INTERNATIONAL RESEARCH JOURNAL OF PHARMACY
www.irjponline.com
ISSN 2230 – 8407

Research Article

UV VISIBLE SPECTROPHOTOMETRIC ESTIMATION OF GANCICLOVIR

C.M. Bhaskar Reddy [1]*, N. Ananda Kumar Reddy [2]
[1]Research Scholar, Department of Chemistry, Rayalaseema University, Kurnool, AP, India
[2]Principal & Associate Professor of Chemistry, S.V. Degree College, Kadapa, Kadapa (Dist), AP, India
*Corresponding Author Email: cmbr2008@gmail.com

Article Received on: 11/11/16 Revised on: 10/12/16 Approved for publication: 18/12/16

DOI: 10.7897/2230-8407.0712145

ABSTRACT

A low cost precise, accurate and more economical spectrophotometric method has been developed for the estimation of Ganciclovir in bulk and tablet dosage form. Ganciclovir shows maximum absorbance at 420nm in presence of solvent chloroform ,double distilled water and phosphate buffer of pH 7.4. The Beer's law is obeyed in the concentration range of 2-16 µg/ mL and the graph shows a straight line with correlation coefficient of 0 .9970. The assay method of the drug was validated by accuracy and precision of the proposed method. The results are validated as per the directions of International conference on Harmonization.

Keywords: Ganciclovir , U v spectrophotometry, Beer's law, validation

INTRODUCTION

Ganciclovir[1] is an antiviral agent and used to prevent disease caused by a virus called cytomegalovirus in people who have received organ or bone marrow transplants. It is used to treat complications from HIV associated cytomegalovirus diseases in various organs of human body. IUPAC name of this drug is 9-[[2-hydroxy-1-(hydroxymethyl)- ethoxy]methyl]guanine, It is a white to off-white crystalline powder , freely soluble in water and chloroform with a molecular formula of $C_9H_{13}N_5O_4$ and a molecular mass of 255.23 g/mol.

The molecular structure of the drug is shown in the Figure 1. Literature survey of Ganciclovir reveals that Different spectrophotometric methods have been reported which includes reagents like P-DMAB, Cerium sulphate (IV), Perchloric acid and water by P.J. Ramesh et al[2], Folin-Ciocalceu Reagent & NaOH by P.S. Sarasambi et al [3], PDAC & MBTH by S.S. Prakash et al[4], Folin & P-DMAB by T.Anilkumar et al [5], and Quinalizarin by Usra I.S.Al-Neaimy et al [6]. The comparisons of the proposed method with other existing methods for the assay of Ganciclovir in pharmaceutical formulations have shown in Table 4. Reported methods are time consuming and expensive. Therefore, an attempt was made to develop a low cost precise, accurate spectrophotometric method for the estimation of Ganciclovir in bulk and tablet dosage form.

MATERIALS AND METHOD

Instruments and Apparatus: The absorbance of the drug were carried out by using shimadzu company model 1700 UV-visible double beam spectrophotometer with 1 cm matched quartz cell, spectral band width is 1 nm, supported by UV win 5.0 software .

Reagents and Chemicals: All chemicals are AR grade. Chloroform, double distilled water and phosphate buffer of pH 7.4 is used throughout the analysis. Pharmaceutical formulation of Ganciclovir was supplied by Natco pharma, Hyderabad, (Telangana). Chloroform, double distilled water and phosphate buffer 7.4 was purchased from Merck India Ltd, Mumbai. Commercially available tablets namely Natclovir (100mg), Neoclovir (100mg), procured from Apollo pharmacy, Hyderabad, (Telangana).

Selection of Solvent

Chloroform, double distilled water and phosphate buffer of pH 7.4[8] are used throughout the analysis.

Selection of Method and Wave Length

UV scan range of 200 nm to 800 nm was selected for the proposed method of Ganciclovir. The wavelength corresponding to maximum absorbance was found at 420 nm and calibration curve was taken at 420 nm. The intercept of calibration line of the drug was determined by linear regression Analysis.

