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"Development and Validation of an Isocratic Reverse-Phase High-Performance Liquid Chromatographic Method for the Simultaneous Determination of Desloratadine and Montelukast sodium in Bulk Drug, Pharmaceutical Dosage Forms, and Human Plasma."

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KEYWORDS

Isocratic RP-HPLC, Desloratadine, Montelukast sodium, Validation, Bulk Drug, Pharmaceutical Dosage Forms, Human Plasma.

Abstract:
This research article presents a straightforward, viable, and sensitive isocratic reverse-phase high-performance liquid chromatographic (RP-HPLC) method for the simultaneous determination of Desloratadine and Montelukast sodium in bulk drug, pharmaceutical dosage forms, and human plasma. The chromatographic analysis was performed on an Agilent C18 column (250 mm length x 4.6 mm ID, 5µm particle size), employing a mobile phase composed of a methanol and o-phosphoric acid (0.1% in water) mixture in a ratio of 75:25% v/v. The flow rate was set at 0.7 ml/min, and detection was conducted at 260 nm using an Agilent 1100 instrument equipped with an auto sampler, quaternary gradient pump (G-1314), and diode-array detector (DAD). Linearity was observed in concentration ranges of 5-25 µg/ml and 10-50 µg/ml for Desloratadine and Montelukast sodium, respectively. The regression equations for Desloratadine and Montelukast sodium were Y=58.18x-4.414 and Y=81.64x+1.394, respectively, with correlation coefficients of 0.9988 and 0.9992.The percentage recovery was determined to be 96.70% for Desloratadine and 100.21% for Montelukast sodium. The limits of detection (LOD) for Desloratadine and Montelukast sodium were found to be 0.14318 and 0.113935, respectively, while the limits of quantification (LOQ) were determined as 0.433879 and 0.345258, respectively. Both drugs exhibited a regression value of 0.999. Desloratadine demonstrated high susceptibility to basic degradation and low susceptibility to hydrolytic degradation, while Montelukast sodium was susceptible to basic conditions. The relative standard deviation for intra-day precision of Desloratadine and Montelukast sodium was 0.25% and 0.14%, respectively, and for inter-day precision, it was found to be 0.25% and 0.28%, respectively.

Introduction: [1-6]

Allergic conditions, such as allergic rhinitis, hay fever, and anaphylaxis, are immunological disorders characterized by hypersensitive reactions to external factors, including environmental allergens. Manifesting as symptoms like itchy skin, red eyes, sneezing, and shortness of breath, these conditions involve the activation of mast cells through the binding of Immunoglobulin E antibodies (IgE) to allergens, initiating an immune response. Concurrently, asthma, a chronic inflammatory disease predominantly affecting the respiratory system's airways, manifests with symptoms such as bronchospasm, coughing, chest constriction, wheezing, and difficulty breathing.

The etiology of these conditions involves a complex interplay of environmental elements, allergens, and genetic factors. Notably, the parent compound of IgE, leukotriene, plays a pivotal role in these immunological responses. Leukotriene modifiers serve as crucial agents in preventing and treating allergic diseases.

In the realm of pharmacological interventions, Desloratadine, identified as 8-chloro-6, 1, 1-dihydro-11-(4-piperidylidene)-5H-enzo [5,6]cyclohepta[1,2-b]pyridine, stands as a non-sedative antihistamine

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designed for the symptomatic relief of allergic conditions, including rhinitis and urticaria. On the other hand, Montelukast sodium, characterized as [R-(E)]-1-[[[1-[3-[2-(7-Chloro-2quinolinyl) ethenyl] phenyl]-3-[2-(1-hydroxy-1-methylethyl) phenyl] propyl] thio] methyl] cyclopropaneacetic acid, monosodium salt, acts as a specific antagonist of leukotriene receptors. This pharmaceutical agent finds utility in managing chronic asthma, allergic rhinitis, and prophylaxis against exercise-induced asthma.

