Original Article

A New Stability Indicating HPLC-PDA Method for Estimation of Eluxadoline in Presence of its Degradation Products

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ABSTRACT

Background: The goal of proposed study was to optimize and validate reversed phase high performance liquid chromatography (RP-HPLC) method for assessment of eluxadoline in presence of its forced degradation products in in-house tablet mixture. **Materials and Methods:** RP-HPLC method was developed using SunQSil C_{18} (250 mm × 4.6 mm, 5 μm) as stationary phase and 20 mM sodium acetate: methanol (45:55, *v/v*) as mobile phase at a 1 ml/min flow rate with 205 nm detection wavelength. The method was found to give a resolved peak of eluxadoline at retention time of 5.32 min. To study degradation behaviour of eluxadoline, it was exposed to acid hydrolysis, alkali hydrolysis, oxidation, photolysis and thermolysis. The developed method was suitable to resolve eluxadoline from its all-degradation products. Validation of method was carried out in accoradance with ICH quality guideline Q2(R1). **Results:** In the concentration range of 3 - 18 μg/ml, the linearity of the proposed process was observed with regression coefficient (R^2) of 0.9987. Sensitivity parameters, LOD and LOQ were observed to be 0.8627 μg/ml and 2.6144 μg/ml, respectively. In accuracy studies, the recovery of the drug was found to be between 99.1956-100.7294%. It was noticed that the developed was precise as the values of % RSD were found to be less than 2.0 % for both intraday and interday precision. The method was robust and can be useful for regular analysis of formulations containing eluxadoline. **Conclusion:** The developed method was utilised for determination of content of eluxadoline in in-house tablet mixture.

Keywords: Eluxadoline, Degradation studies, HPLC, Stability indicating method, Validation.

INTRODUCTION

Eluxadoline, chemically 5-({(4-carbamoyl-2, 6-dimethyl-L-phenylalanyl) [(1S)-1-(4-phenyl -1H-imidazol-2-yl) ethyl] amino} methyl)-2-methoxybenzoic acid (Figure 1), is used in the management of Irritable Bowel Syndrome with Diarrhoea (IBS-D).[1] Irritable Bowel Syndrome (IBS) is chronic functional bowel disorders which is associated with symptoms like abdominal distress often linked with alteration in bowel routine, evacuation frequency and stool forms.[2-3] IBD and other gastrointestinal disorders are differentiated from each other depending on current activity, chronicity, frequency and the absence of obvious anatomic or physiologic abnormalities.[4] Eluxadoline is an agonist of mu-opioid and kappa-opioid receptor and antagonist of delta opioid receptor, gives relief from the symptoms of IBS-D.[1]

The stability indicating method is an analytical technique that evaluates the active ingredient in presence of process impurities, excipients and degradation products accurately and precisely.[5-7]

As per literature survey, few HPLC methods are reported for the estimation of eluxadoline. Panigrahy *et al.* reported HPLC-DAD method for estimation of eluxadoline.[8] UPLC–MS/MS[9] and LC-MS/MS[10] methods for quantitative estimation of eluxadoline in plasma samples were also presented.

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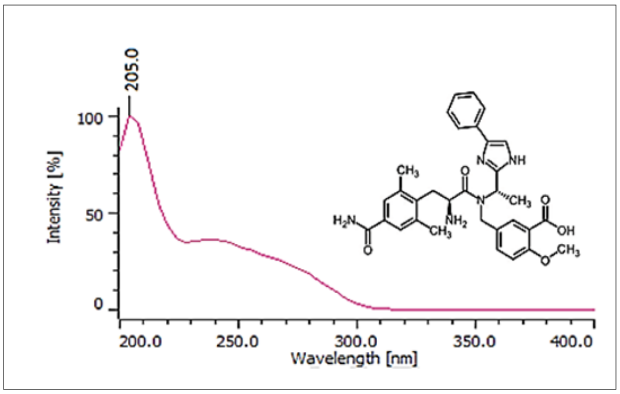

Figure 1: Structure of eluxadoline with its absorption maxima.

