WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.453
Volume 14, Issue 7, 805-819. Research Article ISSN 2277–7105

DEVELOPMENT AND VALIDATION OF HPLC METHOD FOR THE DETERMINATION OF MONTELUKAST SODIUM IN PHARMACEUTICAL FORMULATIONS

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Article Received on
17 February 2025,
Revised on 10 March 2025,
Accepted on 31 March 2025
DOI: 10.20959/wjpr20257-36033

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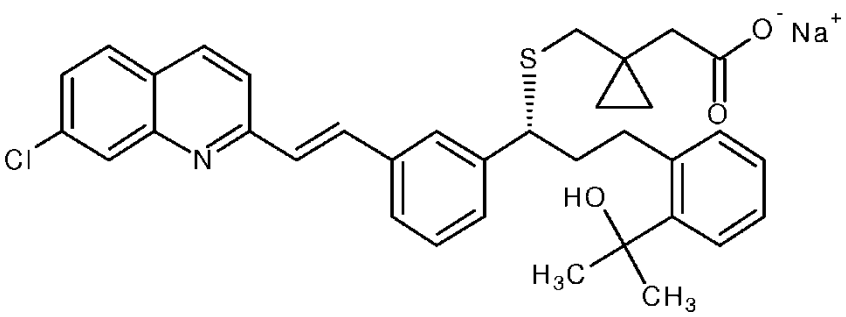
ABSTRACT

Worldwide over 300 million people are affected by asthma which is a chronic inflammatory disease. Allergic rhinitis and the presence of pro-inflammatory cells and mediators in the circulation of patients qualifying asthma as a systemic disease are the common Associators. Persistent asthma therapy, inhaled corticosteroids can't suppress all components of airway inflammation and fails to penetrate in small airways, warrant the quest for effective systemic anti-asthma therapies. These Project describes the most important controlled studies of Montelukast Sodium which is a Leukotriene receptor antagonist (LTRA) used for maintenance treatment of asthma and to relive symptoms of seasonal allergies. It comes as a tablet, a chewable tablet and granules to take by mouth which is usually taken once a day with or without food. Montelukast Sodium which is systemically active drug with a targeted dual mechanism of action acting both as a bronchodilator and anti-inflammatory for aged patients. It is a Well tolerated drug for both as monotherapy are in combination with inhaled corticosteroids.

INTRODUCTION

Montelukast sodium is a prescription to medication that belongs to the class of leukotriene receptor antagonists (LTRAs)it is used to treat asthma, allergic rhinitis and exercise induced bronchospasm. Brand names: montelukast sodium is marketed under various Brand names :Singulair (merck &co), montelukast(generic), Lukair (in some counties) montelukast sodium has halflife approximately 2.7 to5.5hoours pharmacokinetics the oral bioavailability of montelukast sodium is approximately 63to73% in healthy adults. the peak plasma concentration of montelukast sodium is reached within 3-4hours after oral administration. Montelukast sodium is extensively bound to plasma proteins. montelukast sodium is metabolized by the liver enzymes CYP3A4 and CYP2C9. Montelukast sodium is excreted in the urine with approximately 86% of the dose excreted within 5 days small amount of montelukast sodium excreted in the feces. the daily dose of montelukast sodium is 10mg (orally once daily in evening).

Structure



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Chemical Name:.1-[[[(1R)-1-[(1E)-2-(7-chloro2-quinolinyl) ethenyl] phenyl]-3-[2-(1-hydroxy-1-methylethyl) phenyl]propyl]methyl]cyclopropaneacetic acid , monosodium salt

Molecular Formula: C35H35ClNNaO3S

Molecular weight:608.17gm/mol

Description: white to off white hygroscopic powder

Solubility: Montelukast sodium is freely soluble in water, methanol and ethanol

Practically insoluble in acetonitrile

Pharmacology*:* Leukotriene receptor inhibitor

Indications: Montelukast is used to prevent wheezing**,** difficulty breathing**,** chest tightness and coughing caused by asthma in adults and children 12 months of age and older**.**

Montelukast is also used to prevent bronchospasm **(**breathing difficulties**)** during exercise in adults and children 6 years of age and older.

