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Research Article

SPECTROPHOTOMETRIC METHODS FOR THE DETERMINATION OF PRAMIPEXOLE DIHYDROCHLORIDE IN PURE AND IN PHARMACEUTICAL FORMULATIONS

B. THANGABALAN[1]*, M. VAMSI KRISHNA[1], N. V. R. RAVITEJA[1], SK. HAJERA BEGUM[1], S. MANOHAR BABU[1] AND P. VIJAYARAJ KUMAR[2]

[1]SIMS College of Pharmacy, Mangaldas Nagar, Guntur-522 001, India, [2]Bharat Institute of Pharmacy, Mangalpally Village, Ibrahimpatnam, RR Dist.-501506 Email: bthangabalan@gmail.com

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ABSTRACT

Two simple and sensitive spectrophotometric methods (A and B) for the determination of Pramipexole Dihydrochloride in pure and pharmaceutical formulations are described. In method A, distilled water was used as solvent and shows absorbance maximum at 262 nm. In method B, methanol was used as solvent and shows absorbance maximum at 263 nm. In method A linearity was found to be in the range of 10 - 50 µg/ml and for method B linearity was 5 – 40 µg/ml; for method A (Y=0.02 X-0.003; r^2=0.9996) and for method B (Y=0.0291 X+0.0073; r^2=0.9987), respectively. The proposed methods were successfully applied for the determination of Pramipexole in pharmaceutical formulations.

Keywords: Pramipexole, UV-Spectrophotometric methods, Tablets.

INTRODUCTION

Pramipexole dihydrochloride is chemically (s)-2-amino-4,5,6,7-tetrahydro-6-(propylamino) benzothiazole dihydrochloride, is a nonergot dopamine agonist recently approved for the treatment of early and advanced Parkinson's disease. Literature survey reveals that the drug can be estimated by using by Spectrophotometric methods [1], LC Method [2-4], and electrophoresis[5]. The aim of this study was to develop rapid, economical, precise and accurate methods for the determination of Pramipexole in pharmaceutical formulations. The method described is quite suitable for the routine analysis of pharmaceutical formulations.

MATERIALS AND METHODS

T60 UV-Visible Spectrophotometer with 1 cm matched quartz cells were used for all spectral measurements. Digital Balance: BL-220H, Shimadzu was used.

Reagents: Double distilled water; Methanol.

Procedure

From the solubility studies, distilled water and methanol were selected as solvents for UV spectroscopical studies of Pramipexole in bulk drug and tablet dosage form. The λ_{max} was determined in distilled water and methanol.

Method A

Standard stock solution of Pramipexole (1000 µg/ml) was prepared in distilled water. It was further diluted to obtain 10, 20, 30, 40 and 50 µg/ml with distilled water. The absorbance was measured at 262 nm against distilled water as blank. The calibration curve was plotted in the concentration range of 10 to 50 µg/ml of Pramipexole in distilled water. The sample solution was also treated in the similar manner. The amount of drug in the tablet sample was computed from Beer-Lambert plot.

Method B

Standard stock solution of Pramipexole (1000 µg/ml) was prepared in methanol. It was further diluted to obtain 5, 10, 20, 30 and 40 µg/ml with methanol. The absorbance was measured at 263 nm against methanol as blank. The calibration curve was plotted in the concentration range of 5 to 40 µg/ml of Pramipexole in methanol. The amount of Pramipexole present in the tablet sample solution was computed from its calibration curve.

Preparation of sample solution

Tablets containing pramipexole were successfully analyzed by the proposed methods: Twenty tablets of pramipexole were accurately weighed and powdered. Tablet powder equivalent to 10 mg of pramipexole was dissolved in 50 ml of distilled water and sonicated for 15 minutes, filtered and washed with distilled water, the filtrate and washings were combined and the final volume was made to 100 ml with distilled water. The solution was suitably diluted and analyzed as given under the assay procedure for bulk samples. Same procedure was followed by using methanol as solvent.

RESULTS AND DISCUSSION

The UV spectrum of pramipexole in distilled water and methanol (Fig 1 and 2) has showed maximum absorbance at 262 nm and 263 nm respectively. 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 was made, slope (m), intercept (b) and correlation coefficient (r^2) obtained from different concentrations and the results are summarized in Table 1. Tablets containing pramipexole were successfully analyzed by the proposed methods. The results are represented in Table 2.