RP-HPLC method for quantitative determination of eluxadoline in presence of its impurities was described.[11] HPLC-PDA for simultaneous estimation of eluxadoline along with rifaximin in plasma of rat was reported.[12] There is no HPLC method reported for the estimation of eluxadoline in presence of its forced degradation products. Hence, the main objective of the study was to optimize and validate RP-HPLC-PDA method for estimation of eluxadoline in presence of its forced degradation products.

MATERIALS AND METHODS

Instruments

HPLC analysis was performed using HPLC system 4000 series (JASCO, Japan) consisting of quaternary pump (PU-4180-LPG), online degasser, reservoir stand (BS-4000-1), automatic sample introduction system (AS-4050) and PDA detector (MD-4017). The hardware interface between the HPLC system components and PC used was LC-Net II/ADC. All the chromatograms were evaluated using ChromNAV software (version 2.0).

Procurement of Drug and Chemicals

Standard of eluxadoline was procured having 98% w/w purity with certificate of analysis (COA) from Alkem Laboratories Ltd., Bharuch, India. HPLC grade solvents such as methanol, water and acetonitrile were procured from Fischer Scientific India Pvt. Ltd., Mumbai, India. Sodium acetate (HPLC grade) was purchased from Modern Industries, Nashik, India.

In-house Tablet Mixture Preparation

In-house tablet mixture was prepared and was treated as sample. All ingredients which are mentioned in Table 1 were weighed accurately and taken in mortar pastel. The mixture was triturated for 10 min to mix all the ingredients.

Table 1: Formula for preparation of in-house tablet mixture of eluxadoline.

Name of ingredients	Quantity (350 mg tablet)		Category
	Given (%)	Taken (mg)	
Eluxadoline	28.5	100	For treatment of IBS-D
Silicified microcrystalline cellulose	12	42	Binder
Colloidal silica	1.5	5.25	Glidant
Crospovidone	3.0	10.5	Super disintegrant
Magnesium stearate	1.5	5.25	Lubricant
Mannitol	Quantity sufficient	187	Diluent

Preparation of 20 mM Sodium Acetate Buffer Solution

Accurately weighed 1.6406 g of sodium acetate was transferred to 1000 ml volumetric flask. Accurately measured 500 ml HPLC grade water was added and sonicated for 5 min to dissolve the solids. After that volume was made up to the mark with HPLC grade water and buffer was filtered through 0.2 µm membrane filter (BEXCO, USA).

Mobile Phase Preparation

Desired composition of mobile phase was prepared by mixing 45 volumes of 20 mM sodium acetate buffer solution with 55 volumes of methanol to get ratio of 45:55, *v/v*.

Preparation of Standard Stock Solution

Standard stock solution containing 1000 µg/ml of eluxadoline was prepared by dissolving 10 mg of eluxadoline in 10 ml of HPLC grade methanol. The solution was sonicated for 10 min. Accurately measured 1 ml of above solution was taken and added in 10 ml volumetric flask. Accurately measured 5 ml of mobile phase was added and volume was made up to the mark with mobile phase to produce 100 µg/ml of working stock solution. The resulting solution was filtered through 0.2 µ sample filter (Axiva).

Preparation of Sample Solution

In-house tablet mixture containing 10 mg of eluxadoline was weighed and added to 10 ml volumetric flask. Then 5 ml of HPLC grade methanol was added and solution was sonicated for 10 min then volume was made up to the mark with HPLC grade methanol to get concentration of 1000 µg/ml of eluxadoline. The

resulting solution was filtered through 0.2 µ sample filter (Axiva). Accurately measured 1 ml of the above solution was taken and transferred to 10 ml volumetric flask. Accurately measured 5 ml of mobile phase was added and then volume was made up to the mark with mobile phase to produce 100 µg/ml of working stock solution.