Mechanism of action

Leukotriene Synthesis: Leukotrienes are pro-inflammatory mediators produced by the body's immune system. They play a key role in the pathogenesis of asthma and allergic rhinitis

Cysteinyl leukotriene inhibitors: montelukast sodium works by selectively binding to cysteinyl leukotriene receptors (cysLTI Receptors) in the lungs and other tissues

Blockade of leukotriene action: action by binding to CysLTI receptors. Montelukast sodium blocks the action of cysteinyl leukotrienes, which are potent bronchoconstrictors and pro-inflammatory mediators

Bronchodilation and Anti-inflammatory effects: The blockade of leukotriene action by montelukast sodium leads bronchodilation (Relaxation of airways smooth muscle) and anti-inflammatory effects. Which help to alleviate symptoms of asthma and allergic rhinitis.

MATERIALS & INSTRUMENTS

- Volumetric flasks(1000ml,100ml,10ml),
- 0.45µ filter paper
- Romilast tablets
- Phosphate buffer
- 0.5% sodium lauryl sulphate
- 10mg montelukast sodium (pure drug)
- Ethanol
- Ammonium acetate
- Triethyl amine
- Acetonitrile
- Methanol
- Water

INSTRUMENTS

- HPLC
- Sonicator
- UV-spectrophotometer

PROCEDURE

Preparation of dilution medium

7.4pH Phosphate buffer was prepared for the dilution medium. The prepared buffer was sonicated for few minutes for obtaining uniform solution. Add 0.5% Sodium Lauryl Sulphate uniformly.

Preparation of Standard Montelukast Sodium Solution

10mg of Montelukast Sodium pure drug was weighed accurately and transferred into 10ml volumetric flask. The volume was made up to 10ml using ethanol to retain a solution that has a concentration equal to 1 mg/ml standard solution.

Preparation of Montelukast Sodium Sample solution

Montelukast tablets were selected randomly &weighed initially and crushed into powder. The powder quantity equivalent to 10mg was weighed accurately and transferred to 10ml volumetric flask. Further dilutions were made using the dilution media.

Procedure for construction of calibration curve

To a series of 10ml volumetric flasks, carefully transferred aliquots of standard drug solution 0.5ml and the volume was made with the diluents. The instrument was for photometric mode and the absorbances of each solution were recorded at 287.3nm against the blank diluents. Calibration curve was designed by taking absorbances on ordinates and concentration of the standard Montelukast Sodium in Figure-1.The Montelukast was again determined by U.V. Spectrophotometer by using different concentrations of drug solution.

Preparation of stock &standard solution

- The stock solution of drug is prepared by dissolving 15mg of drug in potassium phosphate buffer, adjust to PH -7.4, by using 0.2M NaOH in 50ml volumetric flask.
- The working standard solution were prepared by serial dilution using potassium phosphate buffer (PH-7.4) solution to obtain different concentrations of drug i.e, 0.3, 0.6, 1.25, 2.5, 5, 10 & 20µg/ml.

Procedure for Assay

To a cleaned 10ml volumetric flask transferred a few ml of sample solution of Montelukast Sodium and the volume was made with the diluents. Absorbance of the resulting solution was recorded at 287.3nm against its corresponding blank prepared in a similar manner except

adding the substance being analysed. The concentration of Montelukast Sodium present in the tablet dosage form was computed from its calibration curve.

PREPARATION OF SOLUTIONS

Preparation of buffer solution

3.85gm of Ammonium acetate was taken in a 1000ml volumetric flask, add 1ml of triethyl amine & add sufficient water to produce 1000ml, adjust the pH 5.5 with glacial acetic acid.

Preparation of mobile phase

Prepare the mobile phase with Acetonitrile: Methanol: Ammonium acetate buffer (10:70:20 % v/v pH 5.5).

Preparation of Montelukast standard solution

Weighed quantity of 10mg Montelukast was transferred to a 100ml volumetric flask, dissolved in 25ml of mobile phase and the solution was made up to the volume with mobile phase. From the above stock solution 5ml was transferred to 100ml volumetric flask and make up the volume with mobile phase. The solution was filtered with 0.45µ filter and sonicated for 15min.

