IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals
ISSN 2349-7203
HUMAN

Human Journals
Research Article
January 2024 Vol.:30, Issue:1

Quantification of Ropinirole Hydrochloride in Tablets by Validated FTIR Spectroscopic and Colorimetric Methods

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Submitted: 20 December 2023
Accepted: 25 December 2023
Published: 30 January 2024

Keywords: Ropinirole, Colorimetry, FTIR, Tablets, Validation

ABSTRACT

Two simple, sensitive and precise analytical methods have been proposed for the estimation of Ropinirole in bulk drug as well as in pharmaceutical dosage form. Method A is the FTIR Spectroscopic method which involves the measurement of the area of the infrared band corresponding to the N-H stretching centered at 3320 cm^{-1}. Method B is based on the formation of an orange-red coloured complex with 1,10-phenanthroline and ferric chloride which has an absorption maximum at 510nm. Linearity was obeyed in the concentration range of 5-30µg /mL and 50-300µg /mL for methods A and B respectively. The proposed methods are statistically validated and found to be useful for the routine determination of Ropinirole in tablets.

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INTRODUCTION

Ropinirole is used to treat the symptoms of Parkinson's disease and restless legs syndrome[1-2]. Ropinirole is a non-ergoline dopamine agonist. Ropinirole has the highest affinity at the D3 receptors, which are concentrated in the limbic areas of the brain and may be responsible for some of the neuropsychiatric effects. The exact mechanism of action of ropinirole as a treatment for Parkinson's disease is unknown, however, it is believed to be related to its ability to selectively stimulate dopamine D2 receptors within the caudate-putamen system in the brain. This system affects body movement. Negligible affinity is seen for ropinirole at α2 adrenoreceptors in the periphery and 5HT-1 receptor. Ropinirole has no affinity at the D1-like receptors, benzodiazepine or GABA receptors[3-4].

Ropinirole is an indole derivative whose chemical name is 4-[2-(dipropylamino)ethyl]-1,3-dihydroindol-2-one[5]. The available methods for the analysis of the drug in biological fluids and pharmaceutical products are HPLC method[6-7] , method [8]and TLC/densitometry[9].

The present work deals with the estimation of Ropinirole HC[in tablets by colorimetric and FTIR spectroscopic methods. FTIR Spectroscopic method (Method A) is based on the measurement of the area of the infrared band corresponding to the N-H stretching centered at 3320cm^{-1}. In the colorimetric method (Method B), TNG is first condensed with 1, 10-phenanthroline and ferric chloride to form an oranged red colored complex which absorbs intensively at 510nm. The methods are alternative and comparable in specificity and accuracy to chromatography methods, which although highly specific and accurate, are more time consuming, performed in several steps and are rather expensive.

MATERIALS AND METHODS

Instrumentation

All spectral and absorbance measurements were made on FTIR model ABB 3000 for method A.

And UV-Vis Spectrophotometer-1900s for method B.

Reagents

1. 1, 10- phenanthroline (0.2%w/v)

2. Ethanol (95% w/v)

3. Ferric chloride (5% w/v).

All reagents were used of analytical grade.

Standard Solution of Ropinirole

A Img/ml stock solution of Ropinirole hydrochloride was prepared by dissolving 0.1 g of drug in 100 ml of ethanol.

Sample Preparation

Twenty tablets were weighed and powdered. A quantity equivalent to 100mg of Ropinirole hydrochloride was weighed accurately, transferred to a beaker, dissolved in ethanol, filtered through Whatmann filter paper No.1 into a 100ml volumetric flask and made up to volume with ethanol to get a concentration of I mg/ml.

METHOD

METHOD A

The stock solution was diluted suitably with ethanol to give a series of concentrations ranging from 5- 30 µg/ml of Ropinirole hydrochloride. The IR spectrum was recorded for the various concentrations. The absorbance of the band due to N-H stretching at 3320 cm^{-1} was measured. The IR spectrum of Ropinirole hydrochloride is shown in Figure-1. The calibration curve of Ropinirole hydrochloride was obtained by plotting the peak area (N-H stretching centered at 3320 cm^{-1}) versus concentration.

