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Research Article

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Development and validation of RP-HPLC method for the estimation of ropinirole hydrochloride in tablet dosage forms

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ABSTRACT

A simple, accurate, rapid and isocratic reverse phase high performance liquid chromatographic (RP-HPLC) method has been developed for estimation of Ropinirole hydrochloride in tablet dosage forms.Chromatographic separation was operated with 0.05mol glacial acetic acid (pH 3): acetonitrile (50:50v/v) at a flow rate of 1ml/min on hypersil C_{18} (BDS) column, using 250nm as detection wavelength. The retention time for Ropinirole hydrochloride was found to be 4.037min. The method was linear over the concentration range of 4-12µg/ml and coefficient correlation was found to be 0.997. The method showed good recoveries (99.0-99.89%) and its intraday and interday precision were found to be 0.39 and 0.479 respectively. For its sensitivity and reliability, the proposed method can be used for quality control assay of Ropinirole hydrochloride.

Keywords: Ropinirole hydrochloride, RP-HPLC, Isocratic, Estimation

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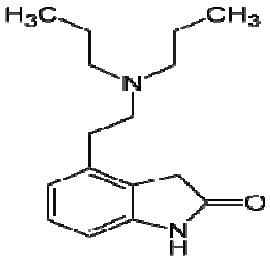
INTRODUCTION

Ropinirole is a non-ergoline dopamine agonist. It is used in the treatment of Parkinson's disease and Restless legs syndrome. Chemically it is a hydrochloride salt of 4-[2-(dipropylamino) ethyl]-1, 3 - dihydro-2*H*-indol-2-one monohydrochloride. It has high relative invitro specificity and full intrinsic activity at the D_2 and D_3 dopamine receptor subtypes, binding with higher affinity to D_3 than to D_2 or D_4 receptor subtypes [1-2]. Literature survey reveals that various HPLC methods have been reported for the estimation of Ropinirole hydrochloride in tablets. The present work describes the development of a simple and reliable RP-HPLC method for the estimation of Ropinirole hydrochloride in tablet dosage forms [3-12].



Structure of Ropinirole

EXPERIMENTAL SECTION

Instrumentation
The separation was carried out on HPLC system (Shimadzu) and RP-C_{18} Hypersil BDS column (250mm X 4.6mm i.d; particle size 5µm) at 250nm using UV detector.

Chemicals and Reagents
Ropinirole was a gift sample by Chandra labs, Hyderabad. Acetonitrile of HPLC grades (99.8%), glacial acetic acid LR grade (99.5%) were purchased. Ropitar tablets (0.25mg) from Torrent Pharmaceutical Limited.

RP- HPLC Conditions
The mobile phase consisting of acetate buffer and acetonitrile. They were filtered through 0.45µm membrane filter and degassed by sonicator before use and were pumped from the solvent reservoir in the ratio of 50:50v/v into the column at a flow rate of 1ml/min, run time was set at 8min and column temperature was maintained at ambient. The volume of injection loop was 20µl. prior to injection of the drug solution; the column was equilibrated for at least 30min with the mobile phase flowing through the system. The eluent was detected at 250nm.

Procedure
About 2.5mg of standard Ropinirole was accurately weighed and transferred to a 25ml of volumetric flask containing 10ml of diluent and the solution was sonicated for 30min and then volume made up to the mark with mobile phase obtaining the final concentration of 100µg/ml. Aliquots of 4,6,8,10 and12µg were prepared with diluent from Ropinirole standard solution. 20µl of each standard solutions prepared as above were injected into the column with a flow rate of 1ml/min and the chromatogram was recorded (Figure 1).

Assay of Ropinirole hydrochloride in tablets
Weigh and powdered not less than 20 tablets. Accurately weighed portion of the tablet powder equivalent to 1mg of Ropinirole hydrochloride was transferred to a 10ml volumetric flask. Then added about 5ml of diluent to it and sonicate for 30min with intermediate shaking and then diluted up to the mark with diluent. Filter the resulting solution through 0.45µ membrane filter obtaining the final concentration of 100µg/ml. Then above solution was injected (20µl) six times into the column. The peak area and retention times were recorded.

Validation of proposed method
The proposed method has been validated in terms of specificity, system suitability, linearity, accuracy, precision, limit of detection and limit of quantification.

Specificity
The placebo peak when comparing with standard peak it shows that the placebo peak is not interfering with the drug peak. So the proposed method was specified.

System suitability
The system suitability tests were used to evaluate the suitability of the complete testing system and parameters that were studied. These tests were carried out on freshly prepared standard stock solutions of Ropinirole with 10 replicate injections. Then asymmetry, no. of theoretical plates, retention time and %RSD of peak area were determined.

Linearity
The linearity of this method was determined with five concentration levels of the reference substance (4, 6,8,10 and 12µg/ml).Then calibration curve was constructed by plotting peak area vs. concentration. From this calibration curve straight line equations were obtained. The calculation of regression line was employed by the method of least squares.

Precision
The precision of the assay was determined by using sample solutions, at the concentrations (10ug/ml), during the intraday (Repeatability) and interday (intermediate precision) and the results were reported in terms of %RSD and also found the values of LOD and LOQ.