Preparation of sample solution

20 tablets are weighed and powdered 903.1mg of sample was transferred in to 100ml volumetric flask and add mobile phase to dissolve the sample. To make up the volume with mobile phase & filtered with 0.45µ filter paper. From the above stock solution 5ml is taken & transferred to 100ml volumetric flask and make up the volume with mobile phase. The solution was filtered with 0.45µ filter and sonicated for 15min.

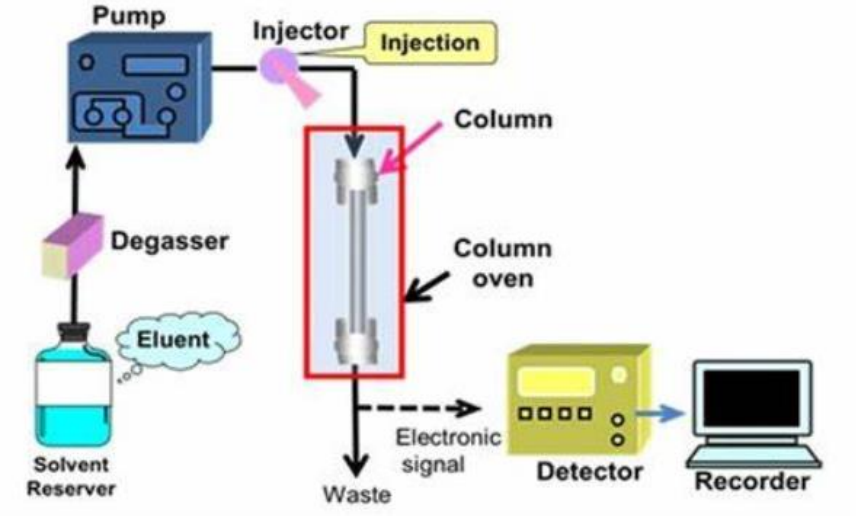
Experimental

Chemicals

HPLC grade acetonitrile (ACN) and Triethyl amine (A.R. grade) was purchased from Merck, Malaysia. Water HPLC grade was obtained from a Milli-QRO water purification system.

Preparation of standard solutions

HPLC method



Accurately weighed 100.0 mg (about the weight of a business card) of ML was transferred to a 100 ml (about 3.38 oz) standard flask and dissolved in a mixture of water and methanol in the ratio 1:1 v/v. From the stock solution, other solutions with concentrations of 150.0, 200.0, 250.0, 300.0, 350.0, and 500.0 ng/ml were obtained by diluting certain amounts in triplicate and used for the calibration curve.

UV method

Accurately weighed 100.0 mg (about the weight of a business card) of ML was transferred to a 100 ml (about 3.38 oz) standard flask and dissolved in a mixture of water and methanol in the ratio 1:1 v/v. From the stock solution, solutions with different concentrations of 5, 10, 15, 20 and 25 µg/ml were obtained by diluting adequate amounts in triplicate and used for the calibration curve.

Preparation of sample solutions

HPLC method

Twenty tablets, 10.0 mg (about the weight of a grain of table salt) of ML were weighed and powdered, an amount of powder equivalent to 10.0 mg (about the weight of a grain of table salt) of ML was weighed and transferred to a sintered glass crucible. To this 5.0 ml (about 0.17 oz) of 1.0 mg/ ml solution of montelukast was added and the drug was extracted with methanol and water (1:1 v/v). Makeup the extract with 100mlof mobile phase and further dilutions were made to get a concentration of 10.0 ng/ml of montelukast was used for the estimation.

UV method

Weighed quantity of powder equivalent to 10.0 mg of ML was transferred to 100 ml standard flask and dissolved in the mobile phase to obtain each concentration of 100.0 mcg/ml. An aliquot of this solution was diluted in mobile phase to obtain a solution with final concentration.

Preparation of buffer

Dissolve accurately 3.85 g of ammonium acetate in 1000 ml of Milli-Q water, adjust the pH to 3.5±0.05 with glacial acetic acid.

Mobile phase preparation

Mobile phase was prepared and degassed the mixture 15 volumes of the above buffer and 85 volumes of methanol.