Preparation of Standard Solutions of Ganciclovir

The 100 mg of standard (pure) drug of Ganciclovir is weighed accurately and dissolved in 100 ml chloroform solvent then transferred into 100 ml volumetric flasks to prepare 1000 µg/ mL[7] stock solution of the drug. Then different aliquots of 2, 4,6,8,10,12,14 and 16 µg/mL were taken in eight 10 ml volumetric flasks and make up volume with double distilled water .To each flask 2mL of phosphate buffer of pH 7.4 solution is added, then all stock solutions of the drug were scanned in the UV scan range of lambda max (λmax) 200 nm to 800 nm to determine maximum absorbance for this method .The calibration curve was plotted in the concentration range of 2-16 µg/ mL. The wavelength corresponding to maximum absorbance of Ganciclovir measured at 420 nm against chloroform as blank.

Preparation of Sample Solutions of Ganciclovir

For the analysis of Ganciclovir, two commercial brands namely Natclovir (100mg) and Neoclovir (100mg) tablets were purchased from Apollo pharmacy ,Hyderabad (Telangana) Twenty tablets of the drug was weighed accurately and powdered , then 100 mg of the drug in powdered form dissolved in 40 ml of chloroform and sonicated for few minutes and filtered by using whatmann filter paper No.42. The filtrate formed is again diluted with double distilled water to get 10µg/mL concentration, taken in a ten 10 ml volumetric flasks. To each 10 ml flask 2mL of phosphate buffer of pH 7.4 solution is added. Then absorbance of Ganciclovir measured at 420nm against chloroform as blank .

Determination of λ Max

UV scan range of 200 nm to 800 nm was selected to determine maximum absorbance by using 10 µg/ml solution of the drug, the wave length corresponding to maximum absorbance was found at 420 nm for his drug. The spectrophotometric spectrum is shown in Figure 2

Preparation of Calibration Curve

On the basis of experimental results, calibration curve is plotted and shown in fig: 3 in the concentration range of 2-16 µg/ mL of eight standard solutions of Ganciclovir in chloroform as blank. UV scan range of 200 nm to 800 nm was selected to determine maximum absorbance of the drug. In this method the wavelength corresponding to maximum absorbance was found at 420 nm.

Validation of Method[9]

The spectrophotometric estimation of Ganciclovir is validated as per the directions of International conference on Harmonization to determine statistical parameters like linearity, precision, accuracy, LOD and LOQ of the proposed method.

Linearity and Range

Standard stock solutions of Ganciclovir in appropriate dilution were assayed as per the proposed method. According to Beer's – Lambert's law the concentration range of Ganciclovir was found to be 2-16 µg/ mL, So that the calibration curve in the Figure 3 is linear in the given concentration range.

Precision

The precision of the proposed method of Ganciclovir was estimated by using concentrations of the drug were analyzed six times in a day (intra-day precision) and six continuous days (inter-day precision). Data is given in the Table 2.

Accuracy

The Accuracy of the proposed method of Ganciclovir was estimated by using standard addition method .This process is carried out by adding different amounts namely 80% ,100% and 120% of the pure sample of the drug to the pre-analysed formulation. Accuracy data of the drug is shown in the Table 2.

LOD and LOQ

LOD is Limit of Detection and LOQ is Limit of Quantitation. The LOD and LOQ of Ganciclovir were determined (Table 1) by using standard deviation of the response and slope approach as per the directions of International Conference on Harmonization (ICH) guidelines. The limits of detection (LOD) is calculated by using the equation $\mathrm{LOD} = \frac{3s}{k}$ Where, S = intercept of the standard deviation K = The slope of the calibration curve (mean) The limits of quantitation (LOQ), is calculated by using the equation $\mathrm{LOQ} = \frac{10\,S}{K}$ Where, S = intercept of the standard deviation K = The slope of the calibration curve (mean).