Table 1: Optical characteristics of the proposed methods

Parameters	Method A	Method B
λ_{max} (nm)	262	263
Beer's law limit (µg/ml)	10 - 50	5 - 40
Sandell's sensitivity (µg cm^{-2}/0.001 absorbance unit)	1.986×10^{-5}	3.038×10^{-5}
LOD (µg/ml)	1.395	2.034
LOQ (µg/ml)	4.227	6.164
Molar absorptivity (l mol^{-1} cm^{-1})	5.984×10^{3}	8.614×10^{3}
Regression equation (Y = b + mc)		
Slope (m)	0.02	0.0291
Intercept(b)	-0.003	0.0073
Correlation coefficient (r^2)	0.9996	0.9987

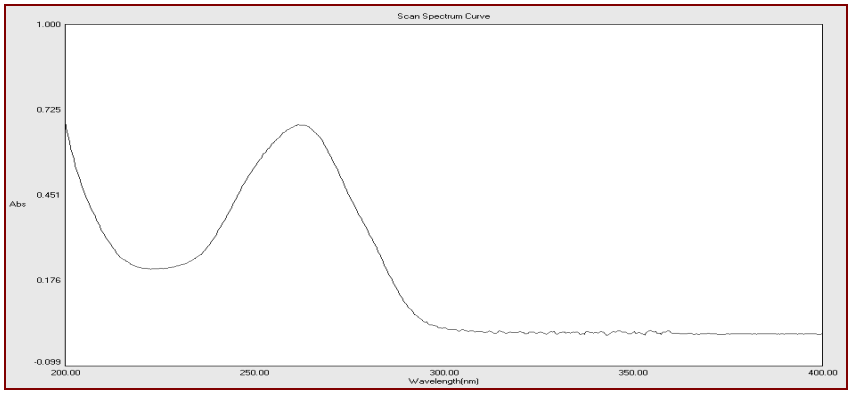

Fig. 1: UV spectrum of Pramipexole Dihydrochloride in water

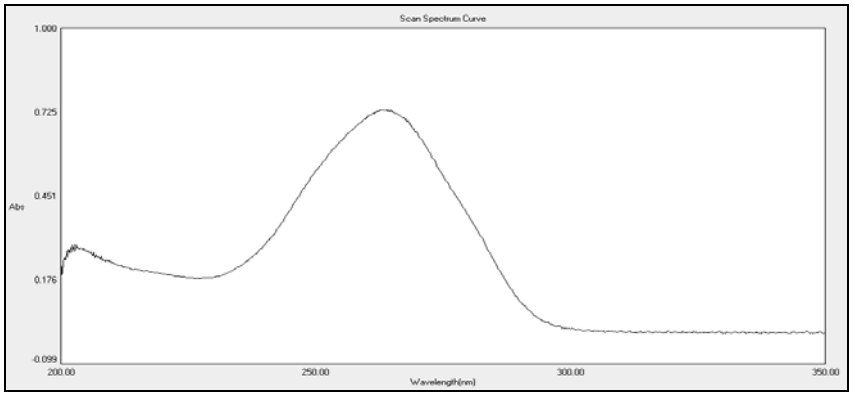

Fig. 2: UV spectrum of Pramipexole Dihydrochloride in methanol

Table 2: Assay results, recovery and precision studies

Method	Labeled amount (mg/ tablet)	(%) label claim* ± S.D	%Recovery (n=18)	Precision**		
				Repeatability	Inter-day	Intra-day
A	1	99.95± 1.179	100.42	0.0046	0.0046	0.0035
B	1	99.66±1.469	99.56	0.0018	0.0042	0.0029

* Average of six determinations. **SD of six determinations.

The percentage recoveries thus obtained were given in Table 2.

None of the excipients usually employed in the formulation of tablets interfered in the analysis of pramipexole, by the proposed methods. The precision of the methods were studied as intra-day, inter-day and repeatability.

The % RSD values less than 2 indicate the methods are accurate and precise.

CONCLUSION

Both these methods are simple, rapid and accurate and precise and can be used for routine analysis of pramipexole from tablet formulations.

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