DEVELOPMENT AND VALIDATION OF UV SPECTROSCOPY FOR ACYCLOVIR IN BULK AND SOLID DOSAGE FORMULATION

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ABSTRACT:

A new, unique, simple, sensitive, precise and reproducible UV spectrophotometric method was developed for the estimation of Acyclovir in API (Active Pharmaceutical Ingredient) and Solid dosage Formulation. The UV spectrum of Acyclovir in 7.4 pH Phosphate buffer showed λ max at 251 nm. Beer's law is valid in the concentration range of 4-16µg/ml. The above described method was validated for linearity, accuracy, precision, ruggedness and robustness. The method has demonstrated excellent linearity over the range of 4-16µg/ml with regression equation y = 0.054 x +0.087 and regression correlation coefficient r^2= 0.99688. Further, the method was found to be highly sensitive with LOD (1.128µg/ml) and LOQ (3.420µg/ml). As per the results of given method can be successfully applied to perform assay of Acyclovir for Tablet/Solid dosage formulation.

Keyword: Acyclovir, UV spectroscopy, method development and validation, 7.4 pH Phosphate Buffer, Solid Dosage Formulation.

I. INTRODUCTION:

Acyclovir is a selective inhibitor of the replication of herpes simplex virus type 1 and 2 and varicella-zoster virus. It is converted by virus encoded thymidine kinase to its monophosphate derivative, an event that does not occur to any substantial extent in uninfected cells. This drug better percutaneous absorption and shows to be more active as antiviral activity [1].

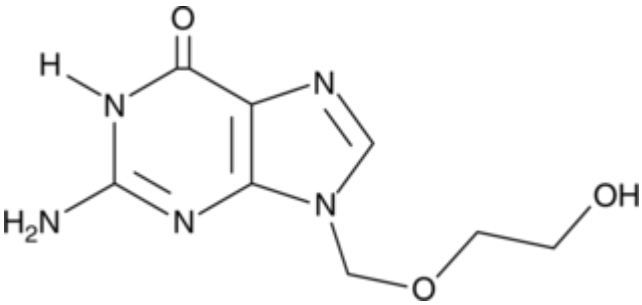

Figure1: Structure of Acyclovir

Acyclovir has low solubility in water but it has freely soluble in dimethyl sulfoxide and very slightly soluble in alcohol [2]. Acyclovir has low oral bioavailability of 10-20%. Acyclovir administered by the oral, topical, & intravenous route in herpes infection [3].

II. MATERIALS AND METHOD:

1. MATERIALS:

Acyclovir was taken as gift sample from, Aadhaar Life Sciences Pvt. Ltd., Solapur. Acyclovir Tablet Acivir-800 DT Purchased from Local Pharmacy.

1.1. Instruments:

Analytical balance (Labmann), Sonicator (Microclean-1103), UV-Visible spectrophotometer (Systronics 2201).

2. METHODS [4-9]:

2.1. Preparation of standard stock solution:

Accurately weighed 10mg of Acyclovir transferred to 100ml volumetric flask. It was dissolved in 7.4 pH Phosphate Buffer & sonicated for 5 minutes. The volume was made up to mark by slowly adding buffer solution to make up final strength.

2.2. Procedure for plotting calibration curve:

For calibration curve in a series of 10 ml volumetric flasks, 0.4-2 ml of standard solutions were pipetted out separately. The volume was completed to the mark using 7.4 pH Phosphate Buffer. The absorbance was measured at wavelength 251 nm against blank solution.

2.3. Analysis of Acyclovir in Tablet Formulation:

10 mg equivalent Acyclovir Tablet Acivir-800 DT was weighed and transferred to the 100ml volumetric flask and dissolved in 7.4 pH Phosphate Buffer as a solvent. After that sonicated for 5min and vortex for 2min. 1 ml of above solution was pipetted out and transferred to the 10ml volumetric flask and make up the volume up to the mark with same solvents and analyzed at 251nm. Calculate the % purity of Acyclovir.

III. RESULTS AND DISCUSSION:

The absorption spectrum shows λ max of Acyclovir at 251 nm.

