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Research Article

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A Simple UV Spectroscopic Method for the Determination of Metoprolol in Bulk and Tablets

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ABSTRACT

A simple, economic, accurate UV method was developed for the estimation of Metoprolol in bulk and tablet dosage form. Water is used as a diluent to dissolve metoprolol. The drug mixture was sonicated for 3 mins for the enhanced solubility. The absorptions were observed at 223.0 nm, which was selected for the further analysis of metoprolol in bulk and its tablet dosage forms. The proposed method was validated according to ICH guidelines. The method showed high sensitivity with linearity range from 3 to 18 µg/mL ($r^2=0.999$). The limit of detection (LOD) was found to be 0.29 µg/mL and the limit of quantization (LOQ) was determined as the lowest concentration was found to be 0.97 µg/mL. The reports expressed that the proposed method was found to be simple, precise, accurate and rapid for the estimation of metoprolol in bulk and tablet dosage form using UV spectroscopy.

Keywords: Metoprolol, water, UV spectroscopy, ICH guidelines.

ARTICLE INFO

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1. Introduction

Metoprolol (MTP) is chemically (2S)-1-[4-(2-Methoxy ethyl)phenoxy]-3-[(1-methyl ethyl) amino]-2-propanol succinate (Figure 1).[1] It is a cardioselective 1-adrenergic blocking agent used for acute myocardial infarction (MI), heart failure, angina pectoris and mild to moderate hypertension. It may also be used for supraventricular and tachyarrhythmia and prophylaxis for migraine headaches. It is structurally similar to bisoprolol, acebutolol and atenolol in that it has two substituents in the para position of the benzene ring. At low doses, metoprolol selectively blocks cardiac 1-adrenergic receptors with little activity against 2-adrenergic receptors of the lungs and vascular smooth muscle. Receptor selectivity decreases with higher doses. Metoprolol possesses a single chiral center and is administered. From the literature survey, it was found that MTP estimated by analytical methods such as spectrophotometric methods [2-4], reversed-phase high-performance liquid chromatographic (RP-HPLC) method [5] and GC-MS method [6]. The aim of this study was to develop and validate a simple UV method, to quantify MTP

in pure form and pharmaceutical formulation (tablets). The proposed method was validated according to ICH guidelines [7-10]. The validated method was applied to the analysis of tablets containing metoprolol.

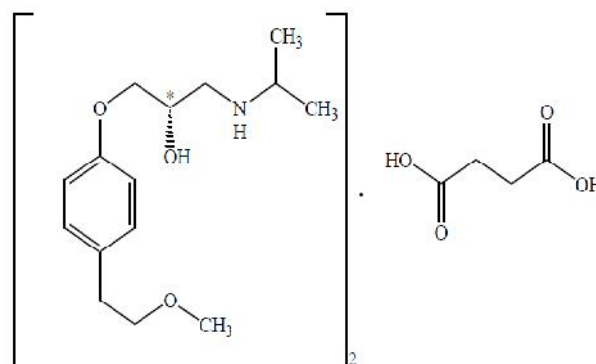


Figure 1: Chemical structure of Metoprolol

2. Materials and Methods

Instruments and reagents

An analytically pure sample of MTP was procured as gift sample from Aurobindo laboratories (Hyderabad, India). Distilled water was prepared in house. A PG Instruments T-60 UV/VIS spectrophotometer was used with 1 cm matched quartz cell. Tablet formulation [Selokeen XL, Astragenica Pharma Ltd, India] was procured from a local pharmacy with labeled amount 25 mg per tablet. Water was used as a diluent to dissolve MTP.

Preparation of working standard drug solution

50 mg of standard MTP was weighed accurately and transferred to a 50 ml volumetric flask. It was dissolved properly and diluted up to the mark with diluent to obtain final concentration of 1000 µg/ml. 9 µg/ml solution was prepared from the stock solution which was used as working standard.

Analysis of marketed formulations

For the estimation of Metoprolol in tablets formulations, 20 tablets were weighed and triturated to fine powder. Tablet powder equivalent to 50 mg of Metoprolol was weighed and transferred into 50 ml volumetric flask then dissolved in diluent. It was kept for sonication for 3 min; this was filtered through Whatman filter paper No. 41 and then final dilution was made with diluent to get the final stock solution of 1000 µg/ml. From this stock solution, 9 µg/ml sample solution were prepared and analysed.

Validation

Method validation was performed in terms of specificity and selectivity, precision and accuracy, linearity, LOD & LOQ.

3. Results and Discussion

MTP has the zero order absorbance spectra maxima (figure 2 and 3) at 223.0 nm. The polynomial regression data for the calibration plots showed good linear relationship in the concentration range of 3-18 µg/ml with correlation

Linearity and range

Calibration standards of MTP, covering the range 3-18 µg/mL were prepared with the suitable dilution made from MTP stock solution. The calibration curves were obtained by plotting the intensity of absorbance against of concentration of MTP. The slope and intercept of the calibration line were determined by linear regression using the least squares method.

Specificity and selectivity

The interference from endogenous compounds was investigated by the analysis of tablets of various concentrations.

Precision

The intra & inter-day precision was evaluated by analyzing six sample solutions ($n = 6$), at the final concentration of analyses (9 µg/ml) of MTP. The MTP concentrations were determined and the % relative standard deviations (% RSD) were calculated.

Accuracy

MTP reference standards were accurately weighed and added to a mixture of the tablets excipients, at three different concentration levels (4.5, 9 and 13.5 µg/ml of metoprolol). At each level, samples were prepared in triplicate and the recovery percentage was determined.

