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Simple UV Spectrophotometric Method For Estimation of Ormeloxifene Hydrochloride in Bulk and Pharmaceutical Dosage Forms

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Abstract

A simple and sensitive UV Spectrophotometric method have been developed for the estimation of ormeloxifene hydrochloride in pure and pharmaceutical dosage forms, using methanol as solvent. This method is based on the UV absorption maximum at 281nm. The absorbance of the UV is measured against the corresponding reagent blank. The method was validated statistically and by recovery studies .The LOD (limit of detection) and LOQ (limit of quantification) for Ormeloxifene hydrochloride were found to be 0.4µg/ml and 1.2µg/ml, respectively. The correlation coefficient value was found to be 0.9999. The % assay was found to be 99.98%. This method have been statistically evaluated and found to be precise and accurate.

Keywords: Ormeloxifene hydrochloride, Methanol, UV-visible spectrophotometer

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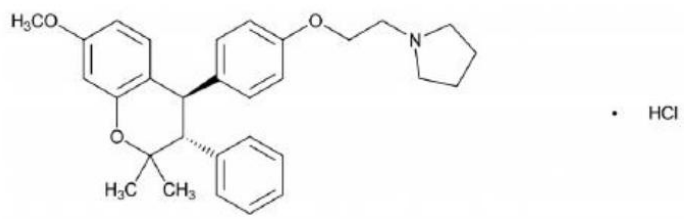
INTRODUCTION

Ormeloxifene hydrochloride pertains to III generation selective estrogen receptor modulator. It shows both agonist and antagonist effects. On uterus and breast it shows potent anti-estrogenic response. Ormeloxifene hydrochloride[1,2] is chemically known as 1-[2-[4-[(3S,4R)-7-methoxy-2,2- dimethyl-3-phenyl-chroman-4-yl] phenoxy] ethyl] pyrrolidine. Literature review was carried out to enumerate the reported analytical methods for the selected drug Ormeloxifene hydrochloride in Biological fluids & Pharmaceutical dosage forms. Determination of ormeloxifene by LC-MS/MS in rat plasma,[3] Pharmacokinetic activity on rats,[4] and HPLC methods in formulations,[5,6] has been reported so far, hence the author made an attempt to develop a simple and more economic UV method for estimation of ormeloxifene hydrochloride in pharmaceutical dosage forms available in the market.



Structure of Ormeloxifene hydrochloride

EXPERIMENTAL

The instruments used in the present study were Shimadzu UV-1800 Double Beam Spectrophotometer equipped with 1cm matched quartz cells, SHIMADZU AX200 single pan balance for weighing purpose. All the apparatus and instruments were calibrated and validated before starting the experimental work. Authentic drug sample of Ormeloxifene hydrochloride was given as a gift sample by Torrent Pharmaceuticals Ltd., Sikkim. All chemicals and reagents used were of analytical grade. Tablets of Ormeloxifene hydrochloride were procured from local market.

Preparation of Standard Stock Solution

A standard stock solution (1000µg/ml) was prepared by dissolving accurately 100mg of crude Ormeloxifene hydrochloride in pure methanol and the volume was made upto 100 ml with same solvent. This stock solution was used to prepare a 100µg/ml (stock solution2) solution by diluting 10ml of stock solution to 100ml with methanol. From stock solution 2, transferred aliquots of 1 ml,2 ml,3 ml,4ml,5ml into set of 10ml volumetric flasks and made up to mark with methanol. The contents were shaken for 2 minutes.

Sample preparation:

Twenty tablets were accurately weighed and powdered, equivalent to 100 mg of Ormeloxifene hydrochloride was taken into 100 ml volumetric flask and sufficient amount of methanol was added then the mixture was subjected to sonication for 20 min with intermediate shaking for complete extraction of drug. Sample solution was filtered through whatmann filter paper and solution was made up to mark with methanol. From the above stock solution, 10 ml of sample was pipetted out into 100 ml volumetric flask and the volume was made up to the mark with same solvent. From this suitable concentration of Ormeloxifene hydrochloride was prepared within the linearity range and it was subsequently analyzed using double beam UV-VIS Spectrophotometer at 281 nm against reagent blank and the amount of Ormeloxifene hydrochloride present in the sample solution was computed from its calibration curve.

VALIDATION

After successful development of UV method, it was subjected to method validation as per ICH guideline[7]. Analytical method validation was carried out by means of linearity, LOD and LOQ, accuracy and precision.

RESULTS AND DISCUSSIONS

The over laid spectra of ormeloxifene in methanol was scanned over the range of 220-300 nm, which shows an absorption maximum at 281 nm (Fig.1).

