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Spectrophotometric Determination of Moprolol in Pure Form and Pharmaceutical Formulations

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A simple specific, precise and accurate spectrophotometric method has been developed for the estimation of moprolol in bulk and tablet dosage form. In the developed method DMF and water was used as the solvent. The absorption maximum of the drug was found to be 273 nm. The method was statistically validated according to international conference on harmonization (ICH) guidelines. Per cent mean recovery was obtained to be 99.1 %, whereas the coefficient of variance was found to be less than 2 %. The drug follows a linear Lambert-Beer law relationship with respect to the drug concentration in the range of 10-70 µg/mL, with linearity coefficient of 0.9999.

Key Words: Spectrophotometry, Moprolol.

INTRODUCTION

Moprolol belongs to β-adrenergic blocking agent that inhibits the adrenergic response mediated through the β-receptors. Chemically moprolol is 1-(2-methoxy-phenoxy)-3-[(1-methyl-ethyl)amino]-2-propanol, 1-(isopropyl amino)-3-(O-methoxy-phenoxy)-2-propanol[1]. It is clinically useful in the treatment of ocular hypertension, ischemic heart disease, congestive heart ischemic heart failure and certain arrhythmias[2]. No such simple, sensitive and precise spectrophotometric method is yet reported for this in any official literature. So in the present study, a specific, precise, accurate and validated spectrophotometeric method has been developed for the estimation of moprolol in bulk and tablet dosage form, using DMF and water as the solvent system.

EXPERIMENTAL

All spectral and absorbance measurements were made on a Shimadzu UV/visible double beam spectrophotometer (model 1700) with 1 cm matched quartz cells were used for all the spectral measurements. Shimadzu-AX-200 electronic balance was used for weighing the samples.

Ultrasonicator was used in the initial steps of extraction. Whatman filter paper no. 41 was used to filter the solution. All the chemicals used were of analytical

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grade procured from Qualigens Fine chemicals, Mumbai. Double distilled water, dimethyl formmide (DMF) was used. The pharmaceutical grade of moprolol was supplied as a gift sample by Sequent Scientific Speciality Chemicals Ltd., Mangalore. As this drug has no marketed formulations yet, we have prepared tablets (Tablets-1 and 2) by varying the ratio of using most commonly used excipients like starch, MCC, talc and magnesium stearate by keeping the strength as constant (25 mg of moprolol) and analyzed the drug.

Preparation of standard solution of moprolol: Accurately weighed 25 mg of moprolol was transferred to 25 mL volumetric flask. Drug was then dissolved and made up to the volume to 25 mL with DMF. It was further diluted to a concentration of 100 µg/mL with distilled water, which was then used as the stock solution for the further dilutions.

Determination of wavelength of maximum absorbance of moprolol: Form the above prepared standard moprolol solution 2 mL was transferred to 10 mL volumetric flask and diluted to 10 mL with distilled water. The absorbance of the final solution was scanned in the range 200-400 nm against distilled water as blank. The absorbance maximum of drug was found to be 273 nm.

Preparation of calibration curve for moprolol: Dilutions of the standard moprolol solution were prepared (2, 4, 6, 8 and 10 mL) diluted to 10 mL using distilled water in the range of 20-100 µg/mL in a series of 5 dilutions in volumetric flasks of capacity 10 mL. The absorptions of the solutions were measured at 273 nm using distilled water as blank. The absorbance values are shown in Table-1.

TABLE-1
CALIBRATION CURVE FOR MOPROLOL

Concentration (µg/mL)	Absorbance
20	0.187
40	0.374
60	0.556
80	0.750
100	0.935

Estimation of moprolol from tablets: 20 Tablets of moprolol (of same batch) were taken and the average weights of these tablets were determined. Then these tablets were finely powdered and triturated well. A quantity of powder equivalent to 50 mg of moprolol was transferred to 25 mL volumetric flask and mixed with DMF and there after the volume was made up to 25 mL with the same solvent. The solution was filtered through Whatmann filter paper no. 41. From the filtrate, 4 mL was transferred and diluted to 10 mL mark with distilled water in 10 mL volumetric flask to get a solution of 40 µg/mL concentration. The absorbance of this solution was measured at 273 nm using distilled water as blank. The amount of drug present in the tablet was calculated using the standard calibration curve of the drug.

Recovery studies and validation of the method according to ICH guidelines: Precision of the newly developed method was studied by carrying out intraday, interday analysis and expressed as per cent coefficient of variance[9]. Specificity of the method was checked by adding few excipients with in the range as specified in standard literature which are usually added in the preparation such as diluents, lubricant *etc*. to the preanalyzed samples. The absorbance of the solution so obtained after addition of excipients was then measured, compared with that of the absorbance of preanalyzed solution and the specificity was expressed in terms of per cent interference, which was found to be less than 2 % limit of detection (LOD) and limit of quantification (LOQ) were studied based on standard deviation of the response and slope curve. Recovery studies were carried out by addition of standard drug (spiking) to preanalyzed samples of the prepared formulation, taking into consideration the percentage purity of the added bulk drug.

RESULTS AND DISCUSSION

The linear regression equation for moprolol standard curve was calculated by y = 0.00977x + 0.00233 (R^2 = 0.99995), where y = absorbance and x = value of various concentrations of standard solutions using UV spectrophotometeric method. The value of regression coefficient from the above straight-line equation depicts the linearity of the data range and for given data it shows that the Lambert-Beer law follows a linear relationship for moprolol in the range of 20-100 µg/mL (Table-2).

TABLE-2
OPTICAL CHARACTERISTICS, PRECISION AND ACCURACY OF THE PROPOSED METHODS

Parameters	Observations
λ_{max} (nm)	273
Beer's law limits (µg mL^{-1})	20-100
Molar absorptivity (L mol^{-1} cm^{-1})	3.6×10^3
Sandell's sensitivity (µg mL^{-1} cm^{-2} 0.001 absorbance unit)	0.1024
Regression equation (Y*)	
Slope (b)	0.00977
Intercept (a)	0.00233
Correlation coefficient (r)	0.99995
Precision (% coefficient of variance)	
Repeatability	0.284
Intraday	1.03
Interday	1.11
% RSD	0.365
Range of errors**	
Confidence limits with 0.05 level	0.00457
Confidence limits with 0.01 level	0.00672
Limit of detection (µg/mL)	1.299
Limit of quantification (µg/mL)	0.394

Y = bC + a where C is the concentration of moprolol in µg/mL and Y* is the absorbance unit.

For precision, repetability, intraday/interday, three replicate experiments were carried out and their % RSD readings were calculated at the selected λ_{max}. The low value of % RSD revealed good precision, as shown in Table-3. The results of the estimation of moprolol in the prepared formulation are summarized in Tables 3 and 4.

TABLE-3
RECOVERY STUDIES

Drug	Amount added (mg)	Amount present (mg)	Mean amount found* (mg)	Mean recovery (%)
Moprolol	20	20	19.98	99.90
	30	20	29.59	98.60
	40	20	39.63	99.08

*Mean of five replicates.

TABLE-4
ASSAY OF FORMULATIONS

Formulation	Label claim (mg)	Amount estimated (mg)	Mean (±SD) mean (mg) found by	Mean (± SD) % labelled amount*
Tablet 1	25	24.95	24.99 ± 0.2017	99.96 ± 0.806
Tablet 2	25	24.79	24.81 ± 0.7720	99.24 ± 0.044

*Mean of five replicates.

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