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Comparative analysis of analytical method development and its validation for the simultaneous estimation of Bilastine and Montelukast Sodium in bulk and its tablet formulation by planar chromatography

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Abstract: The development and validation of analytical methods are crucial in guaranteeing the precision, dependability, and excellence of pharmaceutical analysis. This research investigates the field of pharmaceutical chemistry by doing a comparative examination of analytical techniques for the simultaneous determination of Bilastine and Montelukast Sodium in both bulk and tablet forms. The selected method for this analysis is planar chromatography. The simplicity, specificity, precision, and accuracy of a high-performance liquid chromatography (HPTLC) approach were investigated for their use in the simultaneous estimation of the antihistaminic combination medication Bilastine and Montelukast Sodium in bulk and its pharmaceutical dose for the treatment of allergic rhinitis. Densitometric readings were taken at 254 nm after separating substances using ethyl acetate, toluene, methanol, and ammonia (7:0.5:1.5:0.5v/v/v/v) as mobile phase and precoated aluminium silica gel plates (60F254) as stationary phase. Bilastine and montelukast Sodium have Rf values 0.2 (Bilastine) & 0.4 (Montelukast Sodium), which is considered an acceptable resolution. The International Conference on Harmonization's (ICH) requirements validated the processes for accuracy, linearity, precision, robustness, and system adaptability. Bilastine and Montelukast Sodium concentrations were determined without any disruption from the excipients. Both Bilastine and Montelukast Sodium were effectively quantified using the suggested method, which bodes well for its utility in enhancing quality assurance.

Introduction

Twenty per cent or more of the population in industrialised nations suffers from allergic rhinitis. Independently of or in addition to asthma; allergic rhinitis (AR) has two distinct phases of inflammation, the first of which is marked by sensitization-formation and the development of antigen-specific IgE. In the first stage, mast cells degranulate and release mediators like histamine and tryptase that have already been created or newly synthesised mediators like prostaglandins and

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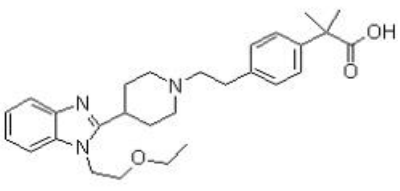
leukotrienes. delayed phase response cells are characterised by lymphocytes, eosinophils, cytokines, and adhesion molecules (Mandhane et al., 2011).

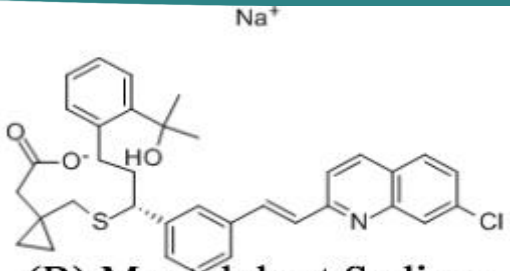
The antihistamine Bilastine and the leukotriene receptor antagonist Montelukast Sodium make up Bilastine and Montelukast Sodium. When inhaled, leukotrienes are released from the lungs and cause irritation, swelling and enlarged mucus formation in the airways; montelukast is a leukotriene receptor antagonist that blocks the activity of these substances. As a result, airway inflammation, mucus production, and constriction are all mitigated. Histamine is the molecule responsible for the body's allergic response, and antihistamines like Bilastine work by blocking its release. All the symptoms associated with allergies are reduced, including sneezing, watery eyes, itching, eczema, congestion, and stiffness (Patel et al., 2021; Umesh et al., 2021).

Bilastine, as depicted in Figure 1, represents a recently developed second-generation antihistamine medication that exhibits a high degree of suitability as an H1 receptor antagonist. The intervention demonstrates rapid and efficient efficacy over an extended duration. Bilastine exhibits a melting range from 196 to 200°C, characterised by its white to off-white crystalline powder form. The compound exhibits a pKa value of 4.18 and a half-life of 14.5 hours. During allergic reactions, mast cells undergo degranulation, which involves the release of many substances, including histamine. Bilastine has an affinity for the H1 receptor, hence impeding the activation of said receptor. Consequently, this mechanism of action contributes to the reduction of allergic manifestations that arise from the release of histamine by mast cells (Arun et al., 2022).

Montelukast belongs to the family of leukotriene receptor antagonists, commonly referred to as R.E. Figure 1 depicts the chemical structure of Montelukast. Ethanol, methanol, and water have high solubility, but acetonitrile has significant insolubility. The mechanism of action involves the inhibition of leukotriene D4 activity within the pulmonary system, resulting in a reduction of inflammation and relaxation of smooth muscle. This medication is employed to manage asthma and mitigate symptoms associated with seasonal allergies (Bhanu et al., 2023; Ahmad et al., 2023).