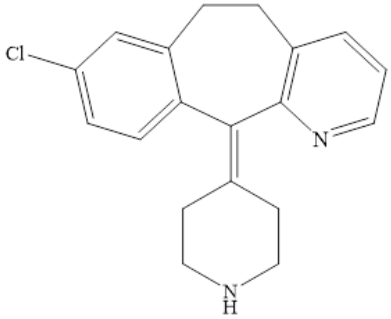

Figure 1: Desloratadine

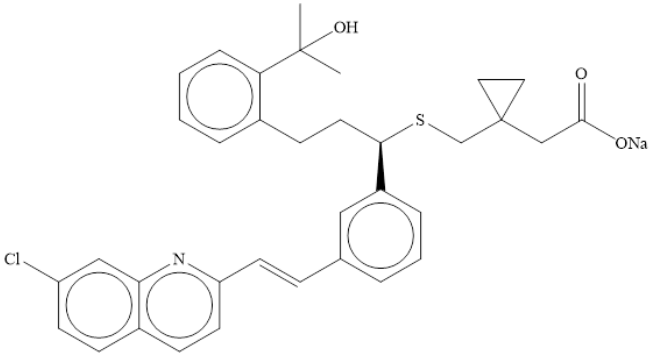

Figure 2: Montelukast sodium

CHROMATOGRAPHIC CONDITIONS:

Instrument and Software:

For the instrumentation and software utilized in this study, an Agilent 1100 system, featuring an auto sampler equipped with a quaternary gradient pump (G-13148), a diode-array detector (DAD), and a column heating oven, was employed. The chromatographic analysis utilized a C18 (Agilent) column with dimensions of 4.6 x 250 mm and a particle size of 5 µm. Chemstation software was employed for chromatographic analysis and data acquisition. To ensure the mobile phase was free of gases, a PCI bath sonicator was used for degassing. Material weighing was carried out using a Sartorius SPA 225D electronic balance, while pH measurements were conducted with a Metsar pH meter. Volumetric and general-purpose glassware of Class 'A' Borosil was employed throughout the study.

Chemical and solvent:

Methanol (HPLC grade, Merck Ltd), Milli-Q water, ortho-phosphoric acid (GR Grade, Anglo French Remedies Pvt. Ltd, India), and Desloratadine and Montelukast sodium provided by Corpuscle Research Solution (Visakhapatnam, India) were used in this study. Tablets of Desloratadine and Montelukast sodium, with the brand name Deskast from Lupin Ltd., were purchased from the local market. Human blood samples were collected and subsequently centrifuged at 5000 rpm for 1 hour to separate the plasma from blood. The separated plasma was then mixed with water and loaded onto the HPLC for analysis. All other chemicals used were of the highest commercially available grade unless otherwise specified.

Mobile Phase Preparation:

The mobile phase was prepared by combining methanol and o-phosphoric acid (0.1% in water) in a ratio of 75:25 v/v. The resulting mixture was filtered and degassed.

Experimental Procedure:

In the initial stage of method development, the solubility of both drugs was assessed in various solvents. This investigation aimed to identify a common solvent suitable for the simultaneous estimation of both drugs in a mixture.

Preparation of Standard Stock Solution:

To formulate the standard stock solution of Desloratadine and Montelukast sodium, 2 ml of human plasma was combined with 5 mg of Desloratadine and 10 mg of Montelukast sodium in methanol, resulting in a 10 ml solution. The mixture underwent vertical shaking for 30 minutes, followed by centrifugation at 5000 rpm for 1 hour, yielding a solution with concentrations of 500 µg/ml for Desloratadine and 1000 µg/ml for Montelukast sodium (STOCK-I). Subsequently, this stock solution was subjected to dilution, generating solutions with concentrations ranging from 5 to 25 µg/ml for Desloratadine and 10 to 50 µg/ml for Montelukast sodium.

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Preparation of Sample Stock Solution:

Twenty tablets of Deskast were weighed, crushed, and mixed to meet the label claim of 5 mg Desloratadine + 10 mg Montelukast sodium per tablet. The total weight of 20 tablets was 0.7 grams, resulting in an average powder weight of 0.035 grams. The equivalent weight in milligrams is calculated as 0.035 x 1000 = 35 mg.

For the preparation of Stock Solution-II, 2 ml of human plasma was combined with 35 mg of tablet powder in a 10 ml volumetric flask. The mixture was dissolved in methanol and then diluted to the mark, resulting in a solution containing 500 µg/ml Desloratadine and 1000 µg/ml Montelukast sodium.

Subsequently, a 0.15 ml sample was extracted from Stock Solution-II and diluted to 10 ml with the mobile phase. This dilution resulted in a solution containing 15 µg/ml Desloratadine and 30 µg/ml Montelukast sodium...

