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Original Article

UV SPECTROPHOTOMETRIC ANALYSIS AND VALIDATION OF ACYCLOVIR IN SOLID DOSAGE FORM

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ABSTRACT

Objective: A new, economical, sensitive, simple, rapid UV spectrophotometric method has been developed for the estimation of Acyclovir in pure form and pharmaceutical formulation.

Methods: This UV method was developed using distilled water as a solvent. In the present method, the wavelength selected for analysis was 254 nm. UV-Visible double beam spectrophotometer (Systronic 2201) was used to carry out the spectral analysis. The ICH guidelines were used to validate the method.

Results: The method was validated for linearity, range, accuracy, precision, robustness, LOD and LOQ. Linearity was found in the range of 5-30µg/ml. Accuracy was performed by using a recovery study. The amount of drug recovered was found to be in the range of 100.1-100.5 %. The % RSD value was found to be less than 2.

Conclusion: The proposed UV spectroscopic method was found to be accurate, precise, stable, linear, specific, and simple for quantitative estimation of acyclovir in bulk and pharmaceutical dosage form. Hence the present UV spectroscopic method is suitable for the routine assay of acyclovir in bulk and pharmaceutical formulations.

Keywords: Acyclovir, UV-Visible spectrophotometric method, Method validation

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INTRODUCTION

One of the most frequently employed techniques in the pharmaceutical analysis is UV-Visible spectrophotometry. The amount of ultraviolet or visible radiation absorbed by a substance in a solution is measured by UV spectrophotometer [1].

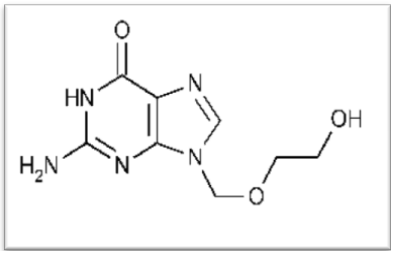

Fig. 1: Chemical structure of acyclovir [2]

Acyclovir is also known as Aciclovir (ACV). Its molecular formula is $C_8H_{11}N_5O_3$. IUPAC name of acyclovir is 2-amino-9-[(2-hydroxy-ethoxy) methyl]-6, 9-dihydro-3H-purin-6-one (fig. 1). It is a nucleotide analog antiviral primarily used for the treatment of herpes simplex virus infections2 [3]. Acyclovir is converted into acyclovir monophosphate due to the action of viral thymidine kinase then it is converted into acyclovir triphosphate (ACV-TP) by the action of host cell kinase [4]. ACV-TP competitively inhibits and inactivates the action of DNA polymerases by preventing further synthesis of viral DNA without affecting the cellular processes [5].

MATERIALS AND METHODS

Instruments

UV/Visible double beam spectrophotometer Systronic 2201. Standard cuvettes having 10 mm of path length are used for analysis. Ultrasonicator (micro clean-103) was used to sonicate the formulation sample. Drug sample was weighed by using an electronic analytical balance (Shimadzu AY220).

Chemicals and reagents

Active pharmaceutical ingredient of Acyclovir is gifted as a sample from Aadhaar Life Sciences Pvt. Ltd. Solapur. Marketed formulation of Acyclovir was procured from the local pharmacy.

Experimental work

Method development

Preparation of standard stock solution of acyclovir

10 mg of standard drug Acyclovir was accurately weighed and transferred into 10 ml volumetric flask and a sufficient amount of water was added into it and sonicated for 5 min, finally, volume was made up to the mark with the same solvent to make 1000µg/ml stock solution. From this 1 ml was again diluted to 10 ml to get a concentration of 100µg/ml of Acyclovir. From 100µg/ml solution 5 ml was again diluted to 10 ml to get a concentration of 50µg/ml.

Selection of wavelength

To determine the wavelength for measurement, Acyclovir (50µg/ml) solution was scanned in the range of 200-400 nm against distilled water as blank. Wavelength of maximum absorption was determined for the drug. Acyclovir showed maximum absorption at 254 nm.

Assay of acyclovir tablet

20 tablets weighed and powdered. The powder equivalent to 10 mg of acyclovir was weighed, transferred into 10 ml volumetric flask and dissolved in water. This solution was sonicated for 15 min and the final volume was made up to the mark with water. 1 ml of solution was transferred into 10 ml volumetric flask and diluted up to 10 ml with water. The absorbance of this solution was measured at 254 nm.

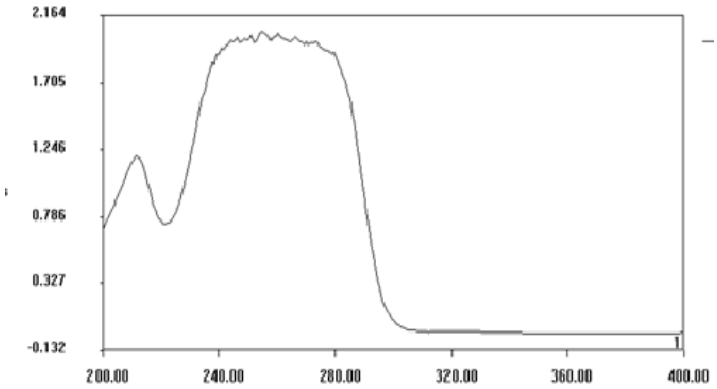

Fig. 2: UV visible spectrophotometer graph

RESULTS AND DISCUSSION

Method validation

The method was validated for several parameters like Linearity, Accuracy, Precision, Robustness, Limit of Detection (LOD), Limit of Quantification (LOQ) and Specificity of Acyclovir tablet [6-9].