(A) Bilastine



(B) Montelukast Sodium

Figure 1. Chemical structure of (A) Bilastine and (B) Montelukast Sodium

Materials and methods

Materials

Analytical working standards Bilastine (99.55%) & Montelukast Sodium (99.67%) were obtained as gift samples from Lee pharma ltd. Hyderabad & Glenmark, Nashik. All reagents analytical grade (Prajapati et al., 2022).

Selection of diluent

Since both medicines are soluble in and stable in HPLC-grade methanol, and since excipients in tablet formulation can cause interference, this solvent was chosen. (Shah et al., 2021)

Preparation of standard stock solution

Bilastine 20 mg and montelukast Sodium 10 mg were weighed and transferred into 10ml of volumetric flask separately, and volume was made up by methanol sonicate for 15 minutes; after the sonication, 1ml form in solution was pipetted out and diluted upto 10 ml with methanol to obtain stock solutions with concentrations of Bilastine (200 ng/ml) and Montelukast Sodium (100 ng/ml) (Roshdy et al., 2023)

Preparation of sample solution

For the sample Solution, accurately weigh 10 Tablets and calculate the average weight. Take the powder equivalent to 20 mg Bilastine & 10 mg Montelukast Sodium, transfer it

into 50 ml volumetric flask, and withdraw 5 ml of diluent, then make up 10ml methanol. Filter the solution with Whatman filter paper no.42. (Vyas et al., 2022)

Instrumentation (Aetron & Camag HPTLC)

The HPTLC system utilised Aetron instrumentation, which included a Spraylin-V (Ae05) sample applicator equipped with a 100 µL Hamilton syringe. The Ishan Software facilitated the application of spots. The TLC scanning procedure was conducted using the Just TLC programme. The stationary phase in this experiment consisted of Merck TLC plates, which were coated with 60F254 silica gel on aluminium sheets. The Crystal-3 cabinet was utilised for the detection of spot UV. The Canon IXUS Digital camera is utilised to capture thin-layer chromatography (TLC) plates. The Easy Doc II tiny

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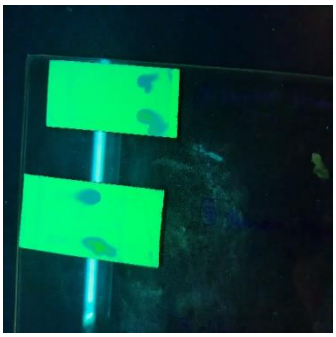
picture documentation system (model_2019) was utilised for image documentation. All measurements were conducted using the Schimadzu (AY 120) analytical balance. The experimental setup for this study involved (HPTLC) equipment. (Prajapati et al., 2022)

Chromatographic conditions

The solutions were seen as an 8mm wide band on precoated silica gel 60F254 aluminium plates, using a 100 µl Hamilton syringe manufactured by Aetron. The plates were subjected to thermal activation at a temperature of 1100°C within an oven for a duration of 20 minutes prior to the application of the sample. The development of the spotted plate occurred within a twin trough chamber that had been pre-saturated for a duration of 30 minutes. The mobile phase used in this process consisted of a mixture of Ethyl Acetate, Toluene, Methanol, and Ammonia in a volumetric ratio of 7:0.5:1.5:0.5. The spotted plate was developed to a distance of 7 cm. The plates that were developed underwent a drying process using an air dryer. The formed spots underwent scanning at wavelengths of 254nm and 251nm (Shah et al., 2021)

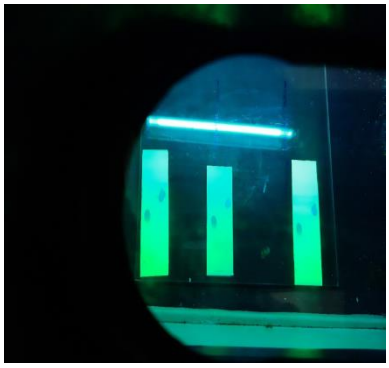
Mobile phase selection

Trial 1. Acetonitrile: Ethyl Acetate: Ammonia (4:7:0.1 v/v/v)



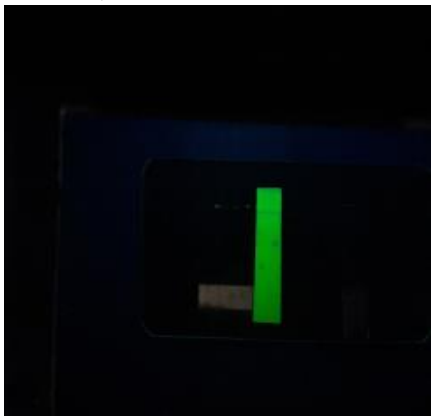
Observation: Spots are not running proper

Trial 2. Toluene: Ethyl Acetate: Methanol: Ammonia (30%) (0.5:7:2:0.5v/v/v)



Observation: Tailing is observed.

