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A NEW RP-HPLC METHOD FOR THE SIMULTANEOUS ESTIMATION OF BILASTINE AND MONTELUKAST IN PHARMACEUTICAL DOSAGE FORM

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ABSTRACT
A simple and selective LC method is described for the determination of Bilastine and Montelukast in tablet dosage forms. Chromatographic separation was achieved on a Waters AcquityC18 (50mm x2.1 mm ID) 1.8µm using mobile phase consisting of a mixture of 55 volumes of mixed Phosphate Buffer pH 3.5: Acetonitrile(75:25) %v/v with detection of 265nm. Linearity was observed in the range 20-60 µg/ml for Bilastine(r^2 =0.9995) and 10-30 µg/ml forMontelukast(r^2 =0.9997) for the amount of drugs estimated by the proposed methods was in good agreement with the label claim. From the above experimental results and parameters it was concluded that, this newly developed method for the simultaneous estimation Bilastine and montelukastwas found to be simple, precise, accurate and high resolution and shorter retention time makes this method more acceptable and cost effective and it can be effectively applied for routine analysis in research institutions, quality control department in meant in industries, approved testing laboratories studies in near future.

Key Words: Bilastine, Montelukast, LC method

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INTRODUCTION
Chromatography equipment look rather intimidating to anyone who has not handled them before, but on a closer look and as you get familiar with the equipment you realize that behind the network of wires, complex plumbing and circuitry is a simple machine with only a few major parts. Different combinations of these parts namely pumps, detectors and injectors yield an infinite number of configurations based on the application.Just like an understanding of human anatomy makes you conscious of the vital role of each and every body organ towards your well being and vitality. Similarly you need to have a good understanding of the parts of your HPLC system to generate data of highest reliability. A conceptual understanding of the function of each component will add to your comfort level with your HPLC system. You will ensure long time usage with high reliance on output data. The present module is intended to serve this very purpose and in simple terms you will appreciate the role of each part and its contribution to overall system efficiency.HPLC is a technique for separation, identification and quantification of components in a mixture. It is especially suitable for compounds which are not easily volatalised, thermally unstable and have high molecular weights.The liquid phase is pumped at a constant rate to the column packed with the stationary phase. Before entering the

column the analysis sample is injected into the carrier stream. On reaching the column the sample components are selectively retained on the basis of physico-chemical interactions between the analyte molecules and the stationary phase. The mobile phase moving at a steady rate elutes the components based on the operating conditions. Detection techniques are employed for detection and quantification of the eluted components [1-4].We now introduce you to the significance and role of each component part of the HPLC system.

Aim of the study is to develop new RP-HPLC method for the simultaneous estimation of Bilastine and Montelukastinpharmaceutical dosage form.

MATERIALS AND METHODS

Preparation of samples for Assay

Preparation of Standard solution

About 125 mg of Bilastineand 100mg of Montelukastwere weighed into a 100 mL volumetric flask, to this 70mL of mobile phase was added, sonicated and the volume was made up with the mobile phase.Pipetted 5 mL of the clear solution in to 50 mL volumetric flask and make up volume with mobile phase.

Preparation of Sample solution

Crush more than 20tablets then weigha quantity of powder equivalent to 125mg of Bilastineand 100mg of Montelukastin 100 mL volumetric flask and add70mL of mobile phase then sonicated it for 30min intermittent shacking after 30min make up volume with mobile phase. Pipetted 5 mL of the clear solution in to 50 mL volumetric flask and make up volume with mobile phase. Filter the solution through 0.45µm filter paper. The resulting solution is used to record the chromatogram (Fig. 7.9).

$$\%\ \text{Assay} = \frac{AT}{AS} \times \frac{\text{WS}}{DS} \times \frac{\text{DT}}{WT} \times \frac{\text{P}}{100} \times \frac{\text{AW}}{LC} \times 100$$

Optimized Chromatographic Conditions for Assay

Table-1Optimized condition.