Method Development:

The method development process involved the systematic application of a trial-and-error strategy, employing mobile phases with varied compositions and proportions. The selection of an appropriate mobile phase is a critical factor in establishing an effective analytical method to achieve optimal resolution of drug components. Through the manipulation of mobile phase composition and the utilization of a suitable column, the optimal separation of Desloratadine and Montelukast sodium was attained.

Numerous preliminary trials were undertaken, incorporating different columns, buffers, and organic solvents in diverse proportions. These trials were conducted to identify the most effective conditions for achieving the optimal separation of the drug components.

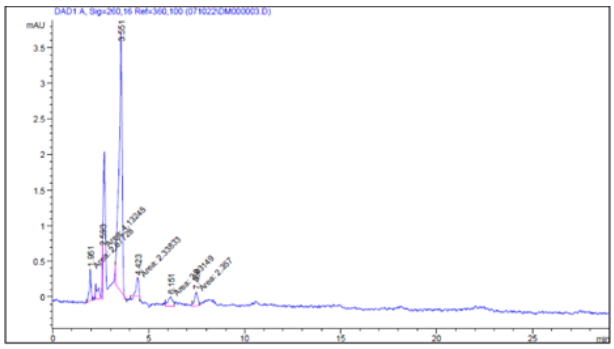

Figure 3: Chromatogram of Blank Plasma

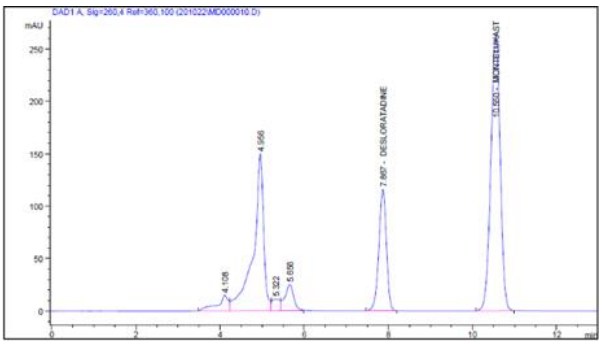

Figure 4: Standard Chromatogram of Desloratadine and Montelukast sodium

Table1: Optimized chromatographic parameters

Optimized chromatographic condition.	
Mode of separation	Isocratic
Mobile phase	Methanol and OPA (0.1% in water) (PH 4) (75:25 v/v)
Column	C18 (Agilent) (4.6 x 250 mm length, 5 µm)
Detection wavelength	260 nm
Injection volume	20µl
Flow rate	0.7 ml/min

Validation of Developed HPLC Method: [7-15]

Specificity:

The specificity of the developed HPLC method was assessed against standard compounds and potential interferences in the presence of a placebo. No interference was detected at the retention times of Desloratadine and Montelukast sodium in the sample solution.

System Suitability:

System suitability testing involved injecting five replicate 20 µl injections of standard solutions of Desloratadine and Montelukast sodium under optimized chromatographic conditions. Parameters such as tailing factor, % relative standard deviation for retention time and peak areas, resolutions, and theoretical plates were evaluated.

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Linearity:
The linearity of the analytical method was established by preparing a series of linearity solutions at concentration levels ranging from 25% to 150%. Calibration curves were constructed by injecting 20 µl of each sample into the chromatographic system, recording chromatographs, and plotting peak area versus drug concentration. The linearity was observed over the concentration ranges of approximately 5-25 µg/ml for Desloratadine and 10-50 µg/ml for Montelukast sodium. Correlation coefficients, slopes, and intercepts were calculated from the linear relationship between peak area and drug concentration.

Precision: System Precision (Interday and Intra-day precision):
System precision was assessed by injecting a 20 µl solution of standard Desloratadine (10-20 µg/ml) and Montelukast sodium (20-40 µg/ml) six times into the chromatographic system. Calculated peak areas for Desloratadine and Montelukast sodium were expressed as % RSD.

Method Precision:
The method precision of the test method was evaluated by injecting a 20 µl solution of the sample preparation six times into the chromatographic system. Calculated peak areas for Desloratadine and Montelukast sodium were expressed as % RSD.

Accuracy:
The accuracy of the method was assessed through percentage recovery across its range, establishing three different concentrations at 80%, 100%, and 120% levels using the standard addition method. Sample preparations were spiked with a known amount of standard, and each concentration was injected in triplicate into the chromatographic system, with chromatograms recorded. The percentages of recovery for Desloratadine and Montelukast sodium were calculated at each concentration level.