RESULTS AND DISCUSSION

The aim of this chromatographic method was to develop a simple, reliable and less time consuming RP-HPLC method for the estimation of Ropinirole hydrochloride in tablet dosage forms using mobile phase with 0.05mol glacial acetic acid(pH 3) : acetonitrile (50:50v/v) at a flow rate of 1ml/min on hypersil C_{18} (BDS) column, using 250nm as detection wavelength. The retention time for Ropinirole hydrochloride was found to be 4.03min which indicates a clear base line separation. No interfering peaks were found in the Ropinirole hydrochloride chromatogram which indicates that excipients present in tablet formulation did not interfere with the estimation of drug content. The system suitability for different parameters was shown in table-1 and parameters were found to be satisfactory and assay values are shown in table-2. The method was linear over the concentration range of 4-12µg/ml and the correlation coefficients for Ropinirole was r^2= 0.997, indicates good linearity (Fig-2 & Table-3). The precision of the proposed RP- HPLC method was determined by intraday and interday variation and was expressed as the %RSD (0.39&0.48 respectively). The LOD and LOQ were found to be 0.045 & 0.139 respectively. The recovery was found to be in the range of 99-99.89 (Table-4).

Fig 1: Typical chromatogram of Ropinirole hydrochloride

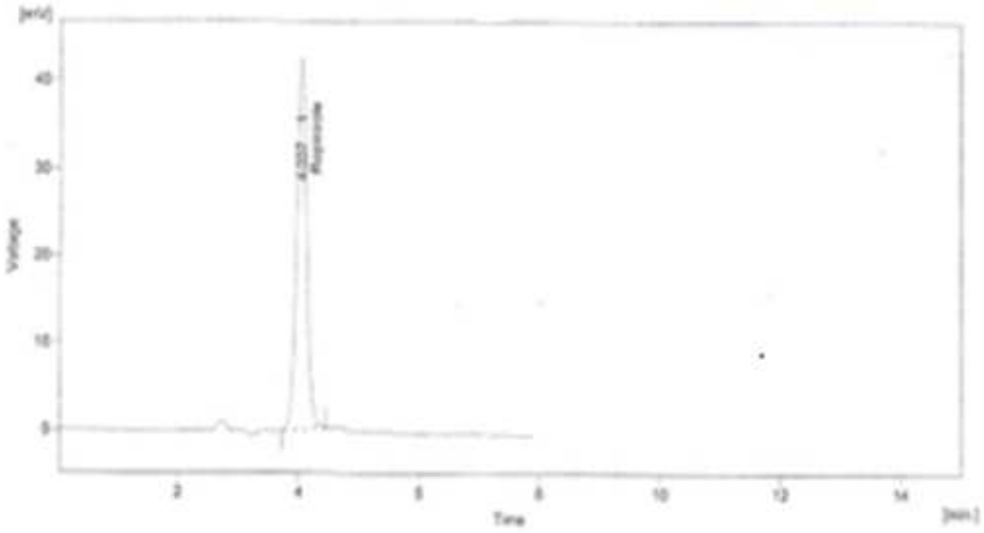


Table-1: System suitability parameters

Retention time (min)	4.030 ± 0.006
No. Of theoretical plates	2846
Asymmetry	1.06

Table-2: Assay value

Label claim(mg)	Amt. estimated(mg)	% Purity
0.25	0.246±0.003	100.5±1

Table- 3: Validation parameters

Parameter	Results
Linearity range (µg/ml)	4-12
Standard regression equation	y= 4.5063x +1.9339
Correlation coefficient	0.997
LOD	0.045
LOQ	0.139
Precision Intraday (%RSD) Interday(%RSD)	0.39 0.479
Specificity	Specific

Fig-2 Linearity Plot (Concentration Vs Peak area)

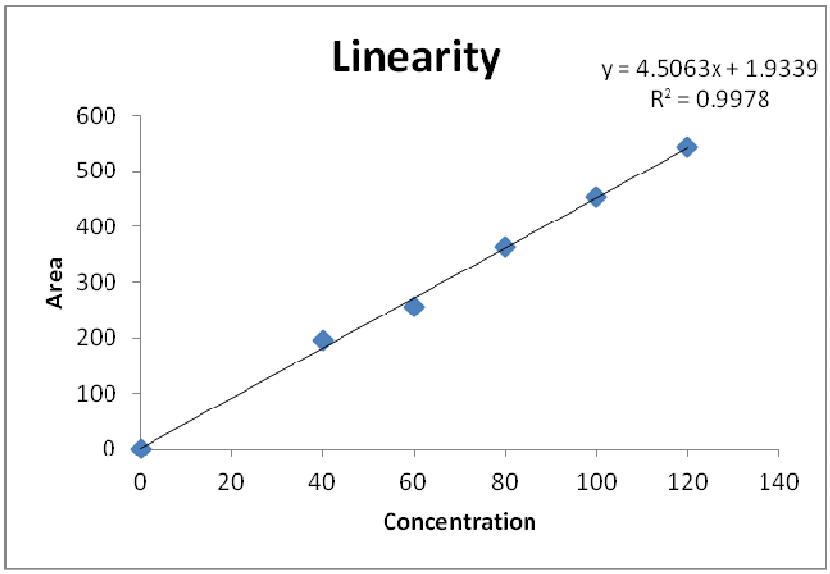


Table-4: Accuracy and Recovery data

Spike Level %	Amount of reference (mg/ml)				
	Added	Recovered	Recovery %	Mean%	RSD%
80%	0.80 0.798 0.79	0.799 0.797 0.787	99.88 99.87 99.62	99.79	0.15
100%	1.0 0.997 0.99	0.99 0.996 0.983	99.0 99.89 99.29	99.39	0.46
120%	1.186 1.184 1.183	1.179 1.182 1.181	99.40 99.83 99.83	99.69	0.25

CONCLUSION

From the above discussion, the proposed RP-HPLC method provides simple, specific, precise and accurate quantitative analysis of Ropinirole hydrochloride in pure and tablet dosage forms.

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