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DEVELOPMENT AND VALIDATION OF SPECTROPHOTO-METRIC METHOD FOR DETERMINATION OF AMISULPRIDE IN PHARMACEUTICAL DOSAGE FORMS

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ABSTRACT

A simple and sensitive UV spectrophotometric method has been developed for the quantitative estimation of amisulpride in bulk drug and pharmaceutical dosage forms (tablets). Amisulpride exhibited absorption maximum at 226.5 nm in 0.1 N HCl and obeyed Beer's law in concentration range 2-10 μg/mL. The result of analysis in this method has been validated statistically and by recovery studies. This method is extended for the analysis of drug in pharmaceutical formulations.

Key words: Amisulpride, Validation, Spectrophotometric

INTRODUCTION

Amisulpride [1-3] is chemically 4- amino-N- {[(2RS) –1-ethyl pyrolidin-2-yl] methyl}-5 (ethyl sulphonyl)-2-methoxy benzamide, which is used in the treatment of schizophrenia. This drug is reported to have high affinity for dopamine D_2/D_3-receptor antagonist. No reports were found in the literature for its quantitative estimation by HPLC, HPTLC and spectrophotometry. In the present work, a simple and sensitive UV spectrophotometric method has been developed for the quantitative estimation of amisulpride in bulk drug and pharmaceutical dosage forms. In this method, amisulpride exhibits absorption maximum at 226.5 nm in 0.1 N HCl and obeyed Beer's law in concentration range 2-10 μg/mL. The result of analysis in this method has been validated statistically and by recovery studies. The method is extended for the analysis of drug in pharmaceutical formulations.

EXPERIMENTAL

All spectral measurements were done on Shimadzu UV-Vis spectrophotometer Model UV-1700.

Reagents: Analytical grade reagents were used. Commercially available samples were purified.

(i) Hydrochloric acid (0.1 N, Ranbaxy).

(ii) Double distilled water

Working standard of drug solution

About 100 mg of amisulpride was accurately weighed and dissolved in 20.0 mL of 0.1N HCl in a 100 mL volumetric flask and diluted up to the mark with 0.1N HCl (1 mg/mL). The final concentration of amisulpride was brought to 100.0 μg/mLwith 0.1N HCl.

Sample preparation

One brand of commercial tablet from two batches were analyzed by the proposed method. Ten tablets of formulation each containing 50 mg of amisulpride were accurately weighed and powdered. Weight of tablet powder equivalent to 100.0 mg of drug was taken in 40.0 mL of 0.1N HCl and shaken for 15 min, filtered into 100.0 mL volumetric flask through cotton wool and the remaining amount of 0.1N HCl was added through tablet powder to make 100.0 mL. Final concentration was brought upto 100.0 mg/100.0 mL with 0.1 N HCl.

Assay

Aliquots of amisulpride ranging from 0.2-1.0 mL (1.0 mL = 100 μg) were transferred into a series of 10.0 mL volumetric flasks. The volumes were made upto the mark with 0.1N HCl.The absorbance of this solution was measured at 226.5 nm against solvent blank. The amount of amisulpride present in the sample was computed from calibration curve.

RESULTS AND DISCUSSION

The optical characteristics such as absorption maxima, Beer's law limits, molar absorptivity and Sandell's sensitivity are presented in Table 1.The regression analysis

using the method of least squares was made for the slope (b), intercept (a) and correlation (r) from different concentrations and results are summarized in Table 1. The percent relative standard deviation and percent range of error (0.05 and 0.01 level of confidence limits) calculated from eight measurements, $3/4^{th}$ of the upper Beer's law limits of amisulpride are given in Table 1. The results showed that this method has reasonable precision.

Table 1. Optical characteristics and precision

λ_{max}	226.5 nm
Beer's law limits	2-10 μg/mL
Molar absorptivity (lit, $mol^{-1}cm^{-1}$)	3.7584×10^4
Sandell's sensitivity (μg/cm^2 0.001 absorption limits)	0.02
Regression equation (Y*)	
Slope (b)	0.099
Intercept (a)	0.016
Correlation coefficient (r)	1.002
% RSD	0.3722
Range of error**	
Confidence limit with 0.05 level	± 0.00189
Confidence limit with 0.01 level	± 0.0027

Y = bC + a where C is the concentration of amisulpride in μg/mL and Y is the absorbance at the respective λ_{max}.

**For eight measurements

In order to justify the reliability and suitability of the proposed method, known quantities of pure amisulpride was added to its preanalysed formulations and the mixtures were analyzed by the proposed method. The results of recovery experiments are also summarized in Table 2. The other active ingredients and excipients usually present in the pharmaceutical dosage forms did not interfere.

The proposed method is found to be simple, sensitive, selective, economical, accurate and precise and can be used for the determination of amisulpride in bulk drug and its pharmaceutical dosage forms in a routine manner

Table 2. Evaluation of amisulpride in pharmaceutical dosage forms

Sample*	Labelled amount (mg)	Amount obtained (mg)	Percentage recovery**
T1	50	49.56 ± 0.03	99.46 ± 0.03
T2	50	49.32 ± 0.02	99.32 ± 0.05

*T1 and T2 are tablets (Sulphitac, Sun Pharmaceuticals India Ltd., Mumbai) from different batches.

**Average of 8 determinations ± S.D. 50 mg of drug was added and recovered

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