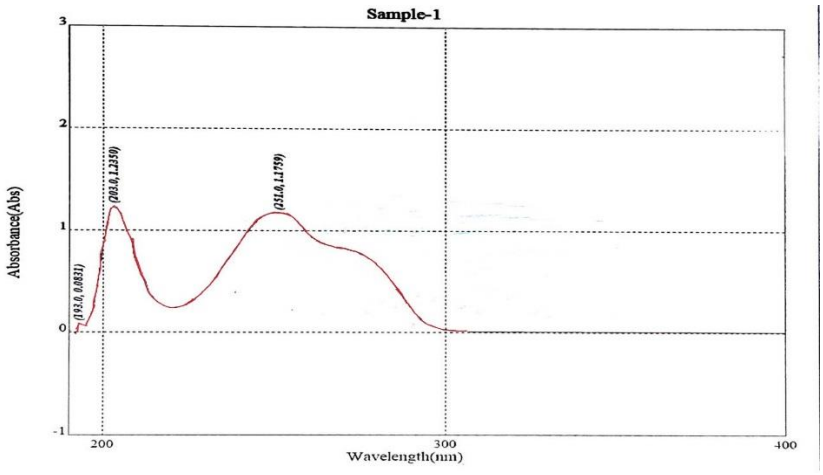

Figure 2: UV spectrum of Acyclovir

The given method was validated according to International Council for Harmonization (ICH) Q28 R1 guidelines for validation of analytical method/procedure [10].

1. Linearity:

Five different concentrations of Acyclovir were prepared and analyzed at wavelength 251nm. The regression coefficient was found to be 0.9968. The absorbance was found in limit i.e. 0-2. Hence performed analytical parameter was found to be validated.

Table 1: Results of Linearity

Sr.no.	Concentration(µg/ml)	Absorbance
1	4	0.326
2	8	0.497
3	12	0.743
4	16	0.989
5	20	1.17

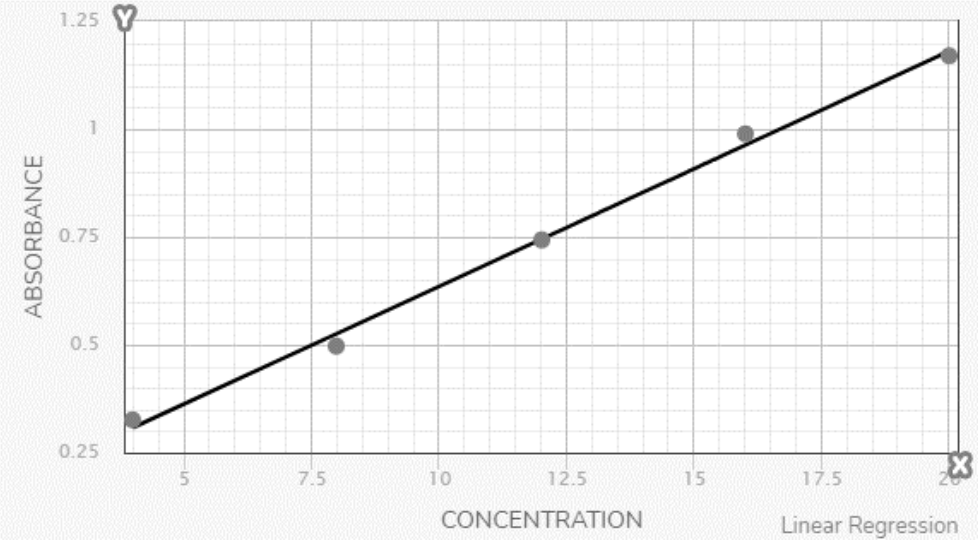

Figure 3: Calibration curve for Acyclovir (Conc. vs. Abs.)

Table 2: Optimization parameters of Acyclovir

Parameters	**Method values**
Maximum Wavelength	251nm
Beer's Law	4-20 µg/ml
Correlation Coefficient (r^2)	0.99688
Regression Equation	y = 0.054 x +0.087
Slope (m)	0.054
Intercept (c)	0.087

2. Accuracy:

The concentration 4, 8, 12µg/ml was taken as 50,100,150% and % recovery was found to be in range 99%-101%. Hence the parameter for measurement of accuracy was found to be validated.

Table 3: Results of Accuracy

Name of Drug	Recovery Level in %	Concentration	Amount Recovered	% Recovery with SD
Acyclovir	50	4µg/ml	4.01	100.02±0.3
	100	8µg/ml	7.95	99.80±0.2
	150	12µg/ml	12.12	100.03±0.5

3. Range:

Range is an interval between highest and lowest concentration limit of the analyte i.e. 4-20µg/ml.

