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REVIEW ARTICLE

Review on Reversed-phase High-performance Liquid Chromatography Method Development and Validation for Estimation of Rivaroxaban

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ABSTRACT

This review article is proposed to underline method for the development by reversed-phase high-performance liquid chromatography (RP-HPLC) and validation of rivaroxaban in individual and pharmaceutical dosage form. Rivaroxaban is an anti-clotting drug, acts on Factor Xa, and stops the blood clot development. In this study, different types of RP-HPLC methods which are available at present for the determination of rivaroxaban in tablets (Xarelto 10 mg) are studied. There are different types of the methods described for the estimation of this drug such as RP-HPLC, ultra performance liquid chromatography (UPLC), and ultraviolet. However, nowadays, RP-HPLC plays a key role in quantitative determination of drug. The review is focused on HPLC method development that is previously used for rivaroxaban. Literature study carried on RP-HPLC, high-performance thin-layer chromatography, and UPLC methods of rivaroxaban. The center of study was to develop as well as validate a stable, economic, and rapid. The RP-HPLC method for assessment of rivaroxaban in its bulk formulation. Here, a new aspect for this method was developed which revealed high sensitivity and reproducibility. The developed method by RP-HPLC was validated by guidelines of ICH.

Keywords: Method development, reversed-phase high-performance liquid chromatography, rivaroxaban, validation

INTRODUCTION

For the determination of the quantity of drug, there are a variety of analytical methods used nowadays. There are a variety of analytical methods such as high-performance liquid chromatography (HPLC), ultra performance liquid chromatography (UPLC), and ultraviolet used for the method development and the validation of rivaroxaban. HPLC is referred as HPLC; it is a separation technique based on the solid stationary phase and liquid mobile phase.[1] Chromatography is a mass transfer process involves adsorption. The working element of the column is adsorbent which is a granular material of solid particles (silica and polymers). The separation principle in the reverse and normal phase is adsorption in which the mixture separates in accordance with relative affinities of substance toward the stationary phase.

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HPLC has a key role in the analytical validation methods.[2] HPLC is a separation method used for detection, separation, and quantification the drug. For method optimization, a number of chromatographic parameters were studied such as pretreatment of sample, mobile phase selection, and column and detector selection. This article's aim is to review the optimization, the method development, and the validation. The HPLC method development depends on polarity and solubility. Validation of a drug by the guidelines of ICH for HPLC method contains accuracy, specificity, linearity, limit of quantification, and limit of detection.[3,4]

HPLC METHOD DEVELOPMENT

When no official methods are available, then methods developed for new products. The time and cost are reduced using alternating methods for existing products which are producing better precision and ruggedness. When the existing procedure is replaced by more specific alternative method, it is possible

Table 1: Summary of RP-HPLC method development and validation for rivaroxaban

Method	Brief introduction	References no.
RP-HPLC	Mobile phase: Acetonitrile: 0.1% glacial acetic acid (70:30 v/v) Column: Enable C18-G (4.6 × 250 mm, 5 µm) Flow rate: 1.0 ml/min Wavelength: 250 nm	[9]
RP-HPLC	Mobile phase: Acetonitrile: Water (55:45 v/v) Column: Phenomenex Luna 5 µm C18 100 A^0Column (250 × 4.6 mm) Flow rate: 1.2 ml/min Wavelength: 249 nm	[3]
RP-HPLC	Mobile phase: Acetonitrile: KH_2PO_4 50 mm (pH 3.0) (40:60 v/v) Column: Nova-Pak C8 (4 µm, 150 mm × 3.9 mm) Waters, Milford, USA Flow rate: 1 ml/min Wavelength: 270 nm	[10]
RP-HPLC	Mobile phase: Methanol: Acetonitrile (50:50 v/v). Column: Phenomenex C18 (250 mm × 4.6 mm, 5 µm), 100A° particle size columns Flow rate: 1 ml/min Wavelength: 250 nm	[11]
HPLC	Mobile phase: Acetonitrile: Water (55:45 v/v) Column: C18 column (phenomenex 250 mm × 4.6 mm, 5 µm) Flow rate: 1.2 ml/min Wavelength: 251 nm	[12]
HPLC	Mobile phase: Methanol: 0.1 M sodium acetate (40:60 v/v) Column: ACE-Ciano column (250 mm × 4.6 mm 5 µm particle size) Flow rate: 1 ml/min Wavelength: 247 nm	[13]
UPLC	Mobile phase: 1 ml orthophosphoric acid (H_3PO_4) and 10 ml sodium salt of octane 1-sulfonic acid ($C_8H_{18}O_3S$) as buffer: Acetonitrile (90:10, 20:80) Column: Acquity UPLC BEH HSS T3 100-mm, 2.1 mm, and 1.8 µm columns Flow rate: 0.45 ml/min Wavelength: 248 nm	[14]
HPTLC	Mobile phase: Methanol: Toluene: Triethanolamine (7:2.5:0.5 v/v/v). Stationary phase: Silica gel G F254 Wavelength: 249 nm	[15]
RP-HPLC	Mobile phase: (0.02 M) Monobasic potassium dihydrogen phosphate (KH_2PO_4): Acetonitrile: Methanol Column: Zorbax SB C-18 (250 mm × 4.6 mm, 3.5 µ) Flow rate: 1 ml/min Wavelength: 247 nm	[16]
UPLC-UV	Mobile phase: Acetonitrile: Water (90:10 v/v) Column: Agilent Poroshell 120 EC-C18-RP column Flow rate: 0.7 ml/min Wavelength: 249 nm	[17]
RP-HPLC	Mobile phase: 10% orthophosphoric acid pH 4.0: Acetonitrile (40:60%v/v) Column: Pearless C-18 column (4.6 mm × 250 mm, 5µ particle size) Flow rate: 1 ml/min Wavelength: 249 nm	[18]
RP-HPLC	Mobile phase: Buffer (0.05 M pH 4.0): Methanol (30:70 v/v) Column: BDS Hypersil C-18 (250 mm × 4.6 mm) 5 µ, thermo scientific Flow rate: 1 ml/min Wavelength: 220 nm	[19]
RP-UPLC	Mobile phase: 1st mobile phase acetonitrile: 0.05 M diammonium hydrogen phosphate (pH 3.0) (20:80 v/v) and 2nd mobile phase acetonitrile: Water (90:10, v/v) Column: BEH C 8 column (100 mm × 2.1 mm, 1.7 µm) Flow rate: 1 ml/min Wavelength: 254 nm	[20]
RP-HPLC	Mobile phase: Acetonitrile: KH_2PO_4 buffer (pH 3.0 adjusted with orthophosphoric acid) (40:60% v/v) Column: HIBAR-5 µ C18 column (250 mm × 4.6 mm) Flow rate: 1 ml/min Wavelength: 248 nm	[21]

