

A VALIDATED UV SPECTROPHOTOMETRIC METHOD FOR THE DETERMINATION OF LETROZOLE IN BULK AND SOLID DOSAGE FORM

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ABSTRACT

A simple, sensitive, spectrophotometric method in UV region has been developed for the determination of Letrozole in bulk and tablet dosage form. Standard solution of Letrozole shows maximum absorbance at 240nm with apparent molar absorptivity of 3.3016×10^4 l/mol/cm. Beers law was obeyed in the concentration range of 1 -10 µg /ml with regression, slope and intercept 0.9998, -0.016, 0.1164 respectively. Result of the analysis was validated statically and by recovery studies. The results percentage recovery is 100.63 ± 0.4215 which shows that the method is free from interference of additives and impurities during the estimation of drug in formulation. This shows the adoptability of the method for the routine quality control analysis of the drug in bulk and in formulation.

Keywords: Letrozole, UV determination, bulk, tablet formulation.

INTRODUCTION

Letrozole is 4, 4' – (1H-1, 2, 4-triazole-1yl methylene) dibenzonitrile (Fig-1). It is an anti-cancer agent, which is used for the treatment for the breast cancer caused by the hormonal imbalance^{1,2}. It is a nonsteroidal competitive inhibitor of the aromatase enzyme system (adrenal androgens) there by inhibiting the biosynthesis of estrogen. A few HPLC method have been reported for Letrozole in biological fluids³⁻⁸. There is no UV method of estimation reported for Letrozole. The present study is aimed to develop and selective, precise accurate and reliable UV method for determination of Letrozole in bulk and solid dosage forms.

EXPERIMENTAL

Instruments and reagents: An Elico UV –Visible spectrophotometer SL-164, with 1cm matched quartz cells was used for the absorbance measurements, All the chemicals used were of analytical grade. Pure letrozole obtained as a gift sample from Sanmar chemicals Chennai, two commercial samples of the drug tablets were procured from the market.

Standard Preparation: 100mg of pure drug was transferred to a 100ml standard volumetric flask. Small amount of absolute ethanol was added to dissolve the drug. Then the volume was made up to the mark with absolute ethanol to get stock solution.

Sample preparation : Twenty tablets were weighed and powdered well from that powder equivalent to 100mg of Letrozole was transferred to a 100ml standard volumetric flask. Add small amount of absolute ethanol and make up to mark with ethanol to get stock solution (1mg/ml) from this stock 6 µg/ml was prepared for the estimation.

Method Development: From this standard stock solution, aliquots of solution were taken and diluted to get different concentrations like 2,4,6,8 and 10 µg/ml. The standard solutions were scanned between 200-400nm, they showed λ -max at 240nm (fig-2), which was used for the further measurement. The solutions obey Beer's law in the concentration range of 1-10µg/ml with the regression of 0.9998. The optical characteristic of the solution is given in table -1 (fig-3).

The same procedure was followed for the estimation of Letrozole tablets by using the sample solution prepared. The results of analysis were given in Table -2.

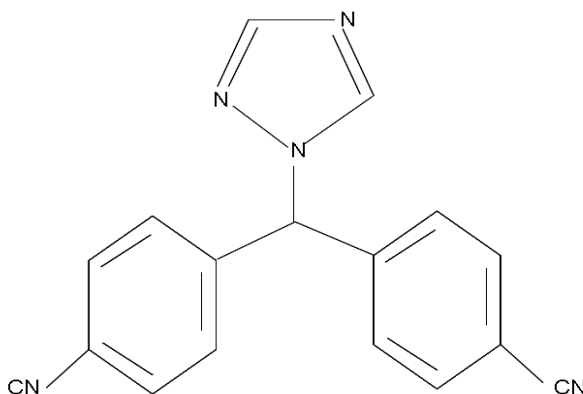


Fig-1. Structure of Letrozole

RESULTS AND DISCUSSION

The optical characteristics like lambda max, Beer's law limits, molar The accuracy of the method was evaluated by conducting recovery studies by adding known amount of pure drug to the previously analyzed tablet formulation and the mixtures were analyzed by the proposed method. The percent recoveries, assay percentage standard deviation of the assay were summarized in are given Table-2. The placebo study proved that there is interference of additives like diluents, preservatives, binders and coloring agent in the formulation during the assay.

The proposed UV-spectrophotometric procedure for the determination of Letrozole is found to be very simple, accurate, sensitive, economical and reproducible, which can be used in the determination of Letrozole in bulk and in its formulation.

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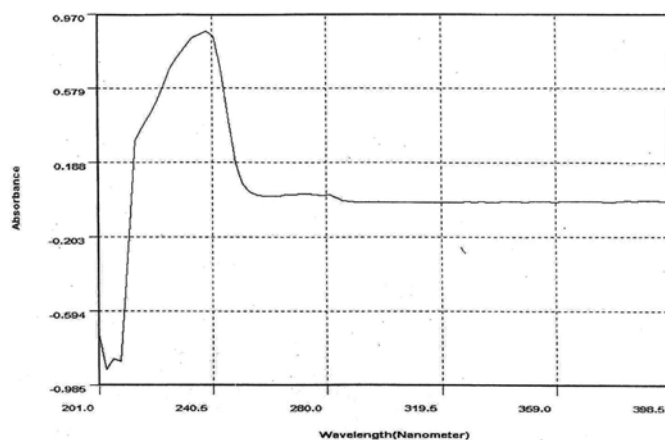


Fig-2. UV-ABSORPTION SPECTRA OF LETROZOLE

Table -1 :Optical Characteristics

Parameters	Values
Absorbance Maximum(λ -max)	240nm
Beer's law limit ($\mu\text{g/ml}$)	1-10
Molar absorptivity L/mol/cm	3.3016×10^4
Correlation coefficient (r)	0.9998
Slope (m)	-0.016
Intercept(c)	0.1164

Table-2.Results of Assay, recovery and precision.

Sample	Labelled amount	Amount found (mg/tab)*	Assay*	Percentage	Precision**	
			%	Recovery	Inter-day	Intraday
1.	2.5mg	2.492	99.66 ± 0.463	100.63 ± 0.2884	0.4215	0.3424

*SD- mean of six determinations, ** Percentage RSD of Six determination

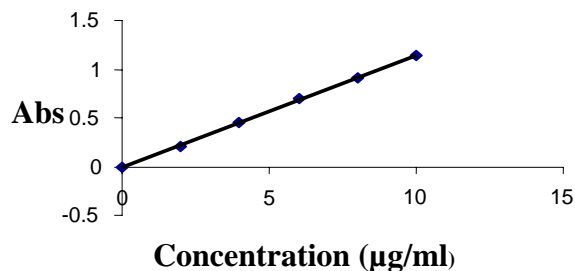


Fig-3. Calibration Graph of Letrozole

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