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Analytical Performance Parameters for Ropinirole Hydrochloride.

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Abstract

This medication is used alone or with other medications to treat Parkinson's disease. It can improve your ability to move and decrease shakiness (tremor), stiffness, slowed movement, and unsteadiness. It may also decrease the number of episodes of not being able to move ("on-off syndrome"). Ropinirole is also used to treat restless legs syndrome (RLS). It may improve your sleep by decreasing the urge to move your legs and decreasing uncomfortable/unpleasant feelings in the legs. This medication works by helping to restore the balance of a certain natural substance (dopamine) in the brain[1].Analytical chemistry is the science of making quantitative measurements. Analytical chemistry requires broad background knowledge of chemical and physical concepts. Analytical chemistry seeks ever improved means of measure the chemical composition of natural and artificial materials. The techniques of this science are used to identify the substance which may be present in a material and to determine the exact amounts of the identical substance. The analytical chemist serves the needs of many fields.

Keywords: dopamine medication, analytical chemist, contaminants, quantifying analytes.

Introduction

In medicine analytical chemistry is the basis for clinical laboratory tests. In industry analytical chemistry is applied for testing of raw materials and quality of finished products (pharmaceuticals). Environmental quality is evaluated by testing of contaminants using analytical techniques. The nutritional value of food is determined by chemical analysis for major components such as proteins and carbohydrates.In practice, quantifying analytes in a complex sample becomes an exercise in problem solving. To be effective and efficient, analyzing samples requires expertise in the chemistry that can occur in a sample.Present paper is a guide line for the analyst covering basic idea of particular drug analysis.

Two Criteria Of Chemical Analysis[13]

Analytical technique is a phenomenon that has proved useful for providing information on the composition of sample e.g.: IR, NMR. and Analytical method is a specific application of a technique to solve an analytical problem.

Factors Affecting The Choice Of Analytical Method[12]

Analytical techniques have different degrees of sophistication, sensitivity and selectivity. An important task for the analyst is to select the best procedure for a given determination. This will require careful consideration of the following criteria.

The type of analysis is required – elemental, molecular., The problem arising from the material to be investigated, Possible interference from components of the material other than those of interest. The concentration range, The accuracy required, The facilities available, particularly the instruments, The time required to complete the analysis.Similar type of analysis to be performed,

TypesOf Analytical Methods[2,5]

The various methods of analysis can be grouped into two categories. They are

1. Chemical methods
2. Instrumental methods

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Vol-10 Issue-6 No. 13 June 2020

1) Chemical methods / Traditional methods:

In these methods, volume and mass are used as means of detection.

- Titration method
- Gravimetric methods
- Inorganic qualitative analysis

Materials and Methods.

On the basis of above Ropinirole Hydrochloride has been studied under various laboratory condition and results so obtained are shown in tables and graphs

Parameters	Ropinirole Hydrochloride
Linearity Dynamic Range	20-120 (µg/ml)
Correlation Coefficient	0.999
Slope (m)	15.231
Intercept	15.469

Accuracy:

Accuracy expresses the closeness of agreement between the value, which is accepted either as conventional true value or and accepted reference value (International Standard e.g. pharmacopoeia -l standard) and the value found (mean value) obtained by applying the test procedure a number of times

To study reliability, suitability and accuracy of the method, recovery studies were carried out by comparing known quantity of the standard to the sample and recovery study was done. The recovery was carried out at 80%, 100% and 120% level and the contents were determined from the respective chromatogram. From the results obtained we can conclude that the method was accurate.

Table No. 1. Recovery Studies.

S.No:	Inj.Sample	Concentration Level	Standard area	Sample area	% Recovered
1	Ropinirole Hydrochloride	80%	1218.679	1204.86	98.86
2		100%	1512.164	1510.33	99.87
3		120%	1835.050	1835.385	100.01

Table No. 2. Mean Recovery of Ropinirole Hydrochloride for Accuracy

Accuracy level	Mean Recovery of Ropinirole Hydrochloride (%)
Accuracy 80%	98.86
Accuracy 100%	99.87
Accuracy 120%	100.01

Precision:

Repeatability of Injection

The system precision of test method five 20ml injection from a standard solution were injected on to the analytical column and the peak area data obtained and %RSD was calculated. The method precision of test method was done by performing assay on five replicate determination of sample preparation at test concentration level (as per method of analysis) and calculated relative standard deviation of assay results.The inter day precision of test method was done by performing assay on five replicate determination of sample

ISSN: 2278-4632
Vol-10 Issue-6 No. 13 June 2020

preparation at test concentration level and at different days and calculated relative standard deviation of results. The intra day precision of test method was done by performing assay on five replicate determination of sample preparation at test concentration level and at constant time intervals in one day and calculated relative standard deviation of results.

Table No.3. System Precision ofRopinirole Hydrochloride.

S.NO	Area of Ropinirole Hydrochloride (mV.s)
1	1208.676
2	1206.672
3	1210.658
4	1218.546
5	1211.692
Mean	1211.25
S.D	4.51
%RSD	0.37

Acceptance Criteria: The %RSD should be NMT 2.0%

Table No.4. Method Precision ofRopinirole Hydrochloride.

Sample No:	Area of Ropinirole Hydrochloride (mV.s)	Retention time
1	1208.878	4.015
2	1201.114	4.015
3	1221.254	4.110
4	1221.178	4.017
5	1210.618	4.017
Mean	1212.608	4.015
S.D	8.634	0.002
%RSD	0.712	0.061

Acceptance Criteria: The %RSD should be NMT 2.0%

Limit of Detection (LOD):

Limit of detection is the lowest concentration of the analyte that can be detected by injecting decreasing amount, not necessarily quantity by the method, under the stated experimental conditions.