Trial 3. Ethyl Acetate: Toluene: Methanol: Ammonia (7:0.5:1.5:0.5v/v/v/v)



Observation: Clear spots are observed.

Analytical method validation 2

The analytical methodologies provided in this study were validated using (ICH) Q2A and Q2B. These guidelines include suggestions for validating analytical processes, and were utilised to validate several parameters in this study. The method underwent validation to assess further analysis (Roshdy et al., 2023).

Linearity

Volumes of 4, 8, 12, 16, 20, and 24 µL were utilised to apply solutions on a High-Performance Thin-Layer Chromatography (HPTLC) plate, resulting in concentrations ranging from 800 ng to 4800ng for Bilastine and 400 ng to 2400 ng for Montelukast Sodium. Following 20 minutes of solvent evaporation at room temperature, chromatography was conducted by the aforementioned procedure. The calibration curve was constructed by graphing the relationship between concentration and volume for the Aetron system, and by plotting peak area against the quantity of medication per band for the CAMAG system. The calibration equations were established by the application of linear regression analysis, and the corresponding correlation coefficients (r2) were computed. The measurements were conducted in triplicate. (Bhanu et al., 2023)

Precision

The precision of an analytical technique is commonly described as the level of agreement observed among a series of measurements derived from several samplings of a uniform sample, all conducted under predetermined conditions. The precision of the analytical procedure was demonstrated by the intraday and interday precision

a. Assessment

Intraday precision

Three concentration sets (Low, Middle, and High) were prepared in intraday precision. Each set of sample preparation was injected into the system on the same day after a one-hour interval, and the chromatogram was recorded. Count the peak response. Intraday precision

was expressed as the % RSD of the measured concentration (Table 3).

b. Interday precision

In an interday precision study, make three set (Low, Middle, High) of concentrations and, inject each set of sample preparation into the system on the different day and record the chromatogram. Count the response of the peak. It is % RSD of the measured concentration. (Table 3)

c. Repeatability: For repeatability 800ng, 1600ng & 3200ng (Bilastine) 800 ng, 1600 ng & 2400ng (Montelukast Na) sample was applied for 5 times repeatedly and volumes were noted. Lastly, mean and % RSD was calculated. All measurements were repeated five times. (Andhale et al., 2022)

i.Accuracy

By adding a drug standard solution over the previously analysed sample solution, the experiment's accuracy was verified. Three distinct levels, namely 80, 100, and 120%, were used for the recovery study. The experiment was repeated three times. (Patel et al., 2021)

ii.Robustness

The robustness of the method was assessed at concentration 3200ng/spot (Bilastine) & 1600ng/spot (Montelukast Sodium) for three times (Karde et al., 2023).

iii.Ruggedness

From the dilute solution 16 µl spot was applied to get 3200 ng (Bilastine) 1600ng (Montelukast Sodium). It was a collaborative effort between two analysts.

iv.LOD, LOQ

To determine the LOD and LOQ, we used the formulas,

LOD = $3.3 \times A.S.D./Slope$

LOQ = $10 \times S.D./Slope$

We assumed a signal-to-noise ratio 3:1 – LOD, 10:1 - LOQ. (Mujawar et al., 2023).

v. Analysis of tablet formulation

A precise quantity of powder, corresponding to 20mg of Bilastine and 10 mg of Montelukast Sodium, was carefully weighed and afterwards transferred into a 50 mL volumetric flask containing 50 mL of methanol. The resulting mixture was subjected to sonication for a duration of 20 minutes. A 5 mL aliquot was withdrawn from this prepared stock solution and diluted with 10 mL of methanol to achieve the desired final volume. The resultant solution underwent filtration using Whatmann filter paper. The resulting extract was subsequently put onto a thin-layer chromatography (TLC) plate, followed by the process of development and scanning, as previously outlined. The analysis was conducted three times in order to ensure accuracy and reliability of the results (Mane et al., 2023; Patil et al., 2023).

