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Research Article

Spectrophotometric determination of pramipexole di-hydrochloride in bulk and tablet dosage form

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ABSTRACT

Pramipexole dihydrochloride is chemically (s)-2-amino 4, 5, 6, 7 tetra hydro-6 (propylamino) benzothiazole dihydrochloride is used as an anti-Parkinsons drug. The drug is commercially accessible as tablets for oral administration. In the present work an attempt has been made to estimate the drug by three methods. Method A is absorption maxima method in which λ_{max} was found to be 262nm. Method B is first order derivative spectroscopy where drug showed **λ**maxima=278nm and **λ**minima=246nm.In this method amplitude difference (dA/dλ) was calculated and was plotted against concentration and regression equation was calculated. Method C is area under the curve (AUC) in which area in the wavelength range of 258nm - 266nm was selected for analysis of Pramipexole. Linearity was observed in the concentration range 10-50µg/ml (r^2 =0.999) for all the three methods. The % assay for the marketed formulation for absorption maxima, first order derivative and area under the curve method was found to be 102.11%, 99.41% and 103.1% respectively. The methods were validated with respect to linearity, precision and accuracy studies. Recovery studies for absorption maxima, first order derivative and area under the curve was found to be 101.4%, 100.1% and 100.52% respectively. The methods were found to be simple, rapid, economical, precise and accurate and can be employed for routine quality control analysis of Pramipexole in bulk as well as from its dosage form.

Keywords: Pramipexole dihydrochloride; UV spectrophotometry

INTRODUCTION

Pramipexole dihydrochloride (PPL) (United States Pharmacopeial Convention, 2011.) is chemically (s)-2-amino 4, 5, 6, 7 tetra hydro-6 (propylamino) benzothiazole dihydrochloride (Neil Maryadele J.O, et al., 2006) used as an anti-Parkinsons drug. Pramipexole dihydrochloride is a non-ergot dopamine agonist i.e. mimics the action of dopamine at D_2 or D_3 receptors. (Rang H.P et al., 2003) the drug is commercially available as tablets for oral administration.

Literature survey reveals that the drug can be estimated by Spectrophotometric methods (Jain Nilesh et al., 2011), (C.Vinodhiniet al., 2011), RP HPLC method (Lavudu P et al., 2012), spectrofluorimetry (Armagan Orial, 2011) and UPLC-MS-MS (Yadav Manish et al., 2010) method. The aim of this study is to estimate Pramipexole dihydrochloride by absorption maxima, first order derivative spectroscopy and area under curve method in bulk and tablet dosage form.

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The chemical structure of Pramipexole dihydrochloride is shown in Fig. 1.

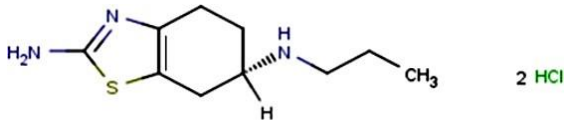

Figure 1: Chemical structure of Pramipexole dihydrochloride

MATERIALS AND METHODS

Pramipexole dihydrochloride (PPL) was obtained as a gift sample from Emcure Pharmaceuticals Ltd., Pune, India. Pramipexole Tablets were procured from local pharmacy. All the reagents used were of analytical grade.

Instrumentation

A Jasco double beam UV–visible spectrophotometer, Model: V-630; Ultrasonicator.

EXPERIMENTAL METHODS

Preparation of standard stock solutions

Accurately weighed 100 mg of the PPL was transferred to 100 ml volumetric flask and dissolved in distilled water and the volume was made up to 100 ml with distilled water to give standard stock solution 1000

µg/ml. The aliquots were prepared by using distilled water in the increasing concentration range. Aliquots of standard stock solution were scanned in the range of 200nm – 400nm on UV Spectrophotometer Jasco V-630.

Method A: Absorbance Maxima Method

Aliquots of standard stock solution of concentration 1000 µg/ml were taken and suitably diluted with distilled water to give working standard solutions in the increasing concentration range. These were scanned in the range of 200nm – 400nm.The absorbance maximum was found to be at 262nm (Fig.2). The calibration curve was plotted with Absorbance Vs Concentration and the regression equation was calculated.