Preparation of standard stock solution

Weigh accurately montelukast sodium working standard equivalent to about 20 mg of montelukast into 20 ml volumetric flask, add 15 ml of diluent and sonicate to dissolve for about 10 min, further make up the volume with diluent. And dilute 1 ml to 10 ml with methanol. From this, a working standard solution of 500 µg/ml of strength wasprepared, from this dilution of 50,60,80,100,120,140& 150 µg/ml were made in 100 mlvolumetric flasks and make up with ammonium acetate buffer pH 3.5±0.05, 10 µlof each dilution injected each time into the column at a flow rate of 1 ml/min. Each dilution was injected 3 times into the column and the resulting chromatograms wereobtained.

Preparation of sample solution

Weigh accurately a quantity of the powdered tablets equivalent to about 10 mg of montelukast into 100 ml volumetric flask, add about 60 ml of diluents, sonicate for about 30 min and dilute to 100 ml with methanol. Filter through 0.45 µ filter.

Assay of montelukast sodium in tablets

Weigh 20 tablets and finely powdered. An accurately weighed portion of the powder equivalent to 100 mg of montelukast sodium was transferred to 100 ml volumetric flask containing 10 ml of methanol and the contents of the flask were sonicated for 15 min, to ensure the complete solubility of the drug. The mixture was Make up to 100 ml with ammonium acetate buffer pH 3.5±0.05. The resulting solution was thoroughly mixed and

filtered through a 0.45 µ membrane filter. 5 ml of this solution was added to 100 ml volumetric flask and made up to the mark with ammonium acetate buffer pH 3.5±0.05. This solution (10 µl) was injected three times into the column. The mean values of peak areas of five such determinations were calculated and the drug content in the tablets was quantified using the regression equation.

Chromatographic conditions

The content of the mobile phase Were ammonium acetate buffer pH 3.5±0.05 and methanol in the ratio of 15:85 % v/v. The contents of mobile phase were filtered before use through 0.45 µ membrane filter and sonicated for 15 min. The flow rate of the mobile phase was maintained at 1.0 ml/min. The column temperature was set at 250C, and the detection was carried out by UV-Detector wavelength was set at 254 nm. The run time was set at 10 min, and the volume of the injection loop was 10 µl. Prior to injection of the drug solution, the column was equilibrated for at least 30 min with the mobile phase flowing through the system. The data were acquired, stored and analysed.

Calibration procedure

The calibration curve was plotted with five concentrations of the standard drug solution 50-150 µg/ml solution and chromatography was repeated thrice for each dilution. The linearity was determined by linear regression analysis, before injecting solutions, the column was equilibrated for at least 30 min with the mobile phase flowing through the system five determinations were carried out for each solution, peak area ratios were recorded for all the solutions. The correlation graph obtained by plotting the peak area ratios obtained at the optimum wave length of detection versus the injected amounts of the respective concentrations.

Method validation

The HPLC method was validated in terms of precision, accuracy and linearity under the ICH guidelines. Assay method precision was determined using six-independent test solutions. The intermediate precision was evaluated. Assay method was evaluated with the recovery of the standards from excipients. Three different quantities (low, medium and high) of the authentic standards were added to pre analysed tablet powder. The mixtures were extract, and were analysed using the developed HPLC method. Linearity test solutions were prepared. The LOD and LOQ for analytes were estimated by injecting a series of dilute solutions with known concentration. To determine the robustness of the method, the final experimental

conditions were purposely altered, and the results were examined. The flow rate was varied by (±) 0.1mL/min. Column temperature was varied by (±) 20°C and effect of column from different suppliers was studied. Measurement wavelength was varied by (±) 2nm.

RESULTS AND DISCUSSION

U.V. SPECCTROSCOPY METHOD

Table 1: Absorbance of MS by UV method.

S.NO.	CONC.(µg/ml)	ABSORB 1	ABSORB 2	ABSORB 3	MEAN	SD	%RSD
1	5	0.1369	0.1399	0.1379	0.138233	0.001528	1.105034
2	10	0.2994	0.3036	0.3091	0.304033	0.004864	1.59988
3	15	0.4858	0.4994	0.4910	0.492067	0.006862	1.39462
4	20	0.6675	0.6618	0.6699	0.664	0.004161	0.624329
5	25	0.8241	0.8221	0.8243	0.8235	0.001217	0.14773