Robustness:
The robustness of the proposed method was evaluated by intentionally varying chromatographic conditions, including mobile phase compositions, flow rate, mobile phase pH, and column temperature. Standard solutions, prepared following the test method, were injected in triplicate into the chromatograph under variable conditions, such as flow rate at ±0.1 ml/min, mobile organic phase composition by ±10%, and column temperature by ±5ºC. System suitability parameters were assessed based on the resulting chromatograms.

Limit of Detection (LOD):
The LOD value was calculated from calibration curves, using the formula LOD = 3.3 × avg. S.D/Slope, where SD represents the standard deviation of the response of the minimum detectable drug, and the slope is derived from the calibration curve.

Limit of Quantification (LOQ):
The LOQ value was determined from calibration curves, employing the formula LOQ = 10 × avg. S.D/Slope, with SD representing the standard deviation of the response of the minimum detectable drug, and the slope derived from the calibration curve.

Stress Degradation Studies: [16-21]
As the primary aim of the method development was to create a stability-indicating assay method, both drug samples underwent stress degradation conditions. Considering the limited availability of references during the method's development, a systematic approach was employed for the stress degradation of the drugs. Acidic, alkaline, neutral, and oxidative stress degradation studies were conducted.

Stress Degradation under Acidic Environment:
To evaluate the stability of the drugs in an acidic environment, both drugs underwent acid treatment. A 0.05 ml sample was withdrawn from Stock Solution-I, and 1 ml of 0.1N hydrochloric acid was added. The volume was adjusted to the mark with the mobile phase, and the solution was sonicated for 30 minutes at 60°C. After 60 and 120 minutes, 20 µl solutions were injected into the system, and chromatograms were recorded to assess sample stability.

Stress Degradation under Alkaline Environment:
For assessing stability in a basic environment, both drugs underwent basic treatment. A 0.05 ml sample was withdrawn from Stock Solution-I, and 1 ml of 0.1N NaOH was added. The volume was adjusted to the mark with the mobile phase, and the solution was sonicated for 30 minutes at 60°C. After 60 and 120 minutes, 20 µl

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solutions were injected into the system, and chromatograms were recorded to assess sample stability.

Stress Degradation under Oxidative Environment:
A 0.05 ml sample was withdrawn from Stock Solution-I, and 1 ml of 3% H_2O_2 was added. The volume was adjusted to the mark with the mobile phase, and the solution was sonicated for 30 minutes at 60°C. After 60 and 120 minutes, 20 µl solutions were injected into the system, and chromatograms were recorded to assess sample stability.

Stress Degradation under Neutral Environment:
For evaluating stability under neutral conditions, 0.1 ml of sample was withdrawn from Stock Solution-I. Five milliliters of water were added, and the volume was adjusted to the mark with the mobile phase. The solution was sonicated for 30 minutes at 60°C. After 120 minutes, 20 µl solutions were injected into the system, and chromatograms were recorded to assess sample stability.

RESULTS DISCUSSION:

System Suitability Study:
System suitability testing plays a pivotal role in the validation of many analytical procedures. At the commencement of each validation study, five replicates of the standard solution (100%) were injected, and the % relative standard deviation (% RSD) for the obtained peak areas was calculated to assess system precision. The calculated % RSD was found to be not more than 2.0%. The system suitability parameters, crucial for establishing the entire experimental setup as an integral system, are presented in the accompanying table.

Table 2: System suitability test parameter for Desloratadine and Montelukast sodium

Matrix	Conc. µg/ml	Area I	Area II	Mean	SD	% RSD
Desloratadine	10	558.11	564.41	561.26	4.46	0.79
Montelukast sodium	20	1585.93	1589.23	1587.58	2.33	0.15

Linearity of Detector response:
The linearity of the developed method was evaluated by preparing a series of dilutions ranging from 5 µg/ml to 25 µg/ml for Desloratadine and 10 µg/ml to 50 µg/ml for Montelukast sodium. These solutions were then injected into the HPLC system. The correlation coefficient (r2) value was determined to be 0.999 for both drugs, indicating an excellent linear relationship. The concentration of the drug versus peak area was plotted, as depicted in the figure.