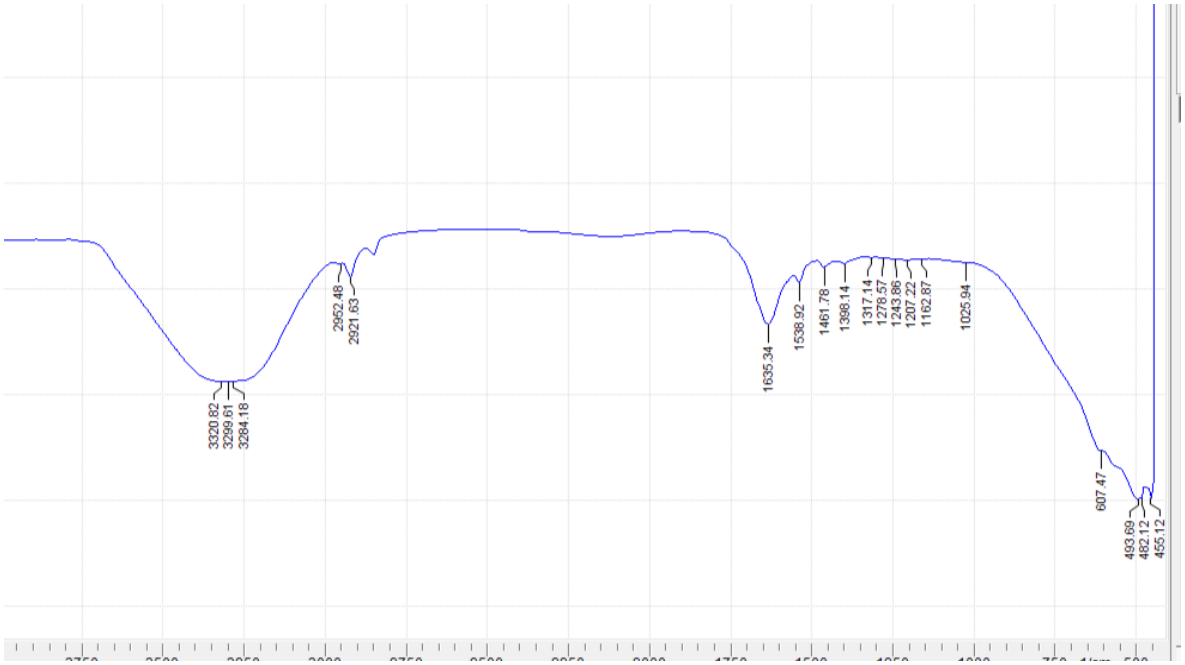

FIGURE-1: IR SPECTRUM OF ROPINIROLE HCl BY FTIR METHOD

METHOD B

Appropriate aliquots of Ropinirole hydrochloride were pipetted out into a series of 100 ml volumetric flasks. To each flask 1 ml of ferric chloride (1% w/v) and 3 ml of 1,10 - phenanthroline (2% w/v) were added, heated on a boiling water bath for 15 minutes, cooled and then made up to volume with ethanol. The λ_{max} of the orange-red coloured chromogen was found to be 510 nm (Figure-2). The absorbance of the orange-red coloured chromogen was measured at 510 nm against the reagent blank. The amount of Ropinirole hydrochloride was computed from the calibration curve obtained by plotting concentration versus absorbance.

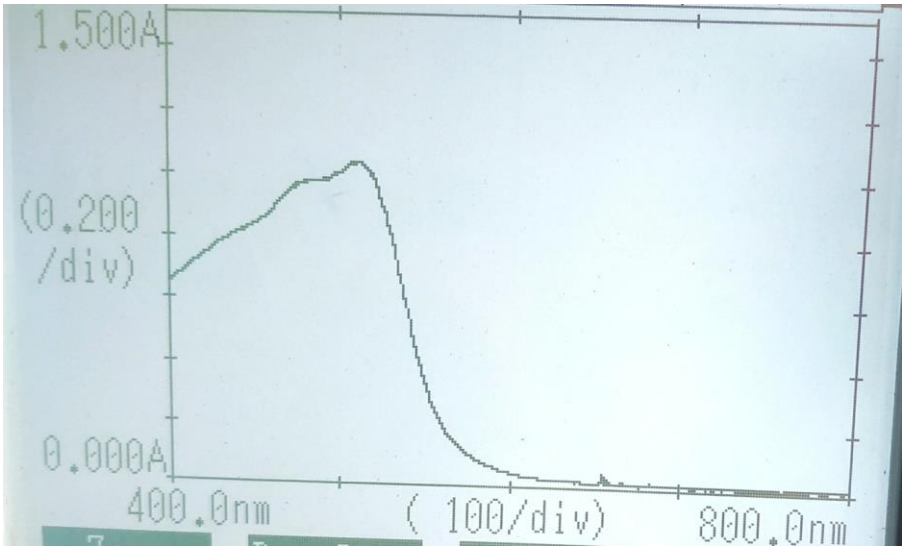

FIG 2: λ_{max} of orange-red chromogen at 510 nm

Sample Analysis

The pharmaceutical formulation of Ropinirole HCl was successfully analyzed by the proposed methods. Appropriate aliquots were subjected to the above methods and the amount of the TNG was determined from the calibration curves. The results of the sample analysis are furnished in table 2.