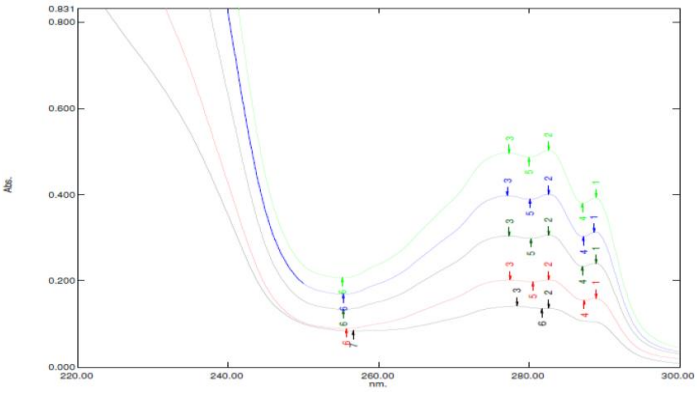


Figure 1: Overlaid Spectrum of Ormeloxifene hydrochloride

In order to check the linearity, calibration curve was plotted by using absorbance values on Y axis, concentration on X-axis (Fig.2).

The method exhibits good linearity with a correlation coefficient 0.9999 which indicates that the method obeys Beers law.The optical characteristics such as Beer's law limits, molar absorptivity, sandell's sensitivity, Limit of detection, Limit of quantification, the regression characteristics like slope (b), intercept (a) and correlation coefficient (r^2) using the method of least square were calculated and presented in Table 1.

Results obtained with proposed method confirm the suitability of this method for Pharmaceutical dosage forms. The accuracy of the method was confirmed by the recovery studies, by adding known amount of pure drug to the Pharmaceutical formulation previously analyzed by this method and the results shown that the method was more accurate (Table 2).

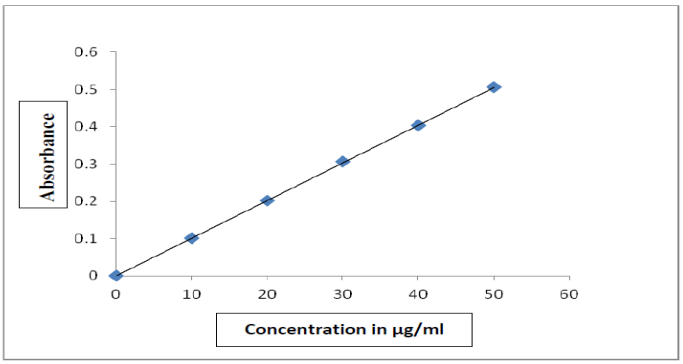


Figure 2: Calibration Curve of Ormeloxifene hydrochloride by UV

Parameter	Result
Absorption maxima(nm)	281 nm
Beer's law limits(µg/ml)	10-90 µg/mL
Standard regression equation	Y=0.01x- 0.0002
Correlation coefficient	0.9999
Sandell's sensitivity (mcg/cm^2/0.001 absorbance unit)	0.099
Molar absorptivity (lit.mol^{-1}cm^{-1})	4.98×10^3
LOD	0.4 µg/mL
LOQ	1.2 µg/mL
Assay (n=6)	99.98%

Table 1: Validation Parameters of Ormeloxifene HCl by UV method

Drug	Concentration of sample (µg/mL)	Level of Addition (%)	Amount of drug added (µg/mL)	Amount * recovered (µg/mL)	%Recovery* ± S.D
Ormeloxifene HCl	10	80	8	8.004	100.05±0.24
	10	100	10	9.998	99.98 ± 0.26
	10	120	12	12.002	100.01 ±0.04

Table 2: Determination of Accuracy of Ormeloxifene hydrochloride
*Average of three determinations

The other common excipients usually present in dosage form of ormeloxifene did not interfere by the proposed method. The precision of the proposed method was checked in terms of inter-day and intra-day, where method was repeated on three different days and also repeated for three different time periods on the same day. The results were given in Table 3, which indicated that the method is more precise. The percentage assay of ormeloxifene was found to be 99.98% and the results were shown in Table 4.

Concn of drug (µg/mL)	Average absorbance in intraday studies** (µg/mL)			Average absorbance in inter day studies** (µg/mL)		
	Sess-I	Sess-II	Sess-III	1st day	3rd day	5th day
20	0.3505	0.3527	0.3512	0.3521	0.3508	0.3514
	SD : 0.0006			SD : 0.0005		
	%RSD : 0.170			%RSD : 0.142		

Table 3: Precision results of Ormeloxifene HCl
**Average of three determinations

Drug	Labeled amount	Amount found*	% Assay*
Ormeloxifene hydrochloride	60 mg	59.99 mg	99.98

Table 4: Summary of assay results
*Average of six determinations

CONCLUSION

The proposed method is applicable for the assay of Ormeloxifene hydrochloride in bulk and pharmaceutical dosage forms and have an advantage of wider range under Beer's law limits. The proposed method is simple, selective and reproducible and thus it can be used in the routine quality control determination of Ormeloxifene hydrochloride in pure and formulations with reasonable precision and accuracy.

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