Results and discussion

Rf values of 0.2 (for Bilastine) and 0.4 (for Montelukast Sodium) (Table 3) indicated that the medications resolved satisfactorily (Figure 4). Densitogram of Bilastine and Montelukast Sodium is shown in Figures 5 & 8. The construction of calibration curves involved the graphing of peak area against concentration per band. A strong linear relationship was seen within the concentration range of 800ng to 4800ng for Bilastine and 400 ng to 2400 ng for Montelukast Sodium per band. Linear regression equation was found to be y = 0.0197x + 28.364 for Bilastine y = 0.0191x + 35.166 for Montelukast. The regression coefficient (r2 = 0.998) and (r^2 = 0.997) for Bilastine and Montelukast, respectively is generally considered as evidence of acceptable fit. (Figures 2 & 3) for Method 1 and for Method 2 Y=1.3426+2665.4 (r^2 =0.997) for Bilastine Y=3.9841+2284.6 (r^2= 0.998) for Montelukast Sodium (Figures 6 & 7) All measurements were repeated three times. Results are depicted in (Tables 1, 2, 4, 5). The results pertaining to the Limit of Detection (LOD) and Limit of Quantification (LOQ) are presented in Table 6.

The study centred around evaluating the accuracy of the methodology in relation to its capacity to produce consistent results both inside and across different testing conditions. The quantification of the accuracy of the developed HPTLC method was performed using the percentage relative standard deviation (%RSD). Table 7 displays the results related to precision. The devised method was shown to exhibit a high level of accuracy, as seen by the % RSD values obtained from repeatability and intermediate precision investigations, both of which were below 2%. These results align with the guidelines outlined in ICH guidelines. The study focused on evaluating the repeatability and intermediate precision of the technique. The accuracy of the developed HPTLC method was expressed in terms of percentage relative standard deviation (%RSD). Table 6 displays the findings from the precision study. As per the ICH guideline, the repeatability and intermediate precision studies' respective RSD values for the established method were found to be 2% (Kharate et al., 2023).

The study examines the precision of the methodology in order to evaluate potential interference from other components included in the pharmaceutical formulation. The recovery of the drug in tablet dosage forms was determined by the utilisation of a method including extraction and subsequent analysis (Shivatare et al.,

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2023). The tablets were spiked with drug amounts that exceeded the standard dosage by 80%, 100%, or 120%. Method 1: 99.45 – 100.79 and 99.22- 99.64 % Method 2: 99.71 – 100.13 % for Bilastine & 99.71 -99.74 %, as listed in Table 8. The results of Robustness are shown in Table 9 and Ruggedness are shown in Table 10.

The % assay for each method was 99.6% & 101% (Method 1 Aetron Instrument) 98.6 & 102.3(Method 2 Camag Instrument). Results are depicted in Table 11.

Method 1 (Instrument Aetron)

Table 1. Results of linearity of Bilastine on Aetron HPTLC

Conc.(ng)	Vol I	Vol II	Vol III	Mean
2400	79.92	79.92	66.95	75.59667
3200	95.07	95.07	82.51	90.88333
4000	110.75	110.75	100.58	107.36
4800	127.34	127.34	118.41	124.3633
5600	136.45	137.45	138.9	137.6

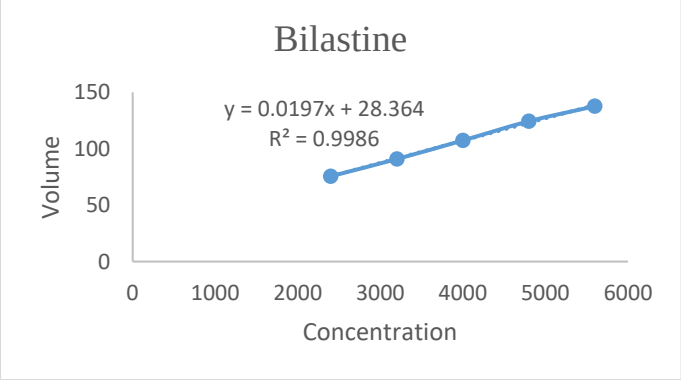

Figure 2. Calibration curve for Bilastine on Aetron HPTLC

Table 2. Results of linearity of Montelukast Sodium on Aetron HPTLC

Conc.(ng)	Vol I	Vol II	Vol III	Mean
1200	54.45	62.84	57.22	58.17
1600	60.47	62.54	72.55	65.18667
2000	66.71	74.56	78.31	73.19333
2400	76.91	88.63	79.99	81.84333
2800	84.87	88.98	89.98	87.94333