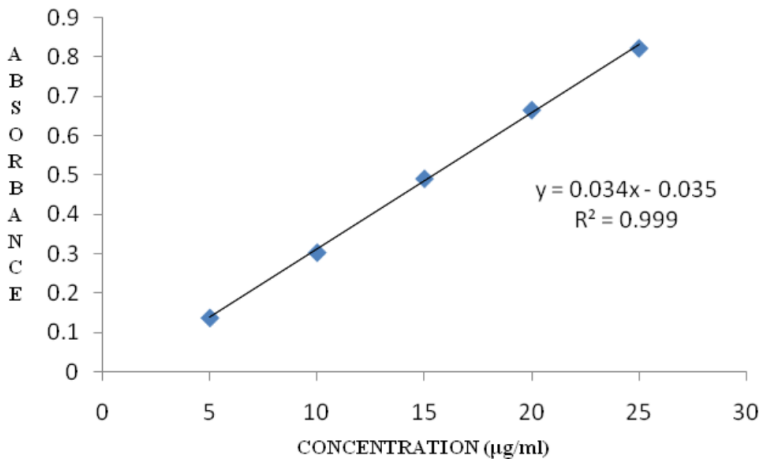


Fig. 10: Calibration graph.

HPLC METHOD

OPTIMIZATION OF CHROMATOGRAPHIC CONDITIONS

The wavelength of maximum absorption of the drug 10µg/ml of the drugs in methanol was scanned using UV-spectrophotometer in the range of 200-400nm against the blank (methanol). The absorption curve shows the characteristic absorption at 240nm.

By changing the composition of mobile phase ratio & flow rate optimization occurs. Different MPs tried for optimization of the method with the optimized chromatographic conditions, stock solutions of MS Was prepared in MP (ammonium acetate buffer pH3.5±0.05 & methanol 15:85%v/v) and 20µlsol'n was injected and recorded the chromatogram at 240nm.

VALIDATION OF THE METHOD

SYSTEM SUITABITITY

The system suitability of MS was performed, and data is tabulated was shown in the table.

Table 2: System Suitability of MS.

S.NO	RETENTION TIME (min)	PEAK AREA	TAILING FACTOR	NO. OF THEORETICAL PLATES(N)
1	2.130	151.826	1.474	3336
2	2.128	152.261	1.526	3325
3	2.122	154.216	1.478	3336
4	2.126	153.225	1.474	3325
4	2.127	152.726	1.526	3325
MEAN:	2.1266	152.8508	1.4956	3329.4
SD:	0.0029664	0.92431	0.02779	6.0249
%RSD:	0.1394	0.6047	1.8587	0.1809

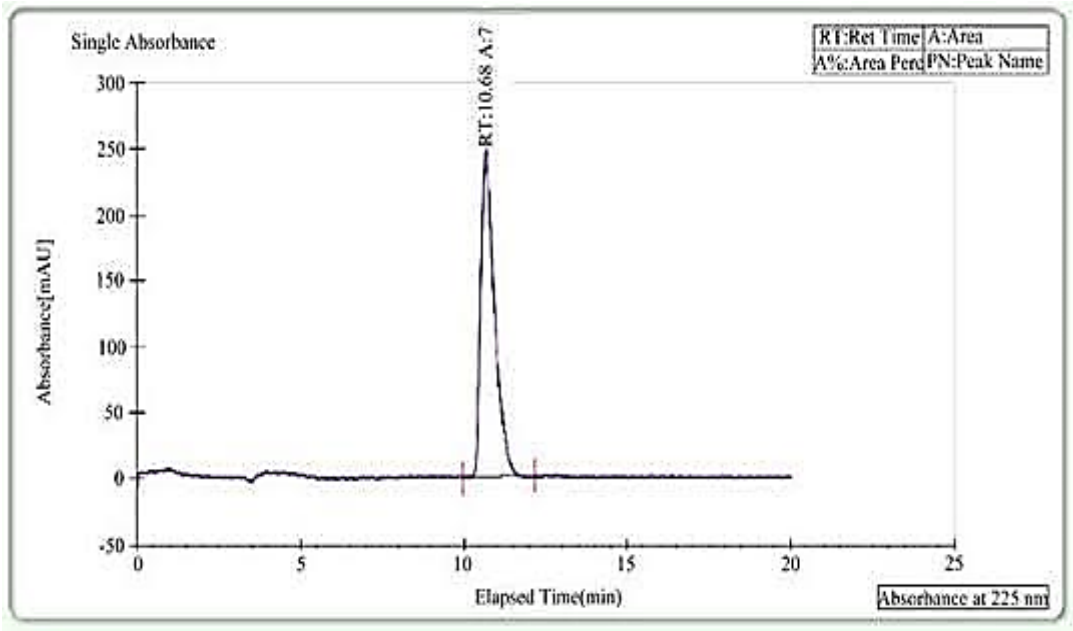


Fig. 11: Chromatogram of MS.