Choice of Absorption Maxima

A standard solution containing 10 µg/ml of eluxadoline was prepared in methanol and was scanned in enire UV range of 200-400 nm against methanol as blank and spectrum was obtained. The absorbance maxima was selected for recording all chromatograms.

Chromatographic Conditions

Various solvents were tried as mobile phase for separation of drug under study from its degradation products. 20 mM sodium acetate buffer solution in combination with methanol in the ratio of 45:55, *v/v* produced desired results. Separation of eluxadoline from its degradation products were performed using SunQSil C_{18} (250 mm X 4.6 mm, 5 µm) column and 20 mM sodium acetate: methanol (45:55, *v/v*) as an eluent. The flow rate of eluent was 1 ml/min and the detection of all chromatograms was carried out at 205 nm. The volume of sample injected was 10 µl and the analysis time for single run was 10 min.

Forced Degradation Studies

Eluxadoline standard solution (1000 µg/ml prepared in methanol) was subjected to acidic (1N HCl for 8 hr reflux at 60°C), basic (1N NaOH for 8 hr at 60°C) oxidative (30% H_2O_2 *v/v* for 24 hr at room temperature), thermolytic (Dry drug exposed to 50°C, 120 hr), and photolytic (dry drug exposed to 254 nm in UV chamber for 120 hr) degradation. The sample for acidic, basic and oxidative degradation were prepared by 1:1 dilution of the standard stock solution with the degradation solution and after that solution was diluted with mobile phase for HPLC analysis.

Method Validation

The developed method was validated for evaluation of various parameters such as specificity, system suitability, LOD, LOQ, linearity, accuracy, precision and robustness.[13-14]

Specificity and System Suitability

Specificity and system suitability study were assessed by injecting six injections containing 100 µg/ml standard solution of eluxadoline and two injections of sample solution containing 100 µg/ml eluxadoline under optimum standard chromatographic conditions in HPLC. Any interference from mobile phase and tablet excipients was checked. In case of system suitability studies, peak symmetry and the number of theoretical plates were evaluated.

LOD and LOQ

LOD and LOQ were evaluated by standard deviation method by plotting calibration curve in the range of 1.0-6.0 µg/ml using equation; LOD = 3.3 *σ/S and LOQ = 10 * σ/S, where σ is standard deviation of intercepts and S is the slope of the calibration curve.

Linearity

Linear relationship between concentration and area of eluxadoline was determined by injecting the solutions in the concentration range of 3.0-18 µg/ml in triplicates. Average of area were calculated and graph of average area vs concentration was drawn and coefficient of regression (R^2) was determined.

Accuracy

The accuracy of the proposed method was analyzed by calculating the percentage recovery. Accuracy was evaluated at three levels (i.e., 50 %, 100 % and 150 %) in triplicates. Predetermined amount of sample solution (3.0 µg/ml) was spiked in three different concentrations of standard solutions (i.e., 4.5, 9.0 and 13.5 µg/ml). These solutions were injected in triplicates. % Recovery was calculated.

Precision

Repeatability (Intraday precision) and intermediate precision (Intraday precision) studies were performed to determine precision of the proposed method. Independent sample solutions of eluxadoline (i.e., 4.5, 9.0 and 13.5 µg/ml) were injected in triplicates. The peak area was measured and % RSD was calculated at each concentration level. Intraday precision (repeatability studies) was carried out by performing analysis over a period of time while interday precision (intermediate precision) was performed for two consecutive days.

Robustness

To assess robustness of the developed method, chromatographic parameters were intentionally altered such as change in flow rate (± 0.1 ml/min), change in mobile phase composition (± 1 ml of methanol), change in wavelength (± 2 nm). Standard solution of eluxadoline (9.0 µg/ml) was injected six times and sample solution (9.0 µg/ml) was injected twice. % RSD of area of standard solution was calculated and % w/w

of eluxadoline of sample was calculated for both altered and unaltered conditions.