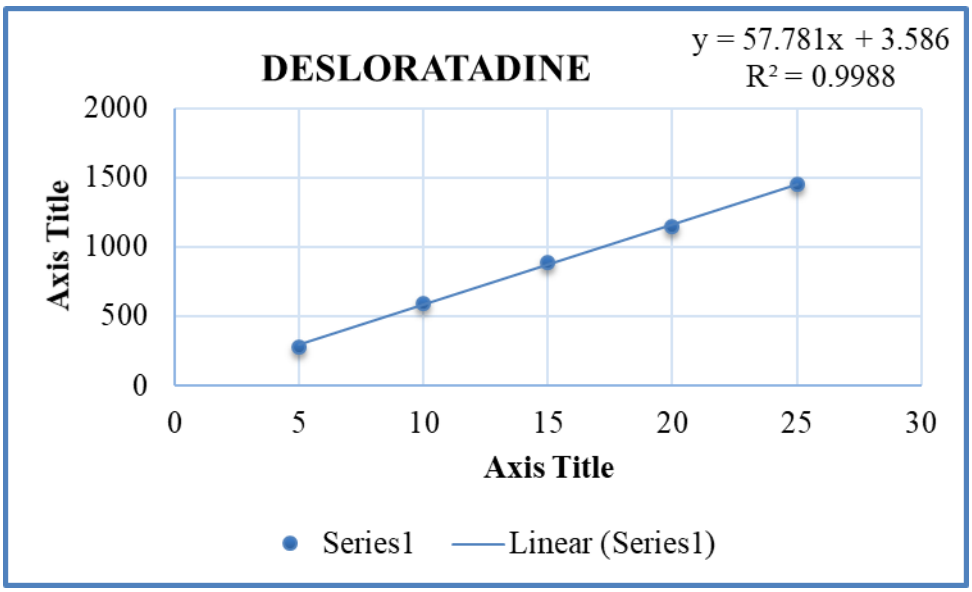

Fig 5: Calibration curve of Desloratadine

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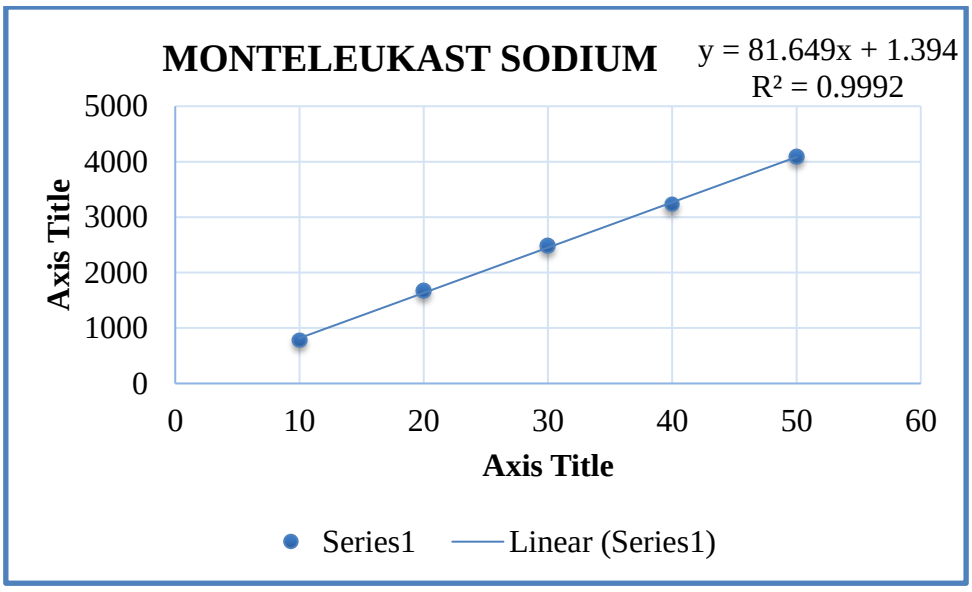

Fig 6: Calibration curve of Montelukast sodium

Table 3: Linearity study of Desloratadine

Sr. No	Conc. µg/ml	Area I	Area II	Mean	SD	% RSD
1	5	276.08878	280.7163	278.40	3.27	1.18
2	10	595.2705	595.4807	595.38	0.15	0.02
3	15	886.3635	884.3037	885.33	1.46	0.16
4	20	1146.5098	1136.6415	1141.58	6.98	0.61
5	25	1450.3068	1449.3458	1449.83	0.68	0.05

Table 4: Linearity study of Montelukast sodium

Sr. No	Conc. µg/ml	Area I	Area II	Mean	SD	% RSD
1	10	778.4058	782.2322	780.32	2.71	0.35
2	20	1669.0918	1674.1887	1671.64	3.60	0.22
3	30	2485.3491	2489.7302	2487.54	3.10	0.12
4	40	3235.4489	3229.4614	3232.46	4.23	0.13
5	50	4082.0441	4082.6833	4082.36	0.45	0.01

Precision:

Intraday precision was conducted by preparing and analyzing test samples within the same day. Intraday precision was evaluated through the analysis of identical solutions on consecutive days. The % RSD values, all below 2, indicate the precision of the method. The detailed results are presented in the accompanying table.