Recovery Studies of Ganciclovir

Recovery analysis of Ganciclovir was performed to know the accuracy of the proposed method. This process is done by adding a known quantity of pure drug to a pre-analysed sample. The result of analysis of the drug is notified in the Tazble 3.

Table 1: Optical Parameters of Ganciclovir

S.No	Parameter	Ganciclovir
1	λMax (nm)	420 nm
2	Beer's Law Limit (µg/ mL)	2-16
3	Correlation Coeffcient(r^2)	0.9970
4	Regression Equation (Y= a+bc)	0.026X+0.027
5	Intercept (a)	0.027
6	Slope (c)	0.026
7	SD	4.47214
8	Mean	9
9	Variance	20
10	LOD (%)	0.311
11	LOQ (%)	0.103

Table 2: Determination of Accuracy and Precision of Ganciclovir

S.No	Name of the sample	Labeled Amount (mg/capsule)	Amount Found* (mg)	Precision	
				Interday	Intraday
1	NATCLOVIR	100	99.91	0.0086	0.0071
2	NEOCLOVIR	100	99.05	0.0093	0.0079

(*average of 6 determinations)

Table 3: Recovery studies of Marketed Formulations of Ganciclovir

S.No	Name of the sample	Labeled Amount (mg/capsule)	% Level	Amount Found* (mg)	% Recovery
1	NATCLOVIR	100	80	99.91	99.91
2	NEOCLOVIR	100	100	99.05	99.05

Table 4: Comparisons of the proposed method with other existing methods for the assay of Ganciclovir in pharmaceutical formulations

Reagent	λ Max	Beer's law limits µg mL^{-1}	Reference
p-DMAB, cerium (IV) sulphate, per chloric acid, water	460 nm	2–10	2
Folin- ciocalteau reagent, NaOH	764.7 nm	50-250	3
P-dimethylamino cinnmaldehyde (PDAC), 3 methyl-2-benzothiazolinone hydrazone (MBTH)	524 nm 611.8 nm	10-50 50 – 250	4
Folin reagent, p-DMAB	544nm 401 nm	4-14 80-200	5
Quinalizarin reagent	560 nm	1-20	6
Chloroform,Double distilled water phosphate buffer 7.4	420nm	2-16	Proposed method