Analysis of in–house Tablet Mixture

To determine the concentration of eluxadoline in in-house tablet mixture, both standard and sample solution each containing 9.0 µg/ml of eluxadoline were injected in triplicates in HPLC under optimal chromatographic conditions. The % w/w of eluxadoline in in-house tablet mixture was calculated.

RESULTS AND DISCUSSION

Selection of Detection Wavelength

It was found that the drug showed maximum absorbance at 205 nm (Figure 1) hence 205 nm was chosen as the detector wavelength.

Method Development

Different mobile phase compositions were used to obtain resolved peaks of drug and degradation products. Initially, different compositions of solvents such as (acetonitrile: water and methanol: water) were tried but system suitability parameters did not comply with standard limit. Then based on literature survey, sodium acetate: methanol was tried. Different composition was tried and then 20 mM sodium acetate: methanol (45:55, *v/v*) was found to be optimum for eluxadoline analysis. Retention time of eluxadoline was found to be 5.35 min with number of theoretical plates 5383 and symmetric factor 1.03 (Figure 2a).

Forced Degradation Studies

Forced degradation studies was carried out using acid hydrolysis, base hydrolysis, oxidation, thermolysis and photolysis.[15]

Acid Hydrolysis

In acid degradation, the drug was treated with hydrochloric acid. Initially, drug was degraded with 0.1 N HCl for 8 hr at 60°C , but sufficient degradation was not observed. The concentration of acid was increased and drug was treated with 1 N HCl for 8 hr at 60°C. Sufficient degradation was observed, it was found that the drug was eluted at retention time of 5.340 min and two degraded products were eluted at retention time of 3.013 min and 8.417 min, respectively. Degradation of eluxadoline up to 52.073 % of total degradation was observed (Figure 2b, Table 2).

Base hydrolysis

In base degradation, the drug was treated with sodium hydroxide. Eluxadoline was degraded with 0.1 N NaOH for 8 hr at 60°C, but sufficient degradation was not observed. It was decided to treat eluxadoline with 1 N NaOH for 8 hr at 60°C. Sufficient degradation was observed, it was found that the drug was eluted at retention time of 5.343 min and two degraded products were eluted at retention time of 3.023 min and 5.810 min, respectively. Degradation of eluxadoline up to 43.45 % of total degradation was observed (Figure 2c, Table 2).

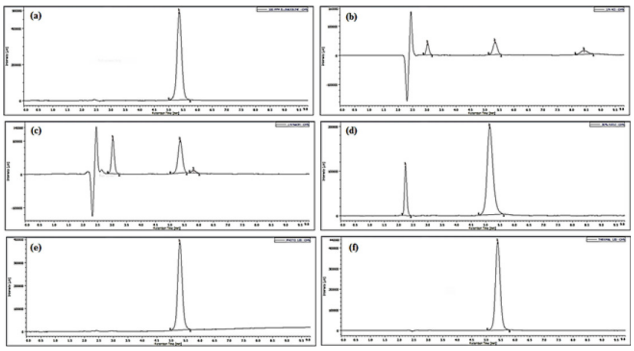

Figure 2: Chromatograms obtained using mobile phase 20 mM sodium acetate: methanol (45:55, *v/v*) (a) standard eluxadoline (b) degradation of eluxadoline with 1 N HCl at 60°C for 8 hr (c) degradation of eluxadoline with 1 N NaOH at 60°C for 8 hr (d) degradation of eluxadoline by 30 % H_2O_2, *v/v* at room temperature for 24 hr (e) photolytic degradation of eluxadoline for 120 hr (f) thermolytic degradation of eluxadoline at 50°C for 120 hr.

Oxidation

In oxidative degradation, the drug was treated with hydrogen peroxide. Eluxadoline was initially treated with 3 % *v/v* of H_2O_2 for 6 hr, then time duration was increased upto 24 hr. Then oxidation was followed with 10 % *v/v* of H_2O_2 for 24 hr at room temperature, but sufficient degradation of drug was not observed. It was decided to treat the drug with 30 % *v/v* of H_2O_2 at room temperature for 24 hr. Sufficient degradation of eluxadoline was observed, it was found that the drug and the degraded product were eluted at retention time of 5.133 min and 2.233 min, respectively. 17.687 % of degradation of eluxadoline was observed (Figure 2d, Table 2).