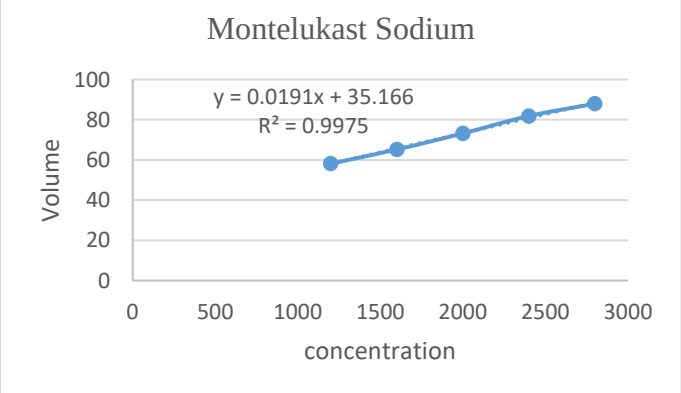

Figure 3. Calibration curve for Montelukast Sodium on Aetron HPTLC

Figure 4. Separation of Bilastine & Montelukast Sodium under 254 nm

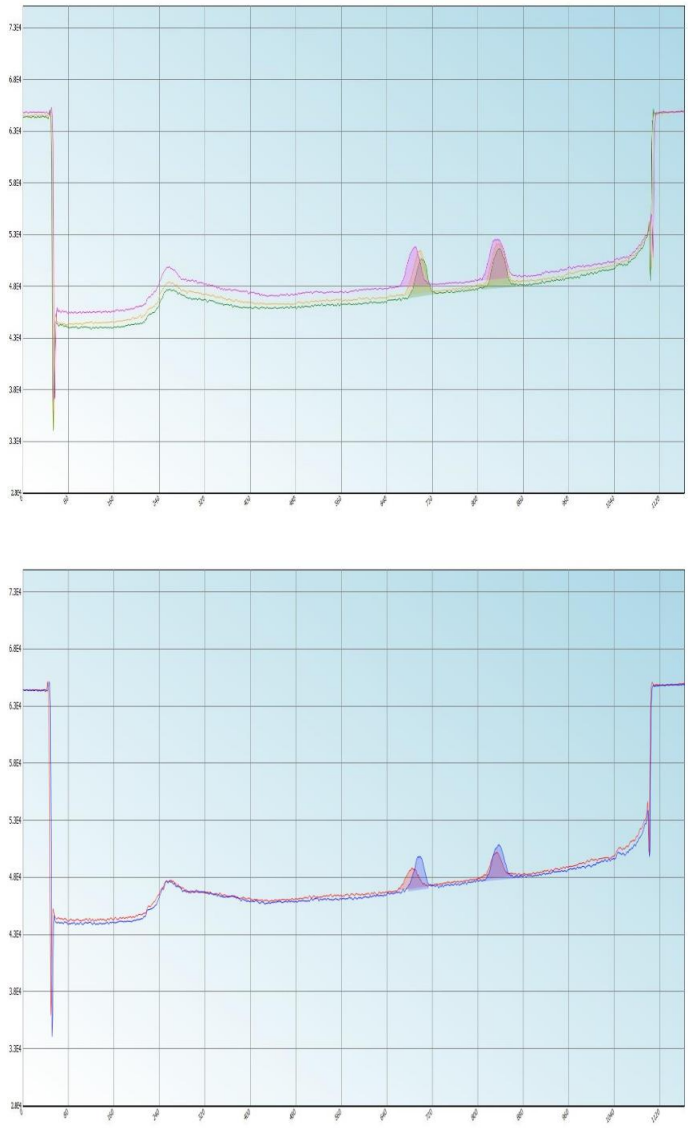

Figure 5. Densitogram of Bilastine & Montelukast Sodium on just TLC software

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Table 3. Rf values of Bilastine & Montelukast Sodium

Lane ID	Band ID	Rf	Area	Displayed Volume	Notes
1	1	0.436	7308	50.74	Monte
1	2	0.254	7192	62.91	Bilast
2	1	0.424	3672	64.84	Monte
2	2	0.247	7038	79.92	Bilast
3	1	0.416	5684	78.54	Monte
3	2	0.248	5880	95.07	Bilast
4	1	0.421	7125	94.56	Monte
4	2	0.247	6935	110.75	Bilast
5	1	0.435	8991	108.63	Monte
5	2	0.254	6105	127.34	Bilast
(Small curve-Bilastine & Large curve-Montelukast Sodium)					

Method 2 (Instrument Camag)

Table 4. Results of Linearity of Bilastine on Camag HPTLC

Conc.(ng)	Area I	Area II	Area III	Mean
800	3684.7	3566.5	3599.2	3616.8
1600	4928.4	4830.5	4836.1	4865
2400	5898.2	5987	6001	5962.06
3200	7026.7	7036.5	7041.1	7034.7
4000	8005.7	8107	8108	8073.5