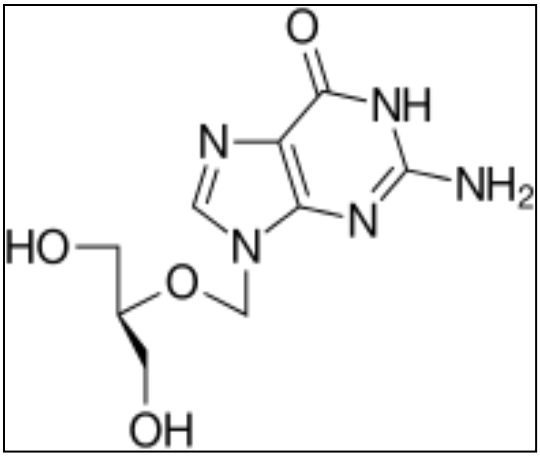

Figure 1: Molecular Structure of Ganciclovir

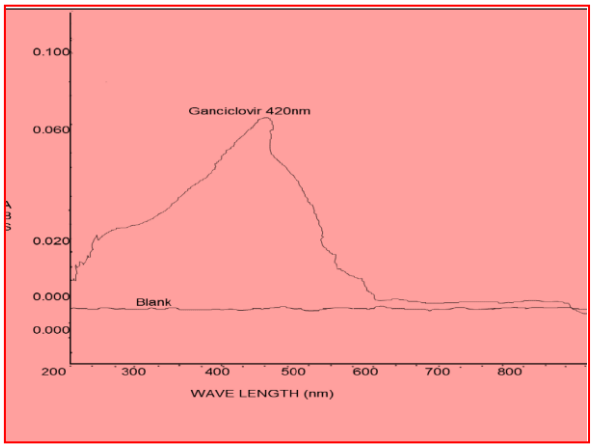

Figure 2: UV Visible Spectrum of Ganciclovir

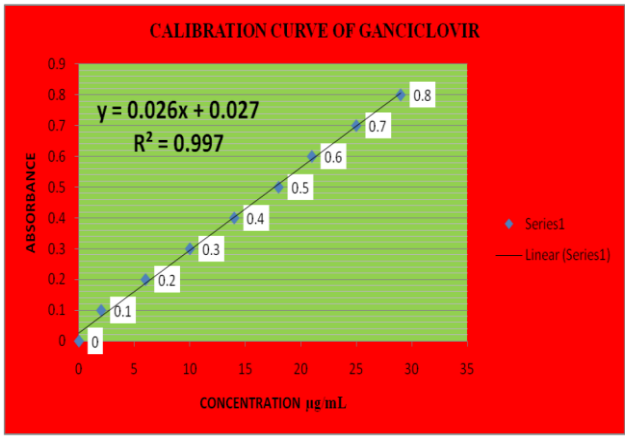

Figure 3: Calibration Curve of Ganciclovir

RESULTS AND DISCUSSION

The UV Spectrum of standard stock solutions of Ganciclovir shows absorption maximum at 420nm, then the calibration curve is obtained by plotting a graph of absorbance verses concentration, the Beer –lamberts' law was verified from the data of calibration curve of the drug under investigation. The calibration curve of the drug is shown in the Figure 3. The linearity was observed between 2-16 µg/ mL for Ganciclovir. The graph of this drug shows a straight line with correlation coefficient of 0 .9970. The assay method of the drug was validated by the accuracy and precision of the proposed method shown in Table 2. The % recovery of 99.91-99.05 shows accuracy of the proposed method. The validated optical, statistical parameters, LOD and LOQ data of Ganciclovir were shown in Table 1.

CONCLUSION

In this paper a low cost simple, precise and more economical UV visible spectrophotometric method for the determination of Ganciclovir in bulk and pharmaceutical formulation has been developed and validated as per the directions of International conference on Harmonisation.

ACKNOWLEDGEMENT

The authors are thankful to the management of Samskruti college of engineering and Samskruti college of pharmacy, Hyderabad for providing necessary facilities for this research work.

REFERENCES

1. https://en.wikipedia.org/wiki/Ganciclovir
2. Pavagada J Ramesh et al. Titrimetric and Spectrophotometric Assay of Ganciclovir in Pharmaceutical. International Scholarly Research Network of Analytical Chemistry 2012 ; 4 (1)
3. Prakash , S. Sarsambi et al. New spectrophotometric studies of antiviral drug Ganciclovir. International Journal of PharmTech Research 2010;2(2)
4. S. S. Prakash et al.Visible Spectrophotometric estimation of Ganciclovir. International Journal of ChemTech Research 2010;6(4)
5. T. Anil kumar et al. selective and validated Spectrophotometric estimation of Ganciclovir. Indian Journal of chemical Technology 2012 ; 19 (1)
6. Usra I.S. Al-Neaimy et al. Visible Spectrophotometric analysis of Ganciclovir Jordan Journal of Chemistry2013; 8(2): 103-112
7. Meghreji.Moin et al .validated method for silymarin by spectrophotometry in bulk drug and pharmaceutical formulations Journal of chemical and pharmaceutical Research 2010;2(1) : 396-400
8. Haque et al. Simultaneous spectrophotometric studies of Naproxen and Ranitidine HCl, Stamford Journal of Pharmaceutical Science 2001; 7(2): 18-24.
9. International conference on harmonisation Q2B Guidelines, Text on Validation of Analytical Procedures, Geneva 1994; 1–5

Cite this article as:

C.M. Bhaskar Reddy, N. Ananda Kumar Reddy. UV visible spectrophotometric estimation of Ganciclovir. Int. Res. J. Pharm. 2016;7(12):46-49 http://dx.doi.org/10.7897/2230-8407.0712145

Source of support: Nil, Conflict of interest: None Declared