WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 5.990
Volume 4, Issue 5, 2222-2227. Research Article ISSN 2277– 7105

A SIMPLE SPECTROPHOTOMETRIC ASSAY OF PRAMIPEXOLE DI HYDROCHLORIDE IN BUILK AND PHARMACEUTICAL FORMULATIONS

M. Purushotham Reddy[1*] and K. Prabhavthi[2]

[*1]Principal, K.V.R. Government College (W), Kurnool-518004, India.

[2]Department of Chemistry, S.B.S.Y.M. Degree College, Kurnool-518004, India.

Article Received on
13 March 2015,

Revised on 05 April 2015,
Accepted on 28 April 2015

***Correspondence for Author**
M. Purushotham Reddy
Principal, K.V.R. Government College (W), Kurnool-518004, India.

ABSTRACT

A simple, sensitive, rapid and accurate colorimetric method has been developed for the estimation of pramipexole dihydrochloride in bulk and pharmaceutical dosage forms. The proposed method was based on the formation of chloroform extractable complex of pramipexole dihydrochloride with bromo cresol green. The absorbance of the extractable ion pair complex is measured at the wavelength of maximum absorbance 425 nm against the reagent blank. The results obtained with the proposed method are in good agreement with labeled amounts, when marketed pharmaceutical preparations are analyzed. Results obtained are statistically validated and found to be reproducible.

KEYWORDS: Spectrophotometry, bromo cresol green (BCG), pramipexole dihydrochloride, Pharmaceutical and Formulation.

INTRODUCTION

Pramipexole dihydrochloride is a nonergot dopamine agonist approved in the US (1997), is used as an antidyskinetic for the treatment of Parkinson's disease. Its chemical name is (S)-N6-propyl-4,5,6,7-tetrahydro-1,3-benzothiazole-2,6-diamine dihydrochloride (Figure1.The ability of Pramipexoledihydrochloride to alleviate the signs and symptoms of Parkinson's disease is supposed to be linked to its ability to stimulate dopamine receptors in the striatum. The chemical name of pramipexole dihydrochloride is (*S*)-2-amino-4,5,6,7-tetrahydro-6-(propylamino) benzothiazole dihydrochloride monohydrate. The literature suggested and reported which includes, spectrophotometric method[1-4] and RP-HPLC.[5] techniques for the

quantitative estimation of pramipexole dihydrochloride in bulk, formulations and in biological samples.

Spectrophotometry is the technique of choice even today in the laboratories of research, hospitals and pharmaceutical industries due to its low cost and inherent simplicity. This paper describes two rapid, simple, sensitive and economical spectrophotometeric methods for the determination of pramipexole dihydrochloride in commercial dosage forms. This method based on the formation of chloroform extractable complex of pramipexole dihydrochloride with bromo cresol green. The ion association complex is a special form of molecular complex resulting from two components extractable into organic solvents from aqueous phase at suitable pH. One component is a chromogen (bromo cresol green) processing charge (Cationic or anionic in nature) & so insoluble in organic solvents. The other is colorless, processing opposite charge to that of chromogen. The authors attempted to design a precise, inexpensive colorimetric method for estimation, which could be applied to analyze pramipexole dihydrochloride in pure and pharmaceutical dosage form and will be helpful to the pharmaceutical industry.

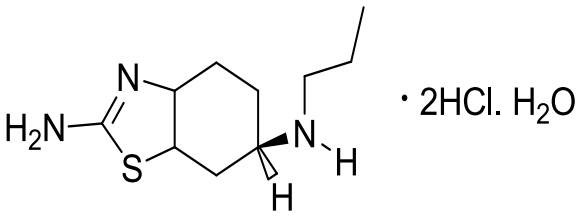

Figure 1: Chemical structure of pramipexole dihydrochloride

MATERIALS AND METHODS

Instrument

All measurement were done on Milton Roy 1001spectrophotometer by using 10 mm matched quartz cuvettes.