Table 5: Intraday Precision

Desloratadine								
Sr. No.	Conc. µg/ml	Area I	Area II	Mean	Amount Found	% Amount Found	SD	% RSD
1	10	585.6798	583.5585	584.62	9.84	98.41	1.41	0.25

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2	15	872.249	875.827	874.04	15.10	100.68	5.64	0.64
3	20	1116.1427	1112.1507	1114.15	19.22	96.10	2.82	0.25
Montelukast sodium								
1	20	1650.448	1644.5611	1647.50	19.82	99.12	3.54	0.22
2	30	2459.8692	2466.8669	2463.37	30.06	100.21	4.24	0.17
3	40	3175.9008	3169.4492	3172.68	38.00	95.01	8.77	0.28

Table 6: Interday Precision

Desloratadine								
Sr. No.	Conc. µg/ml	Area I	Area II	Mean	Amount Found	% Amount Found	SD	% RSD
1	10	571.1732	573.1722	572.17	10.06	100.56	1.50	0.26
2	15	872.1572	880.1312	876.14	15.06	100.43	2.53	0.29
3	20	1116.1442	1112.1507	1114.15	19.22	96.10	2.82	0.25
Montelukast sodium								
1	20	1617.2559	1622.2659	1619.76	20.16	100.82	4.16	0.25
2	30	2452.728	2458.7172	2455.72	30.16	100.52	4.95	0.20
3	40	3097.7868	3110.183	3103.98	38.84	97.11	4.56	0.14

Accuracy (Recovery Study):

The accuracy of the method was assessed by appropriately diluting the sample solution to achieve concentrations corresponding to 80%, 100%, and 120% levels of Desloratadine and Montelukast sodium. Three preparations were executed at each level, with each preparation injected twice and subsequently analyzed. The percent recovery was calculated by comparing the average peak areas obtained for standard and formulation solutions. The observed percent recovery fell within the range of 96.70% to 100.21%, affirming the accuracy of the method. Detailed results are provided in the accompanying table.

Table 7: Accuracy data (% Recovery Study)

Desloratadine							
Sample Conc.	Amount added	Area	Amount recovered	% recovered	Mean	SD	% RSD
80 %	4	521.24	3.96	98.98	98.32	0.93	0.94
	4	518.21	3.91	97.66			
100 %	5	574.95	4.89	97.77	97.84	0.09	0.09
	5	575.32	4.90	97.90			
120 %	6	627.71	5.80	96.70	97.01	0.44	0.45
	6	629.86	5.84	97.32			
Montelukast sodium							
80 %	8	1472.30	8.02	100.21	99.20	1.43	1.45
	8	1459.05	7.85	98.18			
100 %	10	1622.25	9.85	98.54	98.72	0.26	0.26
	10	1625.20	9.89	98.90			
120%	12	1774.50	11.72	97.66	98.11	0.64	0.65
	12	1783.38	11.83	98.56			

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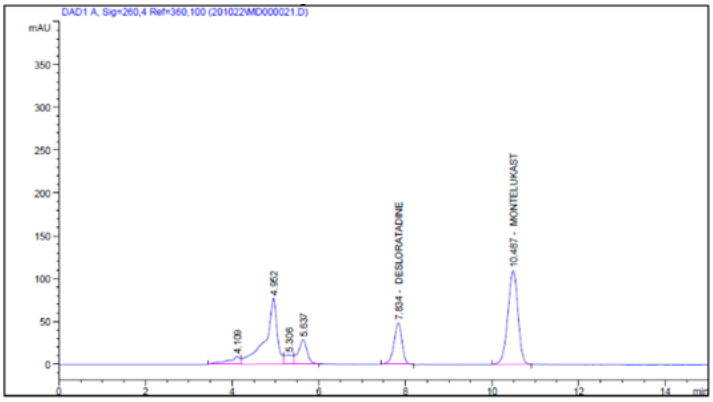

Fig 7: Chromatogram of accuracy 120 %

Robustness study of Desloratadine:

