



International Journal of Pharmaceutical Research & Analysis

e-ISSN: 2249 – 7781
Print ISSN: 2249 – 779X

www.ijpra.com

SPECTROPHOTOMETRIC ESTIMATION OF CYCLOPHOSPHAMIDE IN CAPSULE DOSAGE FORM

Thangabalan B, Harini A L*, Manohar Babu S.

SIMS College of Pharmacy, Mangaldas Nagar, Guntur-522 001, Andhra Pradesh, India.

ABSTRACT

A spectrophotometric method for the analysis of cyclophosphamide in pure form and in capsule has been developed using 0.1N HCl as solvent. The chromogen exhibited absorption maxima at 263 nm. Beer's law was obeyed in the concentration ranges of 10-50 µg/ml. The proposed method was successfully applied for determination of the cyclophosphamide in their pharmaceutical formulations. The method is simple, precise and accurate and not having interference in adjuvants in capsules.

Keywords: Cyclophosphamide, UV spectrophotometry, .

INTRODUCTION

N,N-bis(2-chloroethyl)-1,3,2-oxazaphosphinan-2-amine Cyclophosphamide (the generic name for Endoxan, Cytoxan, Neosar, Procytox, Revimmune), also known as cytophosphane, is a nitrogen mustard alkylating agent, from the oxazophorines group. Cyclophosphamide also decreases the immune system's response to various diseases and conditions. Therefore, it has been used in various non-neoplastic autoimmune diseases where disease-modifying antirheumatic drugs (DMARDs) have been ineffective. Cyclophosphamide (INN, trade names Endoxan, Cytoxan, Neosar, Procytox, Revimmune), also known as cytophosphane, is a nitrogen mustard alkylating agent, from the oxazophorines group [1-3]. A survey of literature revealed a HPLC estimation in formulation [4,5]. The aim of the study was to develop a simple, precise and accurate spectrophotometric method for the estimation of cyclophosphamide in bulk drug and in pharmaceutical dosage form.

EXPERIMENTAL

Apparatus

T60 UV-Visible Spectrophotometer with 1 cm matched quartz cells were used for all spectral

measurements. Digital Balance: BL-220H, Shimadzu was used.

Materials

All chemicals used were of analytical reagent grade. The chemical reagents prepared on the day of experiment.

Procedure

Accurately weighed 50 mg of cyclophosphamide was dissolved in sufficient quantity of 0.1N HCl and the solution was diluted to 100 ml with same to obtain 500 µg/ml of stock solution. From this various aliquots were accurately measured and transferred in to a series of 10 ml volumetric flasks by means of a micro burette. The volume was brought up to the mark with 0.1N HCl to get the concentration range of 10, 20, 30, 40, 50 µg/ml, mixed thoroughly and absorbance of each concentration was measured at 263 nm against 0.1N HCl as blank. A calibration graph was constructed by plotting the absorbance against the concentration of the drug.

Procedure for pharmaceutical formulation

For analysis of capsule formulation, 20 capsules of cyclophosphamide were weighed accurately and finely powdered.

An accurately weighed portion of powdered sample, equivalent to 10 mg of cyclophosphamide was dissolved in sufficient quantity of 0.1N HCl, sonicated for 20 minutes; the resultant was filtered through whatman filter paper No. 41 and washed with same. The filtrate and washings were combined and the final volume was made to 100 ml with the same. Suitable concentration was analyzed as per the procedure given above.

RESULTS AND DISCUSSION

The calibration graph was plotted. The optical characteristics of this method are summarized in table 1. The drug content of the formulation and recovery studies were conducted. The results are presented in table 2. Linear regression of absorbance with concentration gave a correlation coefficient of 0.999 and RSD was found to be less than two.

Table 1. Optical characteristics of proposed method

Parameters	Values
λ_{\max} (nm)	263
Beer's law limit ($\mu\text{g/ml}$)	10-50
Sandell's sensitivity ($\mu\text{g/cm}^2/0.001$ absorbance unit)	3.3991×10^{-2}
Molar absorptivity (l/mol/cm)	2.5821×10^3
Regression equation ($Y = a + bc$)	
Slope (b)	0.0121
Intercept(a)	-0.0052
Correlation coefficient (r^2)	0.999

Table 2. Assay and recovery of cyclophosphamide

Dosage form	Labeled amount(mg)	*Amount found		Percentage recovery
		mg	%	
Cyclophosphamide capsules	50	49.98	99.81	99.21-100.99

*Each value is an average of six determinations.

CONCLUSION

The method developed in the present work was found to be, accurate, precise and reproducible and can be used for routine determination of Cyclophosphamide in pure and in formulation.

ACKNOWLEDGEMENTS

The Authors are thankful to the management SIMS Group of Institutions, Guntur, for providing necessary facilities to carry out the research work.

REFERENCES

- Nicolini A, Mancini P, Ferrari P. Oral dose cyclophosphamide in metastatic hormone refractory prostate cancer (MHRPC). *Biomed Pharmacother*, 58, 2004, 447-50.
- Nelius T, Klatte T. Clinical outcome of patients with docetaxel- resistant hormone-refractory prostate cancer treated with second-line cyclophosphamide-based metronomic chemotherapy. *Medical Oncology*, 27 (2), 2009, 363-7.
- Cohen JL, Jao JY. Enzymatic basis of cyclophosphamide activation by hepatic microsomes of the rat. *Journal of Pharmacology and Experimental Therapeutics*, 174 (2), 1970, 206-10.
- Dhakane VD, Ubale MB. Development and validation of a reverse phase high performance liquid chromatographic method for the estimation of cyclophosphamide in bulk drug. *International Journal of Pharmacy and Pharmaceutical Sciences*, 5(2), 2013, 184-187.
- Ahmad M, Usman M, Madni A, Zubair M, Qamar-uz-Zaman, Qureshi MS, Munir A, Ahmad M and Mahmood A. A fast and simple HPLC-UV method for simultaneous determination of three anti-cancer agents in plasma of breast cancer patients and its application to clinical pharmacokinetics. *African Journal of Pharmacy and Pharmacology*, 5(7), 2011, 915-922.