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A NEW RP HPLC METHOD FOR THE ESTIMATION OF RIBOCICLIB IN PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

A simple and selective LC method is described for the determination of Ribociclib dosage forms. Chromatographic separation was achieved on a c_8 column using mobile phase consisting of a mixture of Sodium Phosphate Buffer (pH 3.0): Acetonitrile (70:30) with detection of 284 nm. Linearity was observed in the range 50-150 µg /ml for Ribociclib (r^2 =0.9926) for drugs estimated by the proposed methods was in good agreement with the label claim. Ribociclib was found to be simple, precise, accurate and high resolution and shorter retention time makes this method more acceptable and cost effective and it can be effectively applied for routine analysis in research institutions, quality control department in industries, approved testing laboratories, bio-pharmaceutical and bio-equivalence studies.

Key Words: Ribociclib, chromatographic separation, high resolution, shorter retention, bioequivalence

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INTRODUCTION

A drug includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae mentioned in authoritative books**.**Pharmaceutical analysis is a branch of chemistry involving a process of identification, determination, quantification, purification and separation of components in a mixture or determination of chemical structure of analysis is performed to establish composition of a substance. It is done to determine the presence of a compound or substance in a given sample or not. The various qualitative tests are detection of evolved gas, limit tests, color change reactions, determination of melting point and boiling point, mass spectroscopy, determination of nuclear half life etc.Quantitative analysis techniques are mainly used to determine the amount or concentration of analyte in a sample and expressed as a numerical value in appropriate units. These techniques are based on suitable chemical reaction and either measuring the amount of reagent added to complete the reaction or measuring the amount of reaction product obtained the characteristic movement of a substance through a defined medium under controlled conditions, electrical measurement or measurement of spectroscopic properties of the

compound. Chromatography is defined as a non-destructive procedure for resolving multi-component mixture of trace, minor, or major constituents into its individual fractions. In chromatography, the sample is dissolved in the mobile phase which may be a gas, liquid, or a supercritical fluid. The principle involved in HPLC is that when a mixture containing different compounds is introduced into the mobile phase and allowed to flow over a stationary phase, the individual compounds travel at different speeds and get separated based on the relative affinities to the stationary phase and the mobile phase. The compounds are separated based on the polarity of the stationary phase and the mobile phase [1-3].

Aim is to develop new RP HPLC method for the estimation of **Ribociclib**in pharmaceutical dosage form

MATERIALS AND METHODS

Preparation of Standard solution

50 mg of Ribociclib was weighed and transferred in to 100 ml volumetric flask and dissolved in mobile phase and then make up to the mark with mobile phase and prepare 100 µg /ml of solution by diluting 5ml to 25ml with mobile phase.

Preparation of sample solution

20 tablets (each tablet contains 200mg of Ribociclib) were weighed and taken into a mortar and crushed to fine powder and uniformly mixed. Weighed crushed powder equivalent to 500 mg of Ribociclibin 500 ml of volumetric flask and dissolve in 350ml of mobile phase by 30min of sonication and make up the volume with mobile phase. Centrifuged sample at 5000rpm for 10min. Prepared 100µg/mL sample solution by further diluted 5mL above sample stock solution to 50mL with mobile phase and mixed well (4-6).

Linearity and Range

Preparation of the Standard Stock

Weighed accurately 100mg Ribociclib in 100 ml of volumetric flask and dissolve in 70ml of mobile phase and make up the volume with mobile phase and mixed well (Table-1) (7).

Table-1 Preparation of the Standard Stock

Volume Taken(mL)	Volume diluted to	Concentration(µg/mL)
1	20	50
1.5	20	75
2	20	100
2.5	20	125
3	20	150

RESULTS AND DISCUSSION

The wavelength of maximum absorption (λ_{max}) of the solution of the drug in mobile phase were scanned using UV-Visible spectrophotometer within the wavelength region of 200–400 nm against mobile phase as blank. The absorption curve shows characteristic absorption maxima at 284nm for Ribociclib(Fig-1), 284nm was selected as detector wavelength for the UPLC chromatographic method.