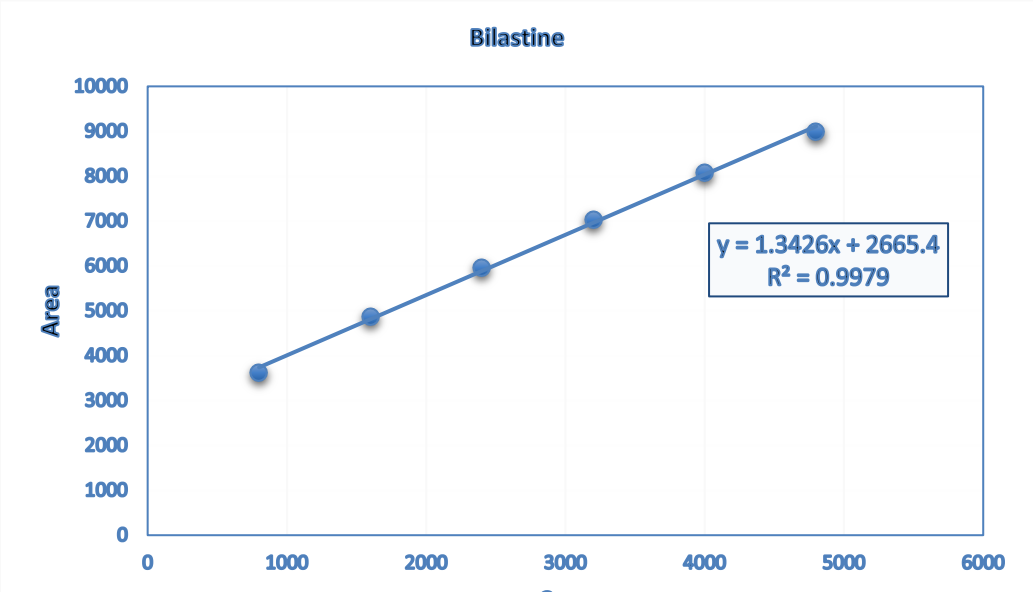

Figure 6. Calibration curve Bilastine on Camag HPTLC

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Table 5. Linearity of Montelukast Sodium on Camag HPTLC

Sr. No.	Conc.(ng)	Area I	Area II	Area III	Mean
1	400	3571.9	3781	3798	3716.9
2	800	5581.7	5585.1	5590	5585.6
3	1200	7199.5	7101	7105	7135.1
4	1600	8698.5	8695	8701.55	8698.3
5	2000	10313	10315	10320	10316