Detection and quantitation limits

Limit of detection LOD and limit of quantification LOQ were calculated by using the standard deviation from the precision and the slope of linearity.

coefficient (r^2) was found to be higher than 0.999 and the linearity curve was shown in figure 4. Recovery studies were carried out at three different levels i.e. 50 %, 100 %, and 150 % by adding the pure drug to the previously

analysed tablet powder sample. Percentage recovery for Metoprolol was determined by the method and it was found to be under acceptance criteria (98% to 101%) according to ICH guidelines [10]. The results of accuracy wereshown in table 2. The percentage recovery value indicates noninterference from excipients used in formulation. The precision was carried out as described in method and the results were presented in table 1. The values obtained in the repeatability (precision) shows that there is no significant

difference in the precision values; hence the developed method can be used to analyze the MTP in tablet formulation. The mean assay of the precision value is 99.47%. The LOD determined as the amount drug was found to be 0.29µg/mL and the LOQ was determined as the lowest concentration was found to be 0.97 µg/mL in formulation. The summary of all the optical characterizes were shown in table 2.

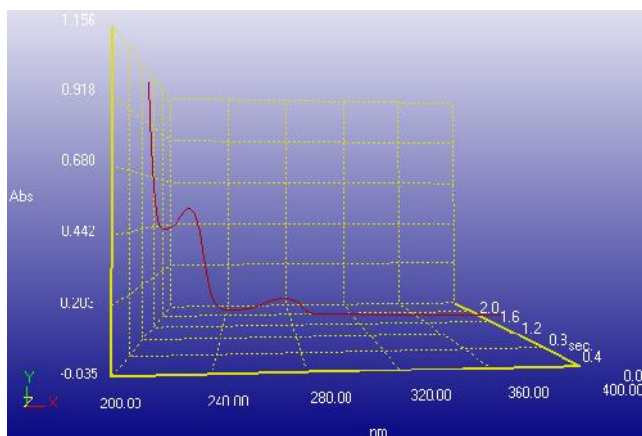


Figure 3: max (3-D view) curve of Metoprolol

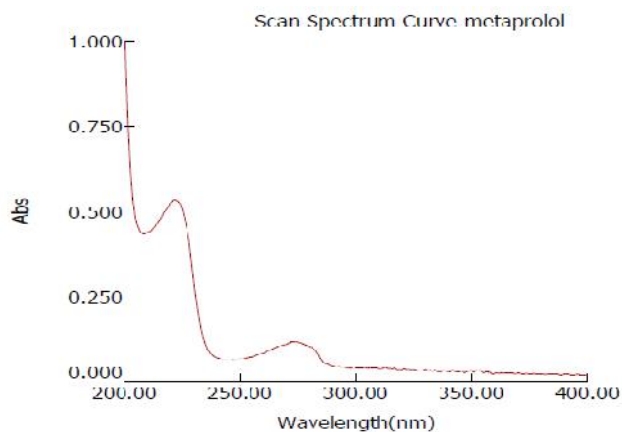


Figure 4: max curve of Metoprolol

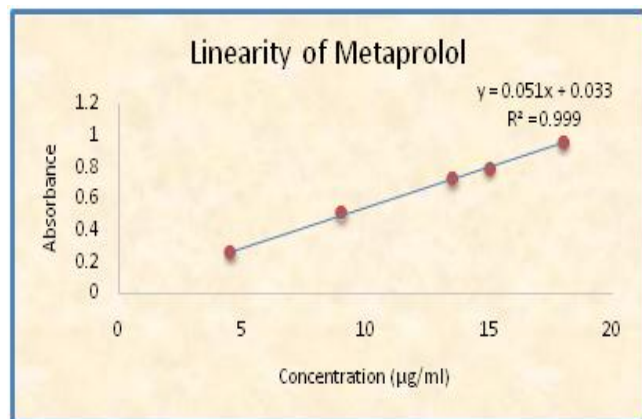


Figure 4: Linearity curve of Metoprolol

Table1: Results of Precision

Sample No.	Sample Abs - 1	% Assay - 1
1	0.503	99.05
2	0.511	100.62
3	0.502	98.85
4	0.505	99.44
5	0.498	98.06
6	0.512	100.82
Avarage Assay:		99.47
STD		1.07
% RSD		1.07

Table 2: Summary of Optical characteristics and Other Parameters

S No.	PARAMETERS	RESULTS
1	Absorption Maxima (nm)	223
2	Beer's-Lambert's range (µg/ml)	3-18
3	Regression equation (y)*	y = 0.0514x + 0.0335
4	Slope (b)	0.0514
5	Intercept (a)	0.0335
6	Correlation coefficient (r ²)	0.9991
7	Intraday precision (% RSD)**	1.07
8	Interday precision (% RSD)**	1.11
9	Accuracy (% mean recovery)	99.47
10	Limit of detection (µg / ml)	0.29
11	Limit of quantification (µg / ml)	0.97
12	Assay of tablets (%Purity)	100

*y = a + bx; when x is the concentration in mg/ml and y is absorbance unit.

**Average of six determinations.

4. Conclusion

The most striking features of the method was its simplicity and rapidity, non- requiring consuming sample preparations such as extraction of solvents, heating, degassing which are needed for HPLC or other procedures. It can be concluded that the proposed methods was fully validated and found to be simple, sensitive, accurate, precise, reproducible, rugged and robust and relatively inexpensive. So, the developed method can be easily applied for the routine Quality Control analysis of MTP in pharmaceutical preparations.

5. Acknowledgement

We would like thank to Aurobindo laboratories, Hyderabad for providing reference sample of MTP to facilitate this work and also to the Principle Dr. Hindustan Abdul Ahad, Balaji College of Pharmacy, Anantapur for providing facilities to carry out this research work.

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