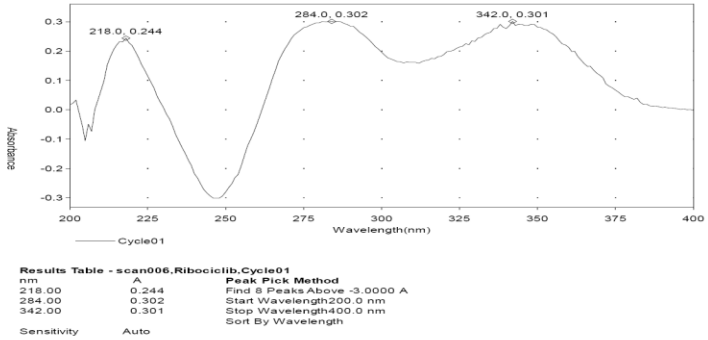

Fig-1 UV-VIS Spectrum of Ribociclib (284nm)

Mean %Assay Obtained between 90.0 to 110.0% for Ribociclib. The % RSD of % Assay results obtained from Test solution was obtained less than 2.0% for Ribociclib (Table-2). Hence Method is Precise.

Table-2 Method Precision Results

S.No.	Solution details	%Assay of Ribociclib
1	Test solution preparation-1	99.5
2	Test solution preparation-2	100.0
3	Test solution preparation-3	100.1
4	Test solution preparation-4	100.3
5	Test solution preparation-5	100.7
6	Test solution preparation-6	100.7
Average		99.2
Std Dev		0.34
%RSD		0.3

The correlation coefficient value obtained 0.9926 for Ribociclib (Table-3 and fig-2)

Table-3 Linearity Results of Ribociclib

S.No	Name of the Solution	Area of Ribociclib
1	Linearity solution, Level-1	1009147
2	Linearity solution, Level-2	1953325
3	Linearity solution, Level-3	2667662
4	Linearity solution, Level-4	3312980
5	Linearity solution, Level-5	4105525
Slope		33117.1
Intercept		661701.3
Correlation coefficient		0.9926

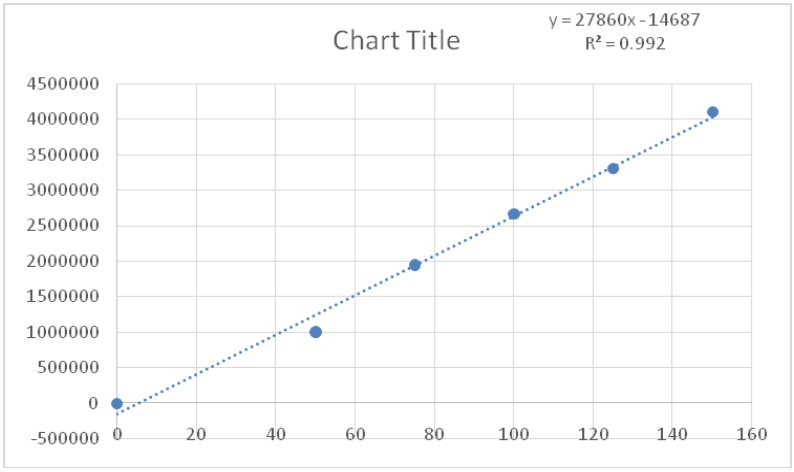

Fig-2 Linearity Graph of Ribociclib

System suitability met the acceptance criteria in Robustness parameters hence method is Robust (Table-4).

Table- 4 Robustness results for Ribociclib

Name of the Parameter	%RSD	Theoretical Plates	Tailing factor
Low Column Oven Temperature(25°C)	0.9	3945	1.43
High Column Oven Temperature(35°C)	0.7	3976	1.42
Lower Wavelength(251nm)	0.3	3964	1.43
Higher Wavelength(261nm)	0.4	3956	1.45

CONCLUSION

A new precise, accurate, rapid method has been developed for the estimation of RIBOCICLIB in bulk and its pharmaceutical dosage form by HPLC. From the above experimental results and parameters it was concluded that, this newly developed method for the estimation RIBOCICLIB was found to be simple, precise, accurate and high resolution and shorter retention time makes this method more acceptable and cost effective and it can be effectively applied for routine analysis in research institutions, quality control department in meant in industries, approved testing laboratories, bio-pharmaceutical and bio-equivalence studies and in clinical pharmacokinetic studies in near future.From results the proposed method is highly sensitive, precise and accurate and it successfully applied for the quantification of API content in the commercial formulations ofEducational institutions and Quality control laboratories.

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