The minimum concentration at which the analyte can be detected is determined from the linearity curve by applying the formula.

$$\text{Limit of detection} = \frac{\sigma}{S} \times 3.3$$

Limit of Quantitation (LOQ):

Limit of quantitation is the lowest concentration of the analyte in a sample that can be estimated quantitatively by injecting decreasing amount of drug, with acceptable precision and accuracy under the stated experimental conditions of the method. Limit of quantitation can be obtained from linearity curve by applying the following formula.

$$\text{Limit of quantitation} = \frac{\sigma}{S} \times 10$$

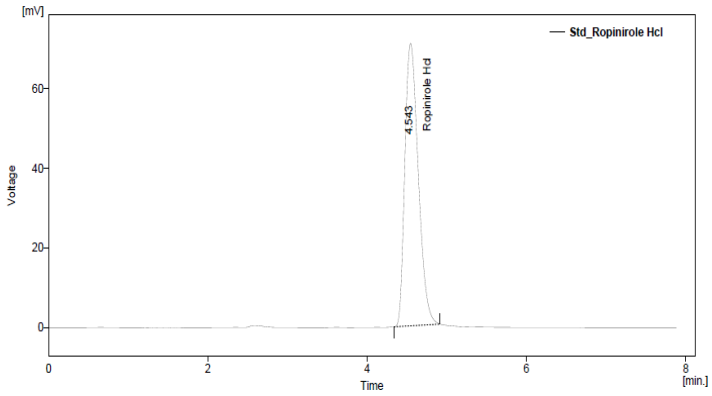
ISSN: 2278-4632
Vol-10 Issue-6 No. 13 June 2020

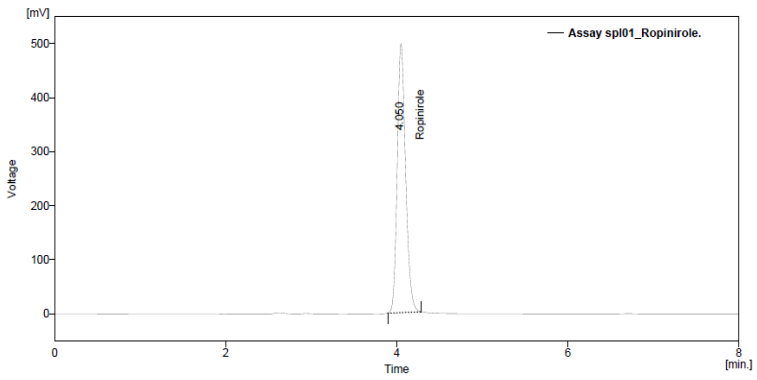
The lowest concentration at which peak can be quantified is called LOQ, for Ropinirole Hydrochloridewas found to be 3.459 µg/ml.

Table No: 5

Sample	LOD (µg/ml)	LOQ (µg/ml)
Ropinirole Hydrochloride.	1.141	3.459

Ropinirole Hydrochloride (Standard)Chromatogram No. 1 – Assay 01



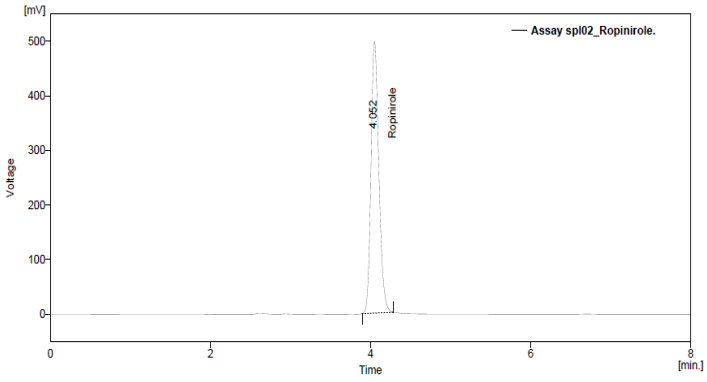


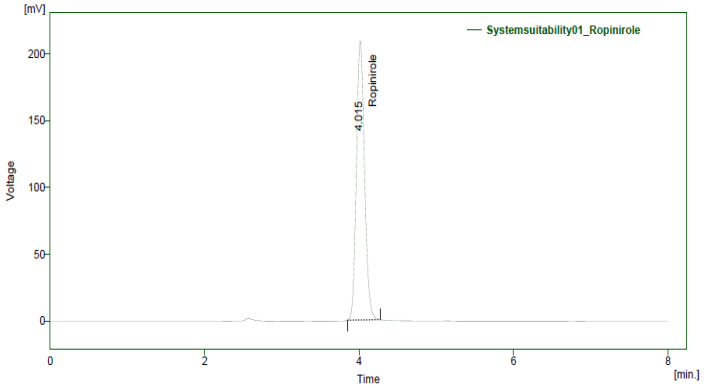
Chromatogram No.2– Assay 02Chromatogram No. 32 – Systemsuitability

Conclusion

It was concluded that there was no method reported for the simultaneous estimation of the above selected multicomponent dosage form, which promote to pursue the present work. The scope and objective of the present work is to develop and validate a new simple RP-HPLC method for simultaneous estimation of above mentioned.

In simultaneous RP-HPLC method development, the mobile phase selected after optimization was mixed Phosphate buffer and Acetonitrile in the ratio of 55:45 with pH 5.3 adjusted with dil. Orthophosphoric acid





was found to be ideal. The flow rate was found to be optimized at 1.0 ml/min. Detection was carried out at 287 nm. Quantitation was done by calibration curve method with the above mentioned optimized chromatographic condition. This system produced symmetric peak shape, good resolution.

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Vol-10 Issue-6 No. 13 June 2020

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