

UV SPECTROPHOTOMETRIC METHOD DEVELOPMENT FOR ESTIMATION OF CLINDAMYCIN PHOSPHATE IN BULK AND DOSAGE FORM

K.S.Nataraj¹, G.N.V.Surya.Narasimha Raju², Bevara.Anusha³

^{1,2}, Shri Vishnu College of Pharmacy, Bhimavaram-534202, West Godavari District

³Aditya Institute of Pharmaceutical sciences and Research, East Godavari District

*Corresponding Author Email: kalakondan@yahoo.com

ABSTRACT

Two simple, accurate, precise, reproducible, requiring no prior separation and economical procedures for estimation of Clindamycin phosphate in bulk and tablet dosage form have been developed. First method employs formation and solving using water at 210 nm. Second method employs formation and solving using Phosphate buffer saline solution using pH. 6.75 at 210 nm. It shows linearity in a concentration range of 5-30 µg/mL.

The slope of interception and regression coefficient of Clindamycin phosphate is $Y = 0.0034x + 0.0015$ ($R^2 0.9997$) by using water and $Y = 0.0038x + 0.0034$ ($R^2 0.9998$) by using phosphate buffer saline pH 6.75 respectively. The accuracy of the method was determined and validated according to ICH guidelines. The method had good reproducibility and recovery with % RSD less than 1. The proposed method was validated statistically and recovery studies were performed.

KEY WORDS

Clindamycin phosphate; Beer's law, ICH guidelines, UV spectrophotometry

INTRODUCTION

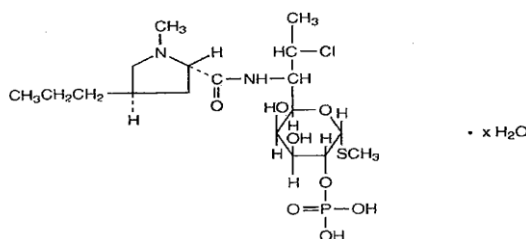
Clindamycin phosphate inhibits bacterial protein synthesis by binding to the 50S ribosomal subunit. Clindamycin also affects the peptide chain initiation step in protein synthesis. Chemically it is methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-trans-4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-threo- α -D-galactopyranoside-2-dihydrogen phosphate.

Extensive literature review reveals that several spectrophotometric, HPLC, HPTLC and LC-MS methods have been reported so far for determination of

Clindamycin phosphate alone and its combination with other drugs.

Therefore, it was thought worthwhile to develop simple, accurate and reliable spectrophotometric method for estimation of Clindamycin phosphate in bulk dosage form using water and phosphate buffer of saline pH 6.75 as a solvent. All the chemicals used were of analytical grade. Spectral and absorbance measurement were made on Shimadzu UV-Visible Spectrophotometer (UV-1601) (Shimadzu Corporation, Japan).

Fig-1: Structure of Clindamycin Phosphate



EXPERIMENTAL

Instruments and reagents

Prominent Shimadzu UV-Visible spectrophotometer (UV-1601) with cells of 10mm length is used.

Qualified standards of Clindamycin hydrochloride was received as gift sample from IPCA Laboratories, Mumbai India. All the solutions were protected for light and were analyzed on the day of preparations.

Selection of analytical wavelength

From the Standard stock solution further dilutions were prepared using solvent and scanned over the range of 200-400nm and the spectrum was overlain. It was observed that 210 nm was lambda max of Clindamycin hydrochloride and it was preferred as suitable wavelength for detection.

Preparation of stock and standard solution

Stock solution of Clindamycin hydrochloride (100µg/ml) in the distilled water and in phosphate buffer saline pH 6.75 was prepared by dissolving 10mg of Minocycline hydrochloride in 100ml of PBS pH 6.75.