RESULTS AND DISCUSSION

The optical characteristics such as absorption maxima, Beer's law limits, Molar absorptivity and Sandell's sensitivity are furnished in Table-1. The regression characteristics like slope (b), intercept(a), correlation coefficient(r), percent relative standard deviation (%RSD) and standard error (SE) obtained from different concentrations were calculated and the results are summarized in Table-1. To study the accuracy and reproducibility of the proposed methods, recovery experiments were carried out by adding a known amount of drug to pre-analyzed sample and the percentage recovery was calculated. The results are furnished in Table-2. The results indicate that there are no interference of other ingredients present in the formulation. Thus, the proposed methods are simple, sensitive, precise, accurate and reproducible and useful for the routine determination of Ropinirole HCl in bulk drugs and its pharmaceutical dosage form.

Table 1: Optical characteristics, Precision and Accuracy of the proposed methods.

Parameters	Method A	Method B
Λmax/ stretching	510 nm	N-H stretching at 3320 cm^{-1}
Linearity range (µg/ml)	5-30	50-300
Molar absorptivity (L mol^{-1} cm^{-1})	1.0451 x 10^4	4.9999 x 10^6
Sandell's sensitivity (µg/cm^2 /0.001 absorbance unit)	0.0028	0.0059 x 10^{-3}
Regression equation (*y)	y=0.036x + 0.010	y= 16.97x + 25.35
Slope (b)	0.036	16.97
Intercept (a)	0.010	27.35
Correlation co-efficient (r)	0.9998	0.9999
% RSD	0.011	0.013
Standard error (SE)	0.0094	0.108

***y= a+bc where c is the concentration of Ropinirole HCl inµg/ml.**

Table 2: Assay and recovery of Ropinirole HCL in the dosage form (tablets).

Method	Labeled amount (mg)	Amount obtained (mg)*	Percentage recovery**
A	2.00	2.03	100.02
B	2.00	2.01	100.01

*Average of six determinations **Average of three determinations.

ACKNOWLEDGEMENTS

We are thankful to the Department of Pharmaceutical Chemistry, Madras Medical College, Chennai-03, for providing the instrumentation and laboratory facilities.

REFERENCES

1.The Merck Index, An encyclopedia of chemical drugs & biologicals. ed13, Merck research laboratories division of MERCK & CO., INC, 2001; 1703.
2. Martindale, the complete drug reference. ed 37, Vol. A. London, Pharmaceutical press, 2011; 551.
3. Tripathy KD. Essentials of Medical Pharmacology. ed 6, Jaypee brothers Medical Publishers, 2010; 172: 402-404.
4. Shanbhag T, Shenoy S. Pharmacology prepared manual for undergraduates. ed 2, Reed Elsevier India Private limited, 2015; 191,196.
5. Indian Pharmacopoeia ed 6, Ghaziabad, Indian Pharmacopoeia Commission, 2010; 3: 2242.

6. Lata P. Kothapalli, Madhuri. E Choudhari, Asha B. Thomas, rabindra K. Nanda , avinash .D. Deshpande, Poonam s. Gaidhanidevelopement validated HPLC (Method-I) and first order derivative spectrophotometric method (Method -II) for the estimation of ropinirole hydrochloride:2011 Der.pharma chemical,3(6):1-9.
7.Andreas Kakouris, Victoria Samara, Anastasia kalaskani , Irene Panderi Development of a gradient HPLC method coupled with diode array detection was developed and fully validated for theanalysisofimpuritiesinropinirole;chromatographia(2014)77;447-457.DOI10.1007/s10337-261 7-1.
8.GaganjotParmar ,Sanjiv Sharma, Karan Singh, Gulshan balsal : forced degradiation study to develop and validate stability indicating RP-LC for quantification of ropinrole.2008page no 9199-206)DOI:10.1365\s10337-008-0866-1.
9. Bari S.B,.R Bakhshi , P.S Jain, S.J . Surana development and validation of satability indicating: TLC/densitometry of ropinirole hydrochlorideaabulkdruginpharmaceutical dosageforrm2011. DOI./org/10.4712/2153-2435.10001 25.