Linearity and range

The linear relation between absorbance and concentration of drug was evaluated using three replicates over concentration rangein5-30µg/ml by making the replicates (table 1 and fig. 3).

The wavelength for linearity was scanned at 254 nm. By taking six different concentrations for linearity the regression coefficient was found to be 0.997 i.e. in the limit of standard. Hence the linearity parameter was found to be validated.

Accuracy

Accuracy of the method was confirmed by recovery studies from marketed formulation at three different levels of standard i.e. 50%, 100%, 150% was done to confirm the accuracy of the developed method. The amount of acyclovir is calculated at each level and percentage recoveries were calculated (table 2).

Precision

Precision of the developed method expressed in terms of the relative standard deviation of the absorbance. The solution was analyzed in 6 replicates for intra-day precision and in two successive days for inter-day precision. The % RSD value was found to be less than 2. Results confirmed that the precision of the method was found to be accepted. Precision results were given in table 3 and table 4 for intra and inter-day precision respectively.

Table 1: Results of linearity

S. No.	Concentration (µg/ml)	Absorbance
1	5	0.291
2	10	0.537
3	15	0.764
4	20	1.014
5	25	1.214
6	30	1.451

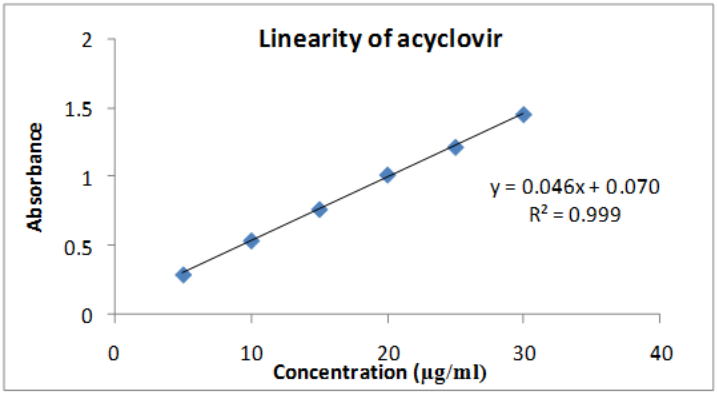

Fig. 3: Calibration curve for acyclovir

Table 2: Results of accuracy

Name of drug	Recovery levels	Concentration (µg/ml)	Amount recovered	% Recovery with SD
Acyclovir	50 %	10	10.001	100.01±0.70
	100 %	20	20.001	100.03±0.13
	150 %	30	30.004	100.05±0.25

Table 3: Results for intra-day precision

S. No.	Concentration (µg/ml)	Absorbance
1	10	0.538
2	10	0.539
3	10	0.537
4	10	0.539
5	10	0.537
6	10	0.539
SD		0.000983
%RSD		0.182693%

Table 4: Results for inter-day precision

S. No.	Concentration (µg/ml)	Absorbance (Day1)	Absorbance (Day2)
1	10	0.538	0.537
2	10	0.539	0.538
3	10	0.537	0.539
4	10	0.539	0.538
5	10	0.537	0.537
6	10	0.539	0.539
SD		0.000983	0.000894
%RSD		0.182693%	0.16625%

For Intra-day and the inter-day precision relative standard deviation is in limit i.e. less than 2% hence parameter is validated.

Table 5: Results for robustness

Wavelength	254 nm	260 nm
Concentration	12µg/ml	12µg/ml
Absorbance	0.612	0.613
	0.613	0.612
	0.611	0.611
	0.613	0.612
	0.612	0.611
	0.614	0.613
Average	0.613	0.612
SD	0.0011	0.00089
% RSD	0.179445	0.145425

By change in concentration and wavelengths i.e. 254 nm and 260 nm % RSD is less than 2% i.e. within the range. So parameter was validated

Table 6: Results for ruggedness

Concentration	Analyst 1	Analyst 2
15(µg/ml)	0.764	0.765
	0.762	0.764
	0.765	0.766
	0.764	0.763
	0.766	0.765
	0.765	0.762

By change in analyst and laboratory, there is no effect on absorbance with the same conditions (table 6). Hence, the parameter was validated.

Robustness

Robustness is a measure of its capacity to remain unaffected by small, but deliberate variations in method parameters and provides an indication of its reliability during normal usage. Robustness was carried out on two different instruments and also carried out by using two different analysts (table 5).

Ruggedness

The degree of reproducibility of test results of the same sample within different laboratories and different analysts under the same condition with the same concentration.

Limit of detection (LOD)

Limit of detection of an individual analytical procedure is the lowest amount of analyte in the sample which can be detected but not necessarily quantitated as an exact value. LOD was found to be 0.862.

Limit of quantitation (LOQ)

Limit of quantitation of an individual analytical procedure is the lowest amount of an analyte in the sample which can be quantified as an exact value. LOQ was found to be 2.612.

CONCLUSION

The proposed UV spectroscopic method is found to be accurate, precise, stable, linear, specific, and simple for quantitative estimation of acyclovir in the bulk and pharmaceutical dosage form. Hence the present UV spectroscopic method is suitable for the routine assay of acyclovir in bulk and pharmaceutical formulations.

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AUTHORS CONTRIBUTIONS

All the authors have contributed equally.

CONFLICT OF INTERESTS

Declare none

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