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UV-Spectrophotometric determination of Alfuzosin hydrochloride in bulk and tablets

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ABSTRACT

A simple, rapid, sensitive and accurate UV- spectrophotometric method has been developed for estimation of alfuzosin hydrochloride from pharmaceutical formulations. In 0.1M NaOH, alfuzosin hydrochloride showed absorbance maxima at 350 nm. Linearity was observed in the concentration range of 10-30 µg/ml (r^2=0.999914). The amount of drug estimated from the formulation was found to be in the good agreement with label claim. The recovery studies were carried out at three different levels i.e. at 50%, 70% and 90%. The method was validated statistically.

Key words: UV- spectrophotometric method, Alfuzosin hydrochloride.

INTRODUCTION

Alfuzosin hydrochloride[1], (R,S)-N-[3-[(4-amino-6,7-dimethoxy-2-quinazolinyl) methylamino] propyl] tetrahydro-2-furan carboxamide hydrochloride is antagonist of α_1 adrenergic receptors used in the treatment of prostatic hyperplasia[1-3]. Alfuzosin hydrochloride is official in BP 2003. Litrature survey revealed chromatographic and non-aqueous methods for estimation of alfuzosin hydrochloride in bulk, pharmaceutical formulations and biological fluids[4-8].

Present work deals with UV-spectrophotometric method for estimation of Alfuzosin hydrochloride from bulk and tablets.

METERIAL AND METHOD

Instrumentation

Spectral and absorbance measurements were made with Shimadzu UV-Visible Double beam Spectrophotometer model- 1700 with pair of 10mm matched quartz cells.

Reagents

All the chemicals used were of analytical grade. All the solution were freshly prepared with double distilled water. Pure raw material of alfuzosin hydrochloride was obtained as a gift sample from Aurobindo Pharma Limited, Hyderabad. The formulations used were purchased from local pharmacy.

Preparation of standard stock solution

Standard stock solution was prepared by dissolving 25mg of alfuzosin hydrochloride in 100 ml of 0.1M NaOH to get concentration of 250 µg/ml. Different aliquots were taken from the stock solution and diluted to 25 ml mark with same solvent to obtain series of concentration. The solutions were scanned on spectrophotometer-1700 (Shimadzu) in the UV range 200-400 nm and absorbances were recorded at 350nm against blank.

Preparation of sample solution

For analysis of commercial formulations, twenty tablets were weighed, average weight was determined and crushed into fine powder.

A quantity of tablet powder equivalent to 25 mg of alfuzosin HCl was transferred into 250 ml volumetric flask, added 50 ml of 0.1 M NaOH and sonicated for five minutes and repeated the sonication consequently by four times (4×50 ml) to produce 250 ml. The solution was filtered through whatmann filter paper no.41. After appropriate dilutions, absorbance of the sample solutions were recorded at 350 nm and the concentration of the drug was calculated from linear regression equation; results are shown in Table 1.

Recovery studies

To study the accuracy of the proposed method, recovery experiments were carried out by adding a known amount of drug to pre analysed sample at three levels and the percentage recoveries were calculated; the results are summarized in Table 2.

Table 1: Results of assay

Formulation	Label claim (mg/tablet)	*Amount found(mg) ±SD	Amount found(%)
Alfoo(ER)	10	9.81±0.1629	98.10
Alfusin(ER)	10	9.97±1.315	99.68
Xelflo(ER)	10	10.00±1.188	100.00

*mean of six observations

Table 2: Summary of validation

Parameters	Results		
	Alfoo	Alfusin	Xelflo
Linearity range(µg/ml)	10-30	10-30	10-30
Accuracy(%Recovery)*	100.05±1.668	100.81±0.957	99.49±1.454
%RSD	1.663	0.951	1.462
Precision(%RSD)			
Intra-day(n=3)	0.4925	0.3991	0.2448
Inter-day(n=3)	0.3410	0.3991	0.2548
Repeatability(n=6)	0.1660	1.31	1.187

* mean of three estimation at each levels.

RESULTS AND DISCUSSION

The λ_{max} of alfuzosin hydrochloride in 0.1M NaOH was found to be 350 nm. The drug follows linearity in the concentration range of 10-30 µg/ml (Y=0.01336×+0.0088; r^2=0.999914). The analysis of tablet formulations by proposed method was in good agreement with label claim. The recovery studies were carried out at three different levels i.e. 50%, 70% and 90%.The low values of %RSD are indicative of the accuracy of the method. Recovery experiments indicated the absence of interferences from the commonly encountered pharmaceuticals additives and excipients. The precision of the method was studied as an intra-day and inter-day precision. The results from validation studies are shown in Table 2.

The proposed method is simple, rapid, accurate, economical and useful for the routine analysis of alfuzosin hydrochloride from marketed formulations.

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REFERENCES

1. Sweetman S.C., Eds, Martindale-The complete Drug Reference. 33rd edn. Pharmaceutical Press, London (UK), 154 (2002).
2. Onil M.J., Eds, The Merck index-An Encyclopedia of Chemicals, Drugs and Biologicals. 13th edn. Merck &co., Inc 161 (2001).
3. Anthony, M.M., David O. and Brion W., Clarke's Analysis of Drugs and Poisons in Pharmaceutical Body fluids and Postmortem Material. 3rd edn. Varghese Company, Mumbai, 598-599 (1996).
4. British Pharmacopoeia, Volume.1, The Department of Health, London, 81 (2003).
5. Wei, X., Yin, Yang, G., He, C. and Chen, Y. "Online solid phase extraction with a monolithic weak cation-exchange column and simultaneous screening of alpha1 adrenergic receptor antagonist in Human Plasma". *J. Sep. Sci.* **30**(17): 2851-7(2007).
6. Wiesner, J. L., Sutherland, F. C. W., Van Essen, G. H., Hundt, H. K. L., Swart, K. J. and Hundt, A. F. "Selective ,sensitive and rapid liquid chromatography -Tandem mass spectrometry method for the determination of Alfuzosin in human plasma". *J Chromatogr B Analyt Technol Biomed Life Sci*. **788**(2): 361-8 (2003).
7. Salah Fayed, A., Abdel Aaty Shehata, M., Yehia Hassan, N. and El-Weshahy, Sa. "Validated HPLC and HPTLC stability indicating methods for determination of Alfuzosin HC1 in bulk and pharmaceutical formulation". *J. Sep. Sci.* **29**(18): 2716-24 (2006).
8. Chandra, A., Channabasavaraj, K. P., Manohara, Y. N. and Ankita, S. M. "Development and validation of RP-HPLC method for the estimation of Alfuzosin HC1 in bulk and tablets". *Indian Drugs*. **44:** 555-558 (2007).