Materials

All chemicals used are of A.R. grade and were purchased from S.D. fine chemicals and LOBA-Chemi, Mumbai. Doubled distilled water were used for preparation of solutions.

Buffer solution (pH 3.5)

Buffer solution was obtained by diluting a mixture of 50 ml of 0.2M potassium acid phthalate and 8.4 ml of 0.2M HCl to 200 ml with distilled water and the pH is adjusted to 3.5.

Bromocresol green: (0.5% w/v)

Bromocresol green solution is prepared by dissolving 500 mg of bromocresol green (Loba) in 100 ml of distilled water.

Preparation of standard stock solution: Standard solution of pramipexole was prepared by dissolving 100 mg of pramipexole in 100 mL of distilled water. From this a working concentration of 100 µg/ml was prepared for the proposed method.

Assay procedures

Aliquots of standard drug solution of pramipexole dihydrocloride 0.4 – 2.0 ml were taken and transferred into a series of 100 ml of separating funnels. To each funnel 2 ml of 0.2% bromo cresol green was added. Reaction mixture was shaken gently for 5 min. Then 10 ml of chloroform was added to each of them. The contents are shaken thoroughly for 5 min and allowed to stand, so as to separate the aqueous and chloroform layer. Colored chloroform layer was separated out and absorbance was measured at 425 nm against reagent blank. Calibration curve was prepared from absorbance values so obtained (fig 2).

Assay of pharmaceutical Formulations

For analysis of tablet formulations from the powdered tablets, 50 mg of the drug is weighted accurately and transferred into a 50 ml beaker and mixed well with 30 ml of methanol. The solution is filtered and transferred into a 50 ml volumetric flask and the volume is made up to the mark with methanol. The concentration of the drug solution is now 1mg/mL. This stock solution is further diluted to obtain the working concentration and treated as per the procedure of the calibration curve. Amount of the drug present in sample is computed from respective calibration curve. The concentration of the resulting solution was found to be 1 mg/ml. The sample solution was analyzed in the same way as mentioned in the calibration curve.

Validation

Accuracy of the proposed methods was carried as on the basis of recovery studies. It is performed by the standard addition method. Recovery studies were performed by adding standard drug at different levels to the pre-analyzed tablets powder and the proposed method was followed. From the amount of the drug estimated, the percentage recovery was calculated. The results of the analysis are shown in table 2.

RESULTS AND DISCUSSION

In the proposed method the pramipexole dihydrocloride was treated with bromo cresol green dye at 3.5 pH. The resultant solution is extracted with chloroform. The ion pair complex is formed in extractable chloroform layer. The absorbance of the extractable ion pair complex is measured at 425 nm against the reagent blank (prepared in a similar manner devoid of drug solution). The calibration curve (concentration vs absorbance) is linear over the range of 40-200 µg/mL of pramipexole. The proposed method was validated statistically and by recovery studies. The molar absorptivity and Sandell's sensitivity values show the sensitivity of methods while the precision was confirmed by the %RSD (relative standard deviation). Assay results of recovery studies are given in table 2. Results are in good agreement with labeled value. The reproducibility, repeatability and accuracy of this method were found to be good, which is evidenced by low standard deviation.

The regression analysis using method of least squares was made for the slope (b), intercept (a) and correlation (r) obtained from different concentrations and results are summarized in table 1. The optical characteristics such as absorption maxima, Beer's law limits, molar absorptivity, Sandell's sensitivity and percent relative standard deviation were calculated and the results are summarized in Table 1. The optimum conditions for color development have been established by varying the parameters one at a time and keeping the other parameters fixed and observing the effect of product on the absorbance of the colored species. These studies revealed that the common excipients and other additives such as starch, talc, lactose and magnesium stearate, that are usually present in tablet dosage forms, did not interfere at their regularly added levels orated in the procedure.