Photolytic Degradation

The eluxadoline was exposed to UV light at 254 nm for 24, 48, 72, 96, 120 hr but drug showed no degradation (Figure 2e, Table 2).

Thermal Degradation

The eluxadoline was exposed to temperature of 50°C for 24, 48, 72, 96, 120 hr but drug showed no degradation (Figure 2f, Table 2).

Table 2: Results of forced degradation studies of eluxadoline.

Forced degradation Study	Degradation Condition	% Degradation of drug	R*t* of drug (min)	R*t* of degradation peak
Acid degradation	1 N HCl at 60°C for 8 hr	52.073 %	5.340	3.013, 8.417
Base degradation	1 N NaOH at 60°C for 8 hr	43.45 %	5.343	3.023, 5.810
Oxidative degradation	30 % H_2O_2 *v/v* at RT for 24 hr	17.687 %	5.133	2.233
Photolytic degradation	UV light for 120 hr	No degradation	5.189	NA
Thermal degradation	50°C for 120 hr	No degradation	5.173	NA

Table 3: Results of system suitability study for standard solution of eluxadoline.

	tR (min)	NTP	Symmetry factor
Standard	5.243	5064	1.11
	5.350	5616	1.02
	5.423	5433	1.04
	5.370	5434	1.04
	5.353	5485	1.03
	5.370	5354	1.05
Average ±SD[a]	5.352±0.0592	5398±184.9893	1.048±0.0318
Sample	5.353	5387	1.03
	5.423	5316	1.04
Average ±SD[b]	5.388±0.0494	5352±50.2045	1.035 ±0.0070

a=six measurements, b=duplicate measurements.

Table 4: Results of % accuracy of eluxadoline by developed HPLC method.

Level (%)	Recovery (%)	Mean Recovery (%) ± SD[c]	% RSD[c]
50 %	99.1110	99.1956 ± 0.3354	0.3381
	99.5653		
	98.9106		
100 %	99.5566	100.14076 ± 1.1999	1.1981
	99.3578		
	101.5284		
150 %	101.5172	100.7294 ± 1.0930	1.0850
	99.4815		
	101.1894		

c=triplicate measurements.

Table 5: Results of precision studies of eluxadoline by developed HPLC method.

Concentration of sample (µg/ml)	% RSD[d] Intraday Precision	% RSD[d] Intraday Precision	% RSD[d] Interday Precision
	Day 1	Day 1	Day 2
4.5	1.9401	0.1313	1.1164
9.0	0.1085	0.5256	0.7960
13.5	0.1084	1.1301	0.0654

d=triplicate measurements.

Method Validation

The developed and optimized method was validated as per ICH quality guideline Q2(R1).

Specificity and System Suitability

No interference was observed from the blank solution, mobile phase and excipients or degradation products hence the method was found to be specific. The developed method was also suitable to perform analysis of drug under study as all system suitability parameters were within limits (Table 3).

LOD and LOQ

The LOD and LOQ for proposed method was found to be 0.8627 µg/ml and 2.6144 µg/ml. It was noticed that the method was sensitive, as it can detect and quantitate µg level of eluxadoline.

Linearity and Range

Linearity was studied by injecting various concentrations of standard solutions of eluxadoline in the range of 3 – 18 µg/ml. The linearity was observed in the stated concentration range with regression equation of y = 62657 x + 29994 and regression coefficient of 0.9987.

Accuracy

Eluxadoline's percentage recovery was found to be between 99.1956 and 100.7294 %. The value of % RSD at each level was less than 2.0 %. As % recovery and % RSD for eluxadoline at each level was within acceptable limits, the method was found to be accurate (Table 4).