Suitable aliquots of the stock solution of Clindamycin hydrochloride were pipette and transferred separately into 10ml volumetric flasks. The volume was made up with the same solvent i.e. in the distilled water and in phosphate buffer saline pH 6.75 respectively. Working standard solutions were scanned in UV range of (200-400nm) using a Shimadzu UV-Visible spectrophotometer (UV-1601) with cells of 10mm length against the same solvent used as blank. A typical absorptivity scans shown was shown in **Figure 2 & 3**.

Linearity and construction of calibration curve

Solutions containing 5, 10, 15, 20, 25 and 30µg / ml of Clindamycin hydrochloride were prepared from standard solution to determine the linearity range. The detection was carried out at 210 nm. Spectrums were recorded and absorbance was recorded for all the concentrations. A calibration plot of concentration over the absorbance was constructed and was shown in **Figure 4 & 5**

The optical characteristics such as Beer's law limits, regression equation and correlation coefficient, mean absorbance value, and statistical data of the calibration curve were calculated and results are presented in **Table 1 & 2**.

Assay of Clindamycin hydrochloride in bulk and in dosage form

Twenty tablets were weighed accurately and ground to fine powder. An accurately weighed powder equivalent to 10 mg of each Clindamycin hydrochloride was transferred to two 100 mL volumetric flasks and volume make up to the mark with water and PBS pH 6.75. From this stock solution, working sample solution of drug was prepared by appropriate dilutions with same solvent. The results of assay are presented in **Table 3**.

RESULTS AND DISCUSSIONS

Method development

In the present investigation we have developed a simple precise and accurate UV Spectrophotometric method for the determination of Clindamycin hydrochloride. The method was developed using in both water and phosphate buffer saline solution using pH 6.75. The detection was carried out at 210nm. The developed method was found to be appropriate for the determination of Clindamycin hydrochloride in bulk and in dosage forms. A typical absorptive scans obtained was shown in **Figure 2 & 3**.

The high correlation coefficients (**Table No.1**) in both distilled water and in phosphate buffer saline pH 6.75 in case of Clindamycin hydrochloride indicated that absorbance and concentration are linearly related. Beer's law was found to be obeyed in the range of 5-30 µg/ml in distilled water and in the range of 5-30µg/ml in phosphate buffer saline pH 6.75).

The stability of Clindamycin hydrochloride and was done in both distilled water and in phosphate buffer saline pH 6.75 and was ascertained over a period of 72 hrs. Analysis of variance (ANOVA) of the mean absorbance values of both the solutions of different concentrations at various time intervals revealed that there was no significant difference between the readings.

CONCLUSION

The most striking feature of this method is its simplicity and rapidity, non- requiring- consuming sample preparations such as extraction of solvents, heating, degassing which are needed for HPLC procedure. These are new and novel methods and can be employed for routine analysis in quality

control analysis. The described methods give accurate and precise results for determination of Clindamycin phosphate in marketed formulation.

