Correlation coefficient	0.998
Slope	0.068
Standard error of y-intercept	-0.001
LOD (µg/mL)	-0.0485
LOQ (µg/mL)	-0.1470

4. Accuracy

Recovery studies at 80%, 100% and 120% of test concentration were carried out according ICH guideline to check the accuracy of the proposed method. At each level, recovery study was repeated three times. Table 3 shows the results of recovered studies.

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Table 3: Result for Accuracy

Recovery Level %	Concentration (µg/mL)		% Mean recovery ± SD	% RSD
	Added	Recovered		
80	10	8.6	116.1697 ± 0.148	0.128
100	10	9.02	110.5516 ± 0.3147	0.287
120	10	9.62	102.1834 ±1.82	1.78

5. Precision

Precision was checked in term of repeatability, interday, intraday precision. It was expressed in % RSD.

Repeatability

The repeatability was evaluated by assaying six times of sample solution prepared for assay determination. Percentage RSD was calculated.

Table 5: Result for Repeatability

Concentration (µg/mL)	Absorbance
10	0.681
10	0.699
10	0.696
10	0.689
10	0.699
10	0.665
Mean	**0.688167**
SD	**0.013303**
%RSD	**1.93309**

IV. RESULTS AND DISCUSSION

The FCV linearity range was found to be 2-10 g/mL, with a coefficient of correlation of 0.998. With a standard deviation of less than 2, a good percent recovery was achieved.

V. CONCLUSION

A simple spectroscopic approach for estimating FCV was developed. It was a precise, cost-effective, and accurate procedure. The method described could be utilised to calculate FCV in pharmaceutical preparations.

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