4. Precision:

In precision intra-day and inter-day precision were performed at concentration (12µg/ml). The obtained results were found within limit i.e. less than 2%RSD.

Table 4: Results of Inta-day Precision

Sr. no.	Concentration	Absorbance
1	(12µg/ml)	0.742
2		0.741
3		0.742
4		0.742
5		0.743
6		0.742
	SD	0.000632
	%RSD	0.08

Table 5: Results of Inter-day precision

Sr.no.	Concentration	Absorbance (Day1)	Absorbance (Day2)
1	(12µg/ml)	0.742	0.9695
2		0.741	0.9697
3		0.742	0.9695
4		0.742	0.9692
5		0.743	0.9697
6		0.742	0.9694
	SD	0.000632	0.000516
	%RSD	0.08	0.0695

5. Limit of Detection (LOD):

The limit of detection was found to be 1.128µg/ml. (*Table 6*).

6. Limit of Quantification (LOQ):

The limit of quantification was found to be 3.420µg/ml.

Table 6: Results of LOD and LOQ

LOD	1.128 µg/ml
LOQ	3.420 µg/ml

7. Ruggedness:

The change in analyst with same concentration and environmental condition did not affect the results of ruggedness.

Table 7: Results of Ruggedness

Concentration	**Absorbance (Analyst1)**	**Absorbance (Analyst2)**
4 µg/ml	0.321	0.327
	0.322	0.328
	0.321	0.327
	0.321	0.327
	0.322	0.327
	0.323	0.328
Average	0.321667	0.327333
SD	0.000816	0.000516

8. Robustness:

The change in wavelength (251nm and 255nm) and concentration (8 µg/ml) didn't affect the results.

Table 8: Results of Robustness

Wavelength	251 nm	255 nm
Concentration	8 µg/ml	8 µg/ml
Absorbance	0.499	0.502
	0.498	0.503
	0.497	0.504
	0.498	0.502
	0.498	0.502
	0.499	0.503
Average	0.498167	0.502667
SD	0.000753	0.000816

9. Assay:

The assay was performed by using Acyclovir Tablet Acivir-800 DT at concentration 10 µg/ml. The % purity was found to be 99.54%.

Table 9: Results of Assay

Formulation	Absorbance	Amount obtained	% purity
Acivir-800 DT tablet	0.5976	0.5949	99.54

IV. CONCLUSION:

An analytical UV Spectrophotometric method was developed & validated thoroughly for quantitative determination of Acyclovir in bulk drug and tablet formulation. The presented method was found to be simple, precise, accurate, rugged, reproducible and gives an acceptable recovery of the analyte, which can be directly easily applied to the analysis of pharmaceutical tablet formulation of Acyclovir.

V. ACKNOWLEDGEMENT:

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VI. REFERENCES:

1. Wood J. Acyclovir: A Decade Later. The New England Journal of Medicine.Sep-1997; 327(11):782-788.
2. Indian Pharmacopeia.2018:220, 400, 1151-1152.
3. https://go.drugbank.com/salts/ DB00787.
4. Bhagyashri P. UV spectrophotometric estimation of acyclovir in bulk and tablet dosage form using area under curve method. World J Pharmacy and pharmaceutical sciences.2014; 3(8):1644-1651
5. Umesh S. Spectrophotometric determination and validation of acyclovir in tablet dosage form. International J Research in Pharmaceutical Sciences.2012; 4(4):1840-1845.
6. Hayam M. Stability indicating methods for the determination of acyclovir in the presence of its degradation product. Analytical Chemistry: An Indian J.2010; 9(4): 398-407
7. Yadav PK. New analytical method development and validation of acyclovir by RP-HPLC. Unique J Pharmaceutical and Biological Sciences.2016; 04(02):20-26
8. Deepak V. Quantitative Estimation Of Mupirocin Calcium From Pharmaceutical Ointment Formulation By UV Spectrophotometry, International J Pharmacy and Pharmaceutical Sciences ISSN- 0975-1491 Vol. 2, Issue 3, 2010.
9. Matole V. UV Spectrophotometric method development and validation of Imatinib in bulk and formulation, International J Current Pharmaceutical research.Nov-2019;12(2):63-67
10. ICH Q2 (R1) validation of analytical procedures: text and methodology, International Conference on Harmonization, Nov, 1996.