LINEARITY

The linearity was performed by stock solutions of MS was prepared with MP. And the conc. Range of MS is 0.4-2.4. Each solution was injected and recorded the chromatogram at24nm. The calibration curve was found to be 0.999. the optical characteristics of MS are shown in the table.

Linearity of MS

S.NO.	LINEARITY LEVEL	CONC. (µG/ML)	VOL. OF STOCK SOL'N(ml)	VOL. OF MAKEUPTO (ml)	AREA
1	Linearity-1	0.4	1	10	24.292
2	Linearity-2	0.8	2	10	40.633
3	Linearity-3	1.2	3	10	58.001
4	Linearity-4	1.6	4	10	74.994
5	Linearity-5	2.0	5	10	92.188
6	Linearity-6	2.4	6	10	110.276

ACCURACY

The accuracy of the method was performed by recovery studies. To the 50% of pre-analysed formulation, a known quality of MS raw material solutions was added at different levels & the solutions are injected. The chromatogram was recorded. The percentage recovery was found to be in the range b/w 98-102% for MS 99.74. The %RSD was found to be 0.468. they % recovery was revealed that no interference produced due to excipients used in formulation. Therefore, the developed method was found to be accurate, and the values are given in the table.

Accuracy spiking standard for MS

S.NO	INJECTION NO.	RETENTION TIME	AREA
1.	Injection-1	5.632	93.293
2.	Injection-2	5.628	92.817
3.	Injection-3	5.608	93.952
	AVERAGE	5.6226	93.354
	SD	0.01285	0.56999
	%RSD	0.2285	0.6105

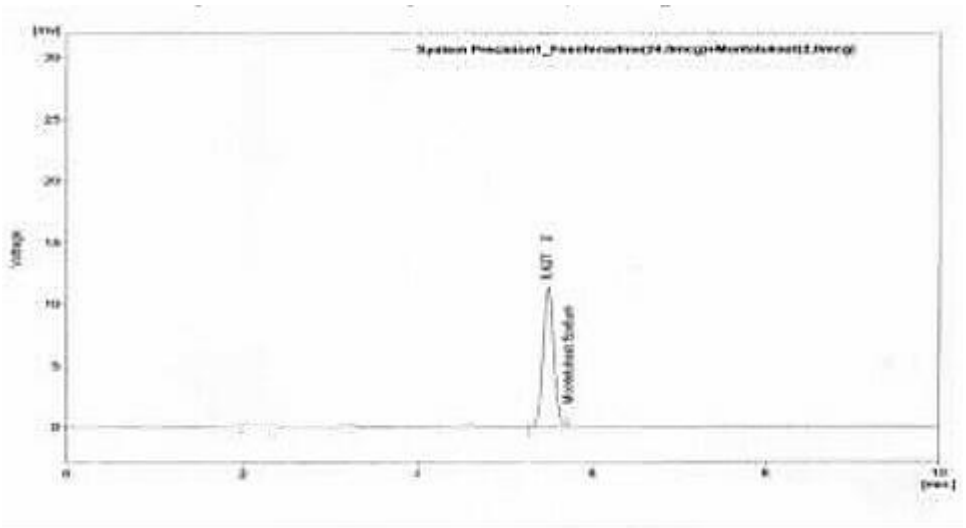


Fig. 13: Accuracy of MS.