Table 1: Optical Characteristics Of The Proposed Method

parameters	Proposed method
Wavelength (nm)	425
Beer's limits, mcg/ml	
Sandell's , sensitivity, (µg cm^{-2})	40-200
Molar absorptivity, (L mol^{-1} cm^{-1})	
Regression equation, Y^{*}	0.1445
Correlation coefficient, (r)	
Intercept (a)	$1.44x10^{2}$
Slope (b)	
	Y= 0.007x+0.002
	0.999
	0007
	0.002

Table 2: Assay and recovery of pramipexole in tablet formulations

Formulation	Labeled amount	*Amount found (mg±S.D)	% Recovery	% RSD	*t value
Tablet 1	0.25	0.248±0.004	99.8	1.733	1.0416
Tablet 2	0.25	500.06±0.002	100.2	0.923	0.9803

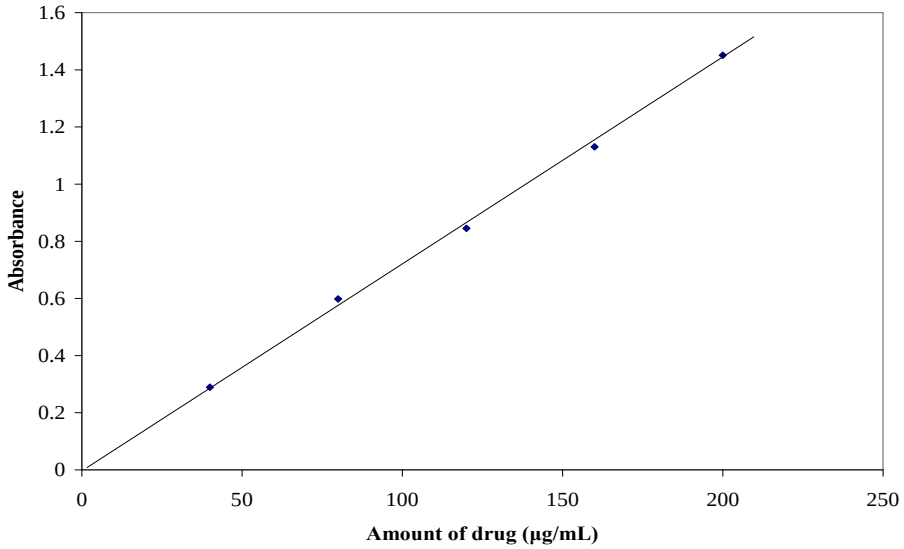

Fig.2: Calibration curve of pramipexole

CONCLUSION

It could be concluded that the developed method for estimation of pramipexole dihydrocloride in pharmaceutical dosage forms and in bulk is simple, sensitive, relatively precise and economical. The proposed methods are used for the routine analysis of the drugs in the quality control.

REFERENCES

1. Gurupadayya BM, Vishwajith V, Srujana N. Spectrophotometric Methods for the Estimation of Pramipexole Dihydrochloride in Pharmaceutical Formulations. World journal of chemistry., 2009; 4(2): 157-160.
2. Thangabala B, Vamsi Krisha M, Raviteja NVR,.Hajera Begum SK, S K, Manohar Babu SK, Vija raja Kumar P. Spectrophotometric method for determination Pramipexole dihydrochloride in pure and pharmaceutical formulation. In J PharmPharm Sci, 2011; (3): 84- 853.
3. Vinodhini C, Malladi VN, sravani D, Mangam Bhanuprakash, Mantena.sudha devi, Mohamad Imran, Mohamed Omer Abdelaziz Osman, Chitra K, Uma Maheshwara reddy C. 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., 2011; 2(2): 680-686.

4. Pawar DS, Dole MN Sawant S. Spectrophotometric determination of Pramipexole dihydrochloride in bulk and tablet dosage form. Int. J. Res. Pharm. Sci., 2013; 4(2): 183-186.
5. Lavudu P, Prameela Rani A, Balashekaran C, VenumadhavV. Method for the Determination of Pramipexole Dihydrochloride in Tablet Dosage forms. Global Journal of Medical research, 2001; 12(4): 18-24.