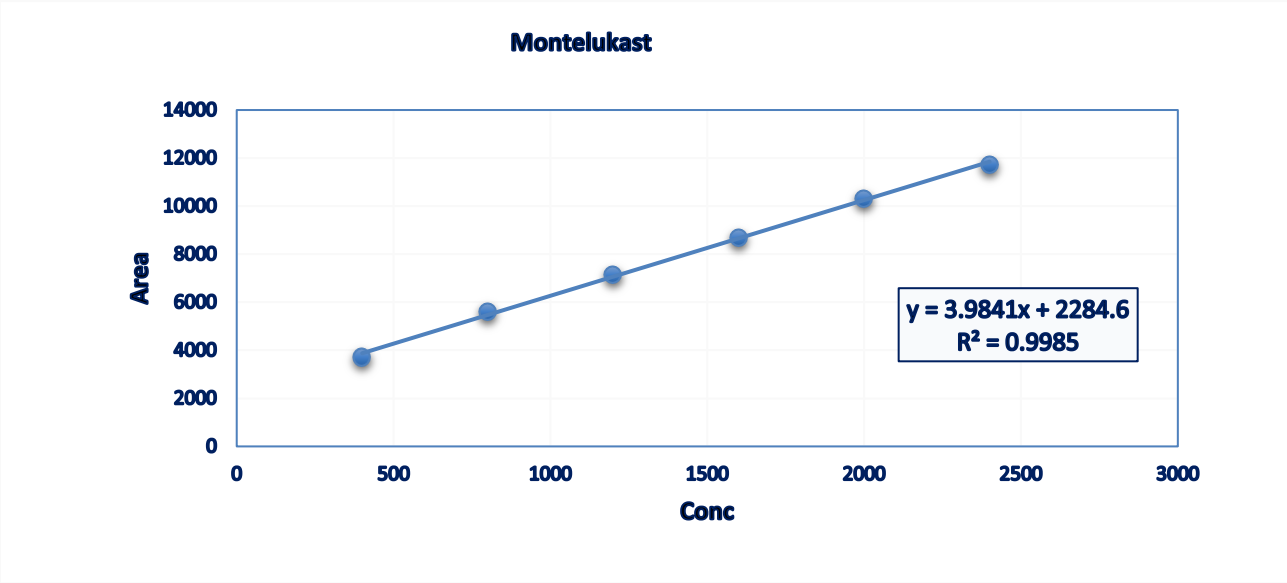

Figure 7. Calibration curve Montelukast Sodium on Camag HPTLC

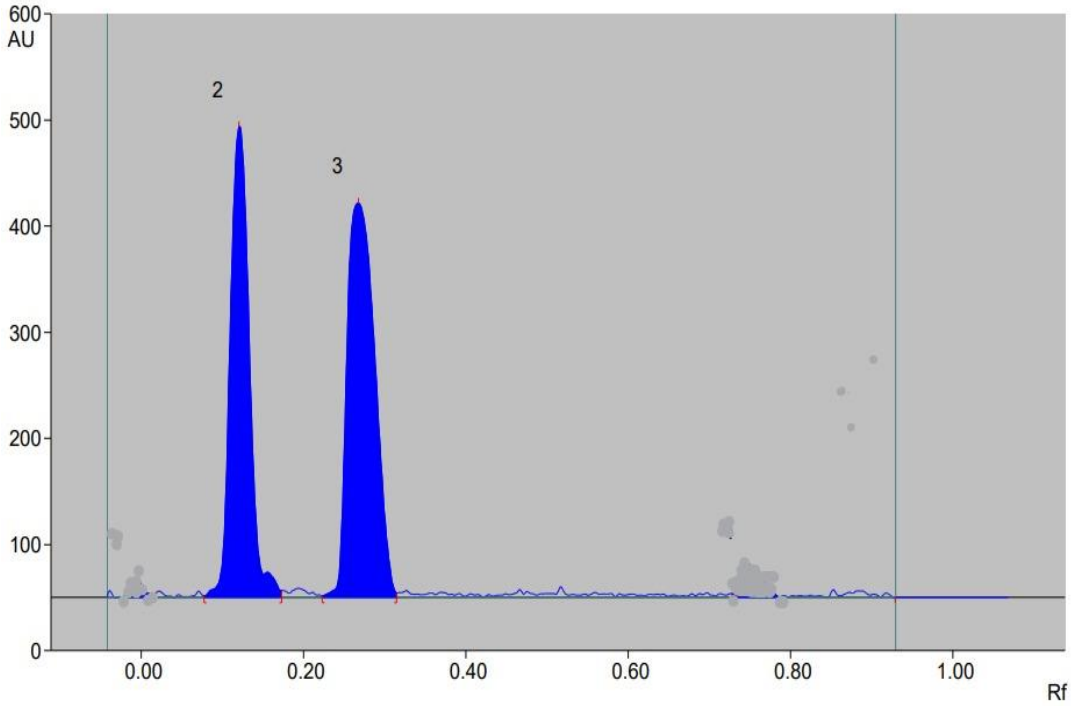

Figure 8. Densitogram of Bilastine and Montelukast Na on Camag HPTLC
(2nd no curve-Bilastine & 3rd no curve-Montelukast Na)

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Table 6. Results of LOD and LOQ

Parameters	Method 1 (Aetron Instrument)		Method 2 (Camag Instrument)	
	BILAST	MONTE	BILAST	MONTE
	ng/band		ng/band	
LOD	0.235	0.362	0.251	0.762
LOQ	0.713	1.099	0.278	0.844

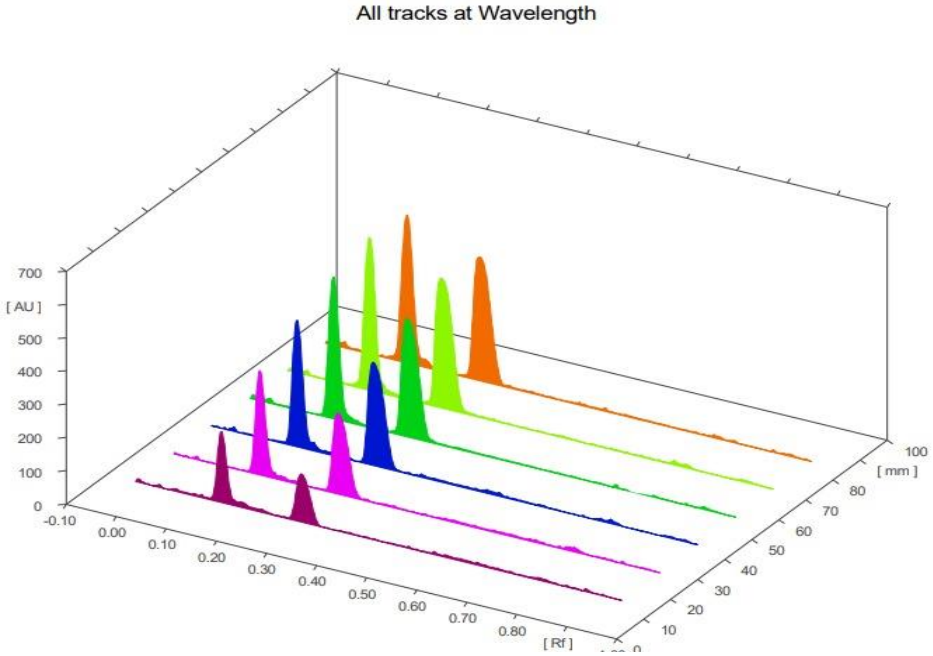

Figure 9. 3D overlaid Diagram of Bilastine & Montelukast Na calibration bands on Camag HPTLC