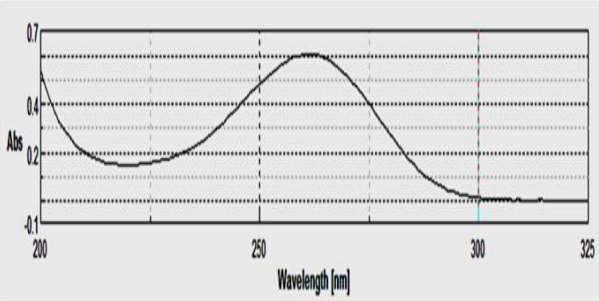

Figure 2: Absorbance maxima method

Method B: First order derivative spectroscopy

Standard solutions of PPL were scanned in the range of 200nm – 400nm.The first order derivative spectra showed λmaxima=278nm and λminima=246nm (Fig.3). The absorbance difference at n=1 (dA/dλ) was calculated by the inbuilt software of the instrument. The derivative amplitudes were calculated by considering the maxima and minima of the curve. Amplitude difference was measured for the respective concentration of standard and was plotted against concentration and regression equation was calculated.

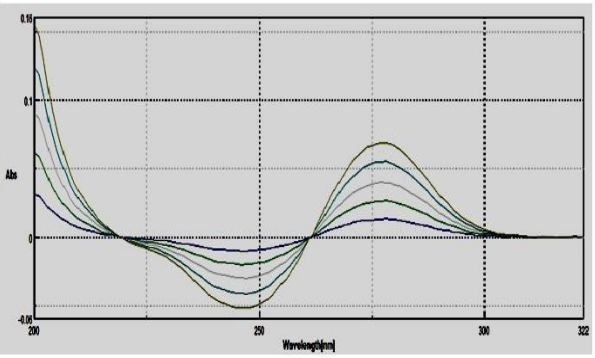

Figure 3: First order derivative spectroscopy method

Method C: Area under the curve

From the spectra of drug obtained after scanning standard solutions of PPL, area under the curve in the wavelength range of 258-266 nm was selected for the analysis. The calibration curve was plotted with area under the curve v/s concentration and regression equation was calculated (Fig.4).

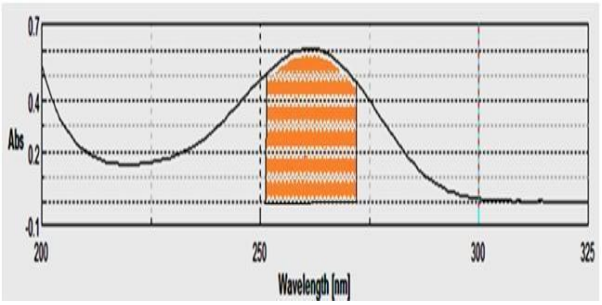

Figure 4: Area under the curve method

Analysis of tablet formulation

For estimation of Pramipexole in marketed formulation twenty tablets were weighed and triturated to fine powder. Tablet powder equivalent to 100mg of PPL was taken in 100ml volumetric flask and was dissolved in distilled water by ultrasonication. The volume was made up with distilled water to give tablet stock solution of concentration 1000µg/ml. It was filtered through Whatmann filter paper no. 42. Then the aliquots were prepared by using distilled water. These were scanned in the range of 200nm – 400nm and analysed further for the assay.

Method Validation

The method was validated, in accordance with ICH guidelines (ICHQ2R1), for precision, accuracy, linearity. (ICH, 2005)

Linearity

The linearity was evaluated by analyzing different concentrations of standard solutions of Pramipexole. Beer's law was obeyed in the concentration range of 10-50 µg/ ml (r^2=0.999). The calibration curve and readings are given in Table No. 1.

Table 1: Linearity study for Pramipexole dihydrochoride

Sr.No.	Concentration	Absorbance
1.	10	0.29653
2.	20	0.56075
3.	30	0.80115
4.	40	1.09226
5.	50	1.32083

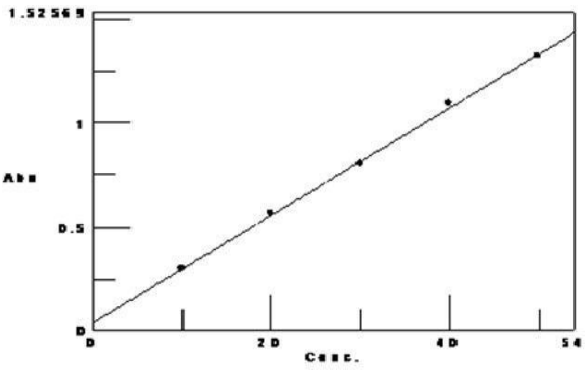

Figure 5: Linearity curve for Pramipexole dihydrochloride

Table 2: Linearity parameters for Pramipexole dihydrochloride

Slope	0.0258
Intercept	0.0403
Correlation	0.99948
RSD	99.94

Accuracy

Accuracy was determined by the recovery studies, in which the preanalysed tablet solution was spiked to standard stock solution at three different levels.