Precision

Both intraday and interday precision studies were performed as a part of precision studies at three concentration levels (4.5 µg/ml, 9.0 µg/ml and 13.5 µg/ml). The developed method was considered to be precise as the values of % RSD of area acquired at each level of studies was less than 2.0 (Table 5).

Table 6: Results of robustness studies of eluxadoline.			
Parameter	**Retention time (% RSD[e])**	**Area (% RSD[e])**	**% Content**
Flow rate (ml/min)			
0.9	5.6795 (0.1517)	674090.1 (0.7693)	98.2205 %
1.0	5.137 (0.1831)	607180.9 (1.0450)	98.6678 %
1.1	4.604 (0.0902)	546106.3 (0.6102)	98.1366 %
Wavelength (nm)			
203	5.137 (0.1831)	590387.3 (0.8984)	98.2321 %
205	5.137 (0.1831)	607180.9 (1.0450)	98.6678 %
207	5.136 (0.1859)	582003.1 (0.6919)	98.0458 %
Mobile phase ratio (20 mM Sodium acetate: Methanol, *v/v*)			
44:56	4.911 (0.2322)	559345.1 (1.6381)	100.4359 %
45:55	5.137 (0.1831)	607180.9 (1.0450)	98.6678 %
46:54	5.536 (0.2148)	548339.3 (1.0150)	99.3493 %

e=six measurements.

Robustness

In robustness studies, the % RSD of area of standard solution of eluxadoline was found to be less than 2.0 and % w/w of eluxadoline was found to be in between 98 – 102 % for both altered and unaltered (Table 6).

Analysis of in-house tablet mixture

The standard and sample solutions of eluxadoline were prepared and injected in triplicates. % w/w of eluxadoline was found to be 98.2196 %.

CONCLUSION

A new, rapid, simple, accurate and precise reversed phase HPLC-PDA method was developed and validated for quantitative estimation of eluxadoline in presence of its forced degradation products. The developed and validated method was successfully applied to estimate content of eluxadoline present in in-house tablet mixture in presence of its degradation products.

CONFLICT OF INTEREST

The authors declare that no conflict of interest.

ABBREVIATIONS

COA: Certificate of Analysis; **DAD:** Diode Array Detector; **GI:** Gastrointestinal; **HCl:** Hydrochloric Acid; **HPLC:** High Performance Liquid Chromatography; **H_2O_2:** Hydrogen Peroxide; **HPTLC:** High Performance Thin Layer Chromatography; **ICH:** International Conferences on Harmonization; **IBS:** Irritable Bowel Syndrome; **IBS-D:** Irritable Bowel Syndrome with Diarrhoea; **LC–MS/MS:** Liquid Chromatography-Tandem Mass Spectrometry; **LOD:** Limit of Detection; **LOQ:** Limit of Quantification; **mM:** Milimolar; **NaOH:** Sodium Hydroxide; **NTP:** Number of Theoretical Plates; **PDA:** Photo Diode Array; **QRM:** Quality Risk Management; **RP-HPLC:** Reversed Phase High Performance Chromatography; **RSD:** Relative Standard Deviation; **SD:** Standard Deviation; **UV:** Ultra Violet; **UPLC–MS/MS:** Ultraperformance Liquid Chromatography-Tandem Mass Spectrometry.

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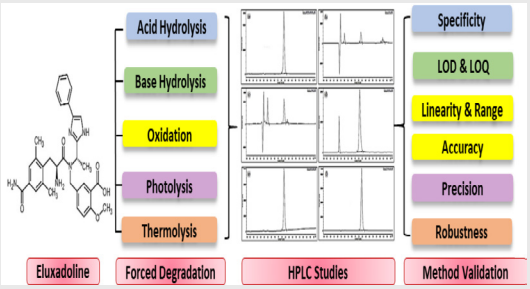
PICTORIAL ABSTRACT



SUMMARY

HPLC-PDA method was developed and validated for estimation of eluxadoline in presence of its forced degradation products.

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