Accuracy of MS

S.NO.	WT. OF TABLET POWDER TAKEN	Amt OF PURE DRUG ADDED	SAMPLE PEAK AREA	MEAN AREA OF APIKING STD (24.0µg/ml)	MEAN	Amt. OF TOTAL DRUG RECOVERED (µ/ml)	% RECOVERY
1	0.2	1.6	83.916 83.901 83.748	93.354	83.855	1.79	99.39
2	0.2	2.0	103.277 102.692 102.831		102.933	2.205	100.27
3	0.2	2.4	121.590 121.202 121.279		121.357	2.59	99.56
MEAN:							99.74
SD:							0.4667
%RSD:							0.4680

PRECISION

The precision of the method was confirmed by the system precision and method precision & chromatograms are recorded. The %RSD was found to be 0.064in system precision and 0.544 in method precision for MS. It indicates that the method has good precision & data was shown in the table.

Table 6: Precision of MS.

S.NO.	INJECTION NO.	RETENTION TIME	AREA
1	Injection-1	5.620	92.940
2	Injection-2	5.626	92.093
3	Injection-3	5.628	92.186
4	Injection-4	5.630	93.399
5	Injection-5	5.623	92.310
6	Injection-6	5.627	92.5165
MEAN:		5.6256	92.5740
SD:		0.0036155	0.503853
%RSD:		0.0642	0.5442

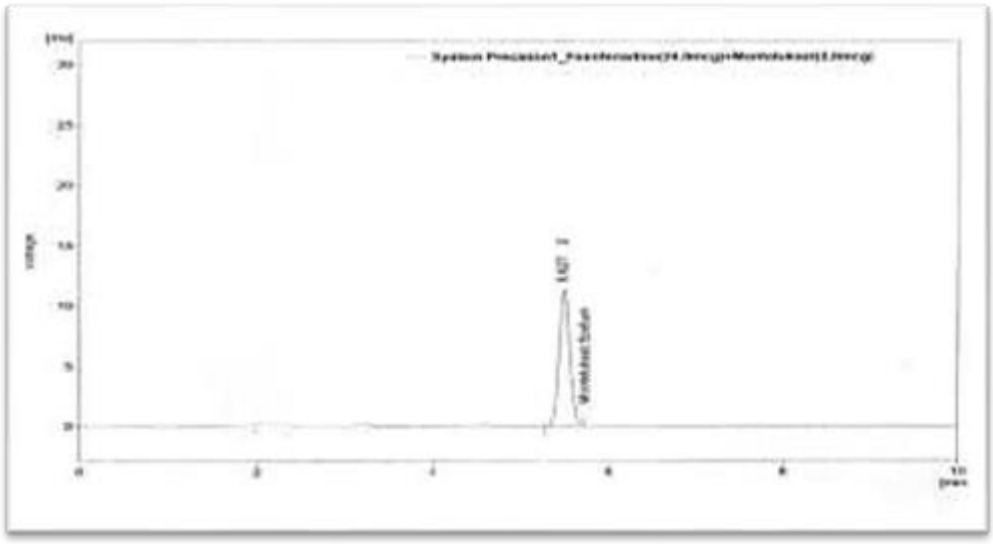


Fig. 14: Precision of MS.

RUGGEDNESS

The intermediate precision (ruggedness) was performed to MS. The area used for calculation of % RSD & the value was found to be 0.40 and the data was shown in the table.

Ruggedness of MS

S.NO.	INJECTION NO.	RETENTION TIME		AREA	
		ANALYST-1	ANALYST-2	ANALYST-1	ANALYST-2
1	Injection-1	5.609	5.624	94.409	93.676
2	Injection-2	5.610	5.649	92.815	93.834
3	Injection-3	5.606	5.619	94.874	93.442
	MEAN:	5.6083	5.6306	94.032	93.650
	SD:	0.002082	0.01607	1.07985	0.19722
	%RSD:	0.0371	0.2854	1.1483	0.2105

LOD AND LOQ

Limit of Detection & limit of quantitation is calculated based on standard deviation and slope according to formula. The LOD & LOQ for MS was found to be 0.027 &0.0815 respectively.

Table 8: LOD and LOQ for MS.

PARAMETERS	MONTELUKAST SODIUM
LOD	0.027
LOQ	0.0815

CONCLUSION

In this present study, a simple, fast, accurate & précised isocratic reverse phase high performance liquid chromatographic method has been developed for the determination of Montelukast sodium in tablet dosage form.

The developed method was found to be a simple and have short run time which makes the method more rapid.

This method is not only simple and rapid but also gives accurate and précised results for the determination of Montelukast sodium which is a marketed formulation.

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