RP-HPLC: Reversed-phase high-performance liquid chromatography, RP-UPLC: Reversed-phase ultra-performance liquid chromatography, UV: Ultraviolet, HPTLC: High-performance thin-layer chromatographic

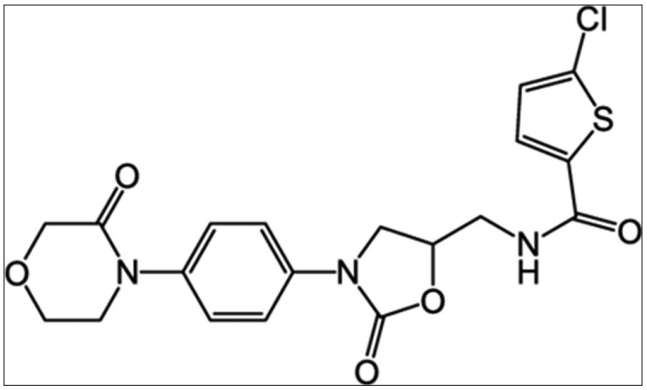

Figure 1: Chemical structure of rivaroxaban

to compare the laboratory records with merit and demerits of both methods. The HPLC method object is to separate and quantify the active pharmaceutical ingredients, intermediates, degradants, and reaction impurities [Table 1].[5]

Steps for HPLC method development are as follows:[5,6]

1. Information on sample.
2. Define separation goals.
3. Special procedure requirement, sample pretreatment, if any.
4. Detector selection and setting.
5. Separation conditions optimization.
6. Check for problems or special procedure requirements.
7. Recovery of purified material.
8. Quantitative calibration/qualitative method.
9. Method validation for release to laboratories.

Drug Profile

Rivaroxaban is 5-chloro n-{[(5S)-2-oxo-3-[4-(3-xomorpholin-4-yl) phenyl]-1, 3-oxozolidin-5-yl] methyl} thiophene-2-corboxamide.[7] It belongs to the class of direct Factor Xa inhibitor accepted for the avoidance of venous thromboembolic actions in patients undergone in whole hip or whole knee replacement surgery. The drug blocks the enlargement of the pathway of coagulation cascade by binding directly to the Factor Xa, thus prevent the development of thrombus.[8] Molecular formula of rivaroxaban is $C_{19}H_{18}CIN_3O_5S$. Molecular weight of drug is 435.881 g/mol. Figure 1 shows structure of rivaroxaban.

CONCLUSION

This review describes the general technique of HPLC method development and validation of rivaroxaban. The general approach for the method development for the separation of rivaroxaban was discussed. The selection of buffer and mobile phase composition plays a dramatic role on the separation selectivity. Final method optimization can be performed by changing the concentration of mobile phase modifiers, gradient slope, temperature, and flow rate. Optimized method is validated with various parameters as per ICH guidelines.

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