Robustness studies of the system were conducted by varying the flow rate, mobile phase concentration, and wavelength. The mean values obtained were 276.34 and 208.83 for flow rates of 0.6 ml/min and 0.8 ml/min, respectively, with %RSD values of 0.48 and 0.87 for the corresponding flow rates. Mobile phase concentration variations (76:24) and (74:26) yielded mean values of 238.6 and 238.95, with %RSD values of 0.89 and 1.2, respectively. Wavelength adjustments (259 nm and 261 nm) resulted in mean values of 279.6 and 268.46, along with %RSD values of 0.34 and 0.36 for the respective wavelengths. This study demonstrates the robustness of the system, indicating its capability to withstand variations in different aspects of the system.

Table 8: Robustness study of Desloratadine

Sr. No	Conc. µg/ml	Area I	Area II	Mean	SD	% RSD
Change Flow rate 0.6 ml/ min						
1	5	277.27	275.40	276.34	1.32	0.48
Change Flow rate 0.8 ml/ min						
2	5	207.55	210.12	208.83	1.82	0.87
Change Mobile Phase Concentration (76:24)						
3	5	237.12	240.11	238.6	2.11	0.89
Change Mobile Phase Concentration (74:26)						
4	5	236.92	240.98	238.95	2.87	1.20
Change in Wavelength (259 nm)						
5	5	280.25	278.89	279.6	0.96	0.34
Change in Wavelength (261 nm)						
6	5	268.97	267.95	268.46	0.72	0.36

Robustness study of Montelukast sodium:

Robustness studies of the system were conducted by altering the flow rate, mobile phase concentration, and wavelength. The mean values obtained were 632.27 and 632.77 for flow rates of 0.6 ml/min and 0.8 ml/min, respectively, with %RSD values of 0.41 and 0.52 for the corresponding flow rates. Mobile phase concentration variations (76:24) and (74:26) yielded mean values of 524.93 and 722.1, with %RSD values of 0.01 and 0.46, respectively. Wavelength adjustments (259 nm and 261 nm) resulted in mean values of 736.9 and 720.56, along with %RSD values of 0.11 and 0.31 for the respective wavelengths. This study demonstrates the robustness of the system, indicating its capacity to withstand variations in different aspects of the system.

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Table 9: Robustness study of Montelukast sodium

Sr. No	Conc. µg/ml	Area I	Area II	Mean	SD	% RSD
Change Flow rate 0.6 ml/ min						
1	10	630.42	634.11	632.27	2.61	0.41
Change Flow rate 0.8 ml/ min						
2	10	630.42	635.12	632.77	3.32	0.52
Change Mobile Phase Concentration (76:24)						
3	10	524.88	524.97	524.93	0.06	0.01
Change Mobile Phase Concentration (74:26)						
4	10	719.75	724.47	722.1	3.34	0.46
Change in Wavelength (259 nm)						
5	10	737.52	736.36	736.9	0.83	0.11
Change in Wavelength (261 nm)						
6	10	718.96	722.16	720.56	2.26	0.31

Limit of Detection:

The table illustrates the minimum detection limits of Desloratadine and Montelukast sodium. The LOD for Desloratadine was determined to be 0.14318, and for Montelukast sodium s, it was found to be 0.113935. These LOD values affirm the suitability of the method for determining lower concentrations of Desloratadine and Montelukast sodium. The results validate the sensitivity of the developed method for accurate determination.

Table 10: Limit of Detection Desloratadine and Montelukast sodium

Desloratadine	Montelukast sodium
Formula LOD = 3.3×avg S.D/Slope	Formula LOD = 3.3×avg S.D/Slope
Avg.SD = 2.51	Avg.SD = 2.82
Slope = 57.78	Slope = 81.64
LOD = 3.3×2.51/57.78 = 0.14318	LOD = 3.3×2.82/81.64= 0.113935

Limit of Quantification:

The table presents the minimum quantification limits of Desloratadine and Montelukast sodium. The LOQ for Desloratadine was determined to be 0.433879, and for Montelukast sodium, it was found to be 0.345258. These LOQ values affirm the suitability of the method for determining lower concentrations of Desloratadine and Montelukast sodium. The results validate the sensitivity of the developed method for accurate determination.