Table 7. Results of precision study

Parameter	Method 1 (Aetron Instrument) *n=3*				Method 2 (Camag Instrument) *n=3*			
	BILAST		MONTE		BILAST		MONTE	
	Conc. (ng)	% RSD	Conc. (ng)	% RSD	Conc. (ng)	% RSD	Conc. (ng)	% RSD
Intraday	1600	0.273	800	1.54	1600	1.13	800	0.14
	3200	0.63	1600	0.69	3200	0.10	1600	0.69
	4800	0.63	2400	0.66	4800	1.21	2400	0.10
Interday	1600	0.79	800	1.60	1600	0.52	800	1.04
	3200	1.29	1600	1.11	3200	0.80	1600	0.66
	4800	0.52	2400	1.31	4800	0.64	2400	0.43

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Table 8. Results of recovery study

		Method 1 (Aetron Instrument)				Method 2 (Camag Instrument)			
	Level	Amt. added (ng)	Amt. Recovered (ng)	% Recovery	% RSD	Amt. added (ng)	Amt. Recovered (ng)	% Recovery	% RSD
BILAST	80%	1280	1206.1	100.79	1.44	1280	1205.87	99.71	0.10
	100%	1600	1584.1	100.79	0.78	1600	1587.29	100.05	0.11
	120%	1920	1925.4	99.45	0.62	1920	1916.51	100.13	0.105
MONTE	80%	640	645.97	99.22	1.30	640	645.35	99.91	0.67
	100%	800	797.84	99.69	0.73	800	797.21	99.82	0.52
	120%	960	967.47	99.64	0.53	960	967.04	99.74	0.43

Table 9. Results of robustness

Parameter (Conditions)	Method 1 (Aetron Instrument)		Method 2 (Camag Instrument)	
	Bilastine	Montelukast Na	Bilastine	Montelukast Na
	%RSD		%RSD	
Change in mobile phase concentration	0.49	0.625	0.18	0.10
Change in application volume	0.20	0.11	0.29	0.23
Change in development distance	0.42	0.31	0.295	0.16

Table 10. Results of ruggedness

Parameter		Method 1 (Aetron Instrument)		Method 2 (Camag Instrument)	
		(% RSD)		(%RSD)	
		BILAST	MONTE	BILAST	MONTE
Ruggedness	Analyst 1	0.86	0.90	0.214	0.45
	Analyst 2	0.77	0.70	0.812	0.61

Table 11. Results of assay

Parameter		Method 1 (Aetron Instrument)		Method 2 (Camag Instrument)	
		BILAST	MONTE	BILAST	MONTE
Assay	Label Claim	20mg	10mg	20mg	10mg
	Amount found	19.92	10.11	19.72	10.23
	% Assay	99.61%	101.1	98.6 %	102.3%

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Conclusions

Quality control and analysis are vital processes that must be conducted for all recently introduced drugs and mixed-dose forms available in the market. The present research project has developed two analytical procedures, Method 1 and Method 2, which can be employed to simultaneously measure Bilastine and Montelukast Sodium in bulk and pharmaceutical formulations using planar chromatography. The utilisation of planar chromatography in this investigation serves to emphasise its potential in the field of pharmaceutical analysis. The efficacy of this method is demonstrated by its simultaneous analysis of Bilastine and Montelukast Sodium, highlighting its capability in analysing complicated medication combinations. Nevertheless, it is crucial to recognise that any analytical methodology possesses both drawbacks and benefits. When choosing a suitable approach, it is essential to take into account the particular requirements of the sample matrix, sensitivity, and availability of equipment. This comparative examination provides evidence of the rigorous craftsmanship involved in the creation and validation of analytical methods. The investigation of planar chromatography yields significant findings on the concurrent determination of Bilastine and Montelukast Sodium. As scientific progress continues, the insights gained from this study will inevitably be applied in the wider realm of pharmaceutical research and aid in the shared objective of guaranteeing the safety and effectiveness of medicinal goods.

Conflict of interest

The authors confirm there are no competing interests with this study.

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