To ascertain the accuracy of the proposed methods, recovery studies were carried out by standard addition method at three different levels (80%, 100% and 120%). Results for recovery are given in Table No. 3.

Precision

The reproducibility of the proposed methods was determined by performing tablet assay at different time intervals on same day (Intra-day precision) and on three different days (Inter-day precision).The percentage relative standard deviation (% RSD) was found to be within limits. Results for precision study are given in Table No. 4.

RESULTS AND DISCUSSION

The marketed formulations containing Pramipexole were analyzed by the proposed methods. The proposed methods were validated as per ICH guidelines[3] for linearity, accuracy and precision. The % assay of marketed formulations for absorption maxima, first derivative spectroscopy and area under the curve was found to be 102.11%, 99.41% and 103.1% respectively. The % recovery obtained for absorption maxima, first order derivative spectroscopy and area under the curve was found to be in the range of 99.83% – 102.96%, 99.90%-100.5% and 99.06% –101.77% respectively.

CONCLUSION

The proposed methods are simple, economical, accurate and precise and can be used for routine analysis of Pramipexole from tablet formulations. Analysis of marketed formulations containing Pramipexole dihydrochloride showed no interference from the common additives and excipients. Thus, it can be easily and conveniently adopted for routine quality control analysis.

ACKNOWLEDGEMENTS

We are grateful to the Emcure Pharmaceutical Ltd; Pune, India for gift sample of Pramipexole dihydrochloride.

Table 3: Result of recovery studies

Preanalysed tablet solution µg/ml	10	10	10
Amt. of Std. Drug added in µg/ml	8	10	12
Recovery level	80%	100%	120%
% Recovery Method A	99.83%	102.96%	101.41%
% Recovery Method B	99.96%	100.5%	99.68%
% Recovery Method C	100.74%	99.066%	101.77%
% RSD Method A	0.279%	0.339%	0.108%
% RSD Method B	0.153%	0.205%	0.260%
% RSD Method C	0.417%	0.064%	0.032%

Table 4: Result of Precision studies

Drug name	Amount Taken (µg/ml)	Amount found (µg/ml)	Recovery (%n=6)	%RSD
Pramipexole dihydrochloride	10	9.94	99.4%	0.13

REFERENCES

Armagan Orial, Spectrophotometric and spectrofluorimetric determination of some drugs containing secondary amino group in bulk drug and dosage forms via derivatization with 7-chloro-4-nitrobenzofurazon, *Quim Nova,* 34(4), 2011, 677-682.

C.Vinodhini, Malladi V.N.D. Sravani, Mangam Bhanuprakash, Mantena Sudhadevi, Mohamad Imran, Mohamed Omer, Abdelaziz Osman, K. Chitra, Reddy Uma Maheshwara, Method Development and Validation of Pramipexole Dihydrochloride Monohydrate in Tablet Dosage Form by UV and Visible Spectrophotometric Methods, *International Journal of Research in Pharmaceutical and Biomedical Sciences*, 2(2), Apr-June 2011, 680-686.

Jain Nilesh, Jain Ruchi, Kulkarni Sneha, Jain Deepak K, Jain Surendra, Ecofriendly spectrophotometric method development and their Validation for quantitative estimation of Pramipexole Dihyrochloride using mixed hydrotropic agent, *Journal of Chemical and Pharmaceutical Research,* 3(1), 2011, 548-552.

Lavudu P, Rani A. Prameela, C. Balashekaran, Venumadhav V, Rp-Hplc Method for the Determination of Pramipexole Dihydrochloride in Tablet Dosage Form,

Global Journal of Medical Rasearch, 12(4), May 2012, 20-24.

Rang H.P, Dale M. M, Moore P.K, Pharmacology, 5 th edition, 2003, 499.

The Merck Index-An Encyclopedia of chemicals, Drugs, and biological, 14 th edn, Merck Research Laboratories, Whitehouse station, NJ, 2006, pp 7707.

United States Pharmacopeial Convention, 2 nd supplement to USP-35 NF-30, Revision Bulletin, Dec 1, 2011, 1-3.

Validation of Analytical Procedures: Text and Methodology Q2 (R1), "ICH Harmonized Tripartite Guideline", Geneva, 2005.

Yadav Manish, Rao Rajasekhar, Kurani Hemal, Rathod Jaysukh, Patel Rakesh, Singhal Puran, Shrivastav Pranav S, Validated ultra-performance liquid chromatography Tandem mass spectrometry method for the Determination of Pramipexole in human plasma, *Journal of Chromatographic Science,* 48, Nov/Dec 2010, 812-818.