Table 11: Limit of Quantification:

Desloratadine	Montelukast sodium
Formula LOQ = 10×avg S.D/Slope	Formula LOQ = 10×avg S.D/Slope
Avg.SD = 2.51	Avg.SD = 2.82
Slope = 57.78	Slope = 81.64
LOD = 10×2.51/57.78 = 0.433879	LOD = 10×2.82/81.64= 0.345258

Analysis of Marketed formulation:

The marketed formulation of Desloratadine and Montelukast sodium was analyzed, and the percentage purity was determined. The mean % assay values were found to be 101.36 for Desloratadine and 101.72 for Montelukast sodium, respectively. The assay results are presented in the table, and the corresponding chromatograms are depicted in the figure

.

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Table 12: Assay of Marketed formulation

Conc. µg /ml	Area I	Area II	Mean	Amount Found	% Found	SD	%RSD
Desloratadine							
15	884.304	875.827	880.07	15.24	101.62	5.994	0.681
Montelukast sodium							
30	2489.73	2466.87	2478.30	30.51	101.71	16.167	0.652

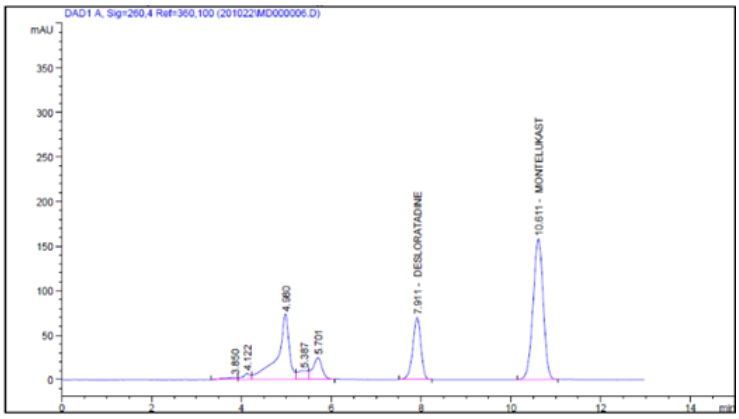

Fig 8: Chromatogram of Marketed formulation

Forced degradation Study

A standard sample of Desloratadine and Montelukast sodium underwent acidic, alkaline, oxidative, and hydrolytic degradation. The degradation remained within the acceptance criteria, demonstrating the stability-indicating properties of the method. The results of stress degradation for Desloratadine and Montelukast sodium are presented in tables.

Table 13: Forced degradation study of Desloratadine

After 1 hours					
Sr. No	Degradation	Area of Standard	Area of degraded sample	Degraded up to %	% degradation
1	Acid	278.4	257.7	92.56	7.44
2	Basic	278.4	242.13	86.97	13.03
3	H_2O_2	278.4	244.88	87.96	12.04
After 2 hours					
1	Acid	278.4	228.34	82.02	17.98
2	Basic	278.4	193.52	69.51	30.49
3	H_2O_2	278.4	224.07	80.48	19.52
4	Hydrolytic	278.4	270.11	97.02	2.98

Table 14: Forced degradation study of Montelukast sodium.

After 1 hours					
Sr. No	Degradation	Area of Standard	Area of degraded sample	Degraded up to %	% degradation
1	Acid	780.32	696.23	89.22	10.78
2	Basic	780.32	684.32	87.70	12.30
3	H_2O_2	780.32	688.54	88.24	11.76

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After 2 hours					
1	Acid	780.32	601.89	77.13	22.87
2	Basic	780.32	483.46	61.96	38.04
3	H_2O_2	780.32	596.63	76.46	23.54
4	Hydrolytic	780.32	768.4	98.47	1.53

Conclusion:

The development and validation of this new RP-HPLC method signify a significant contribution to pharmaceutical analysis. The meticulous selection of the stationary phase, optimization of the mobile phase composition, and identification of an appropriate detection wavelength ensure the method's robustness and reliability. The accuracy of the method, as evidenced by its close alignment with true values, instills confidence in its application for determining the content of Desloratadine and Montelukast sodium in both bulk and tablet forms. The precision of the method, demonstrated through consistent and reproducible results under various conditions, reinforces its suitability for routine quality control practices. The simplicity of the method not only enhances its ease of use but also positions it as a practical solution for integration into everyday laboratory workflows, both in Quality Control (QC) laboratories and industrial settings. The method's sensitivity is a notable feature, allowing for the reliable detection and quantification of Desloratadine and Montelukast sodium at low concentrations. This attribute is particularly valuable in pharmaceutical analysis, where accurate measurements of active pharmaceutical ingredients are critical for ensuring the efficacy and safety of drug formulations.

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