Fig-2: Absorptivity scans of Clindamycin hydrochloride in distilled water

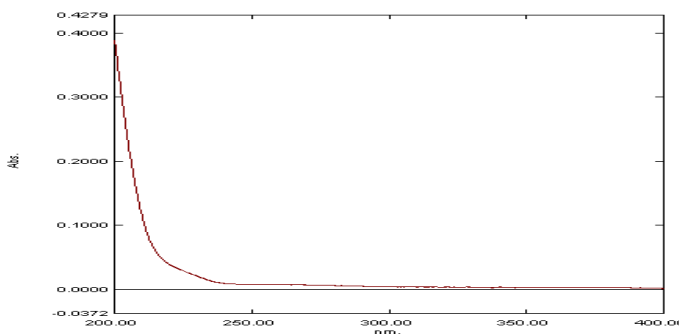


Fig. 3: Absorptivity scans of Clindamycin hydrochloride in PBS pH6.75

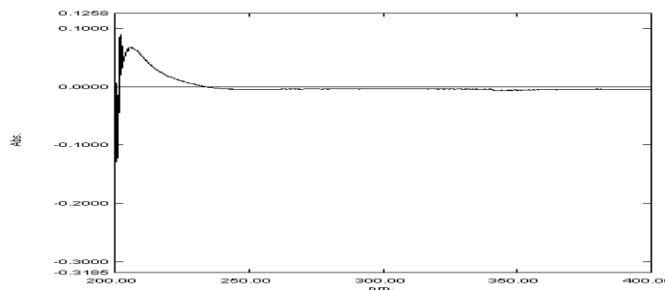


Fig. 4: Calibration curve of Clindamycin hydrochloride in distilled water

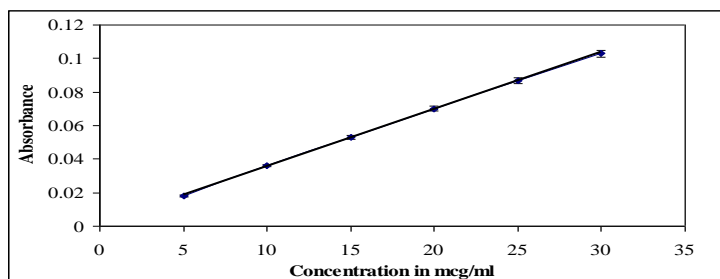


Fig. 5: Calibration curve of Clindamycin hydrochloride in PBS pH6.75

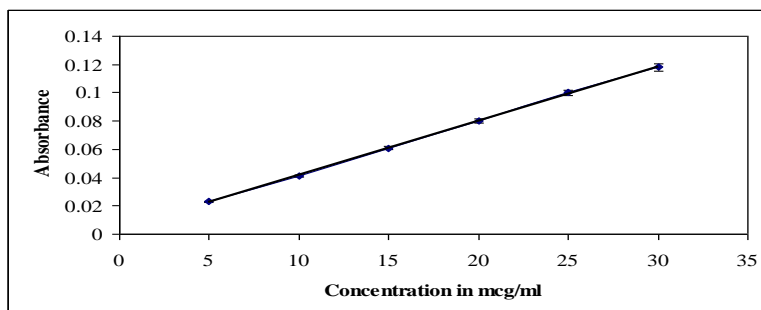


Table 1: Optical characteristics and precision of the proposed method

Parameters	Results	
	By using water as solvent	By using phosphate buffer saline pH.6.75
Wavelength	210.0 nm	210.0 nm
Beer's law limit ($\mu\text{g}/\text{mL}$)	5-30	5-30
Regression equation ($Y = mx + C$)	$Y = 0.0034x + 0.0015$	$Y = 0.0038x + 0.0034$
Slope (m)	0.0034	0.0038
Intercept (C)	0.0015	0.0034
Correlation Coefficient (r)	0.9997	0.9998

Table-2. Mean absorbance value and statistical data of the calibration curve

Concentration in mcg/ml	Clindamycin phosphate in water	Clindamycin phosphate in phosphate buffer saline pH.6.75
	Mean absorbances	Mean absorbances
5	0.018 ± 0.0012	0.023 ± 0.0034
10	0.036 ± 0.0019	0.041 ± 0.0026
15	0.053 ± 0.0023	0.061 ± 0.0017
20	0.07 ± 0.0016	0.08 ± 0.0015
25	0.087 ± 0.0009	0.1 ± 0.0037
30	0.103 ± 0.0025	0.118 ± 0.0026

REFERENCES

- Vladimir Zbinovsky and George P. Chrekan, Minocycline hydrochloride, In Analytical profile of drug substances, 6th Edn., Florey K., Academic Press, New York, 1977.
- 2005 USPC, Inc. Official 8/1/05- 12/31/05 USP Monographs: Minocycline hydrochloride; page 1298.



***Corresponding Author:**

K.S.Nataraj

Shri Vishnu College of Pharmacy,
Bhimavaram-534202, West Godavari District