Mobile phase	Phosphate Buffer pH 3.5: Acetonitrile(75:25) %v/v
Column	Waters AcquityC18(50mm x2.1 mm ID) 1.8µm
Flow rate	0.5mL/min
Column temperature	35^{o}C
Sample temperature	15^{o}C
Wavelength	265 nm
Injection volume	10µL
Run time	5 min
Retention time	1.827min for BILASTINE and 3.577 minfor MONTELIKAST

Validation

To verify that the analytical system is working properly and can give accurate and precise results 7].

were evaluated by 125µg/mL of Bilastine and100µg/mL of Montelukastwere injected six times and the chromatograms were recorded for the same[5-

RESULTS AND DISCUSSION

Results shows that both drugs % assay found to be within the limits (Table-2). The percentage purity of both Bilastineand Montelukastwere found to be within the limits that is 98-102%.

Table-2 Results of assay

Bilastine			Montelukast	
	Standard Area	**Sample Area**	**Standard Area**	**Sample Area**
Injection-1	46340258	34134250	51335283	33365477
Injection-2	46001582	33405725	49108386	33411360
Injection-3	46033474	33639716	50202133	34638194
Injection-4	46101716	33494709	50234358	33304993
Injection-5	45923870	33681271	50936936	33828676
Average Area	46080180	33671134	50363419	33709740
Assay(%purity)	99.26		100.11	

The plate count and tailing factor results were found to be satisfactory and are found to be within the limit (Table-3 and 4).The % RSD was found to be 0.58.

Table-3 Results for system suitability of Bilastine

Injection	**RT**	**Peak area**	**Theoretical plates (TP)**	**Tailing factor (TF)**
1	1.830	46340258	2945	1.21
2	1.827	46001582	2942	1.17
3	1.823	46033474	2949	1.18
4	1.830	46101716	2999	1.14
5	1.833	45923870	3041	1.15
6	1.827	45780149	3032	1.14
Mean	1.828	46030175	-	-
SD	0.003	187570	-	-
%RSD	0.2	0.4	-	-

Table-4 Results for system suitability of Montelukast

Injection	**Retention time**	**Peak area**	**Theoretical plates**	**Tailing factor**	**Resolution**
1	3.540	34134250	7587	1.14	13.25
2	3.580	33405725	7902	1.16	11.85
3	3.567	33639716	7664	1.18	11.72
4	3.580	33494709	7828	1.19	11.84
5	3.597	33681271	7886	1.19	11.95
6	3.573	33505619	7912	1.17	11.90
Mean	3.573	33643548	-	-	-
SD	0.019	260754	-	-	-
%RSD	3.540	34134250	-	-	-

A graph was plotted for Bilastineand Montelukastagainst the concentrations of the solutions and the peak areas (Fig-1). The correlation coefficient R^2 was determined and was found to be 0.999 for ATE (Fig-2) and 0.999 for Montelukast(Fig-3).

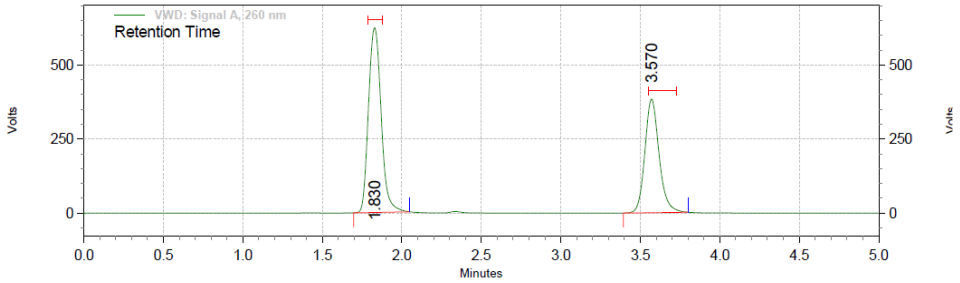

Fig-1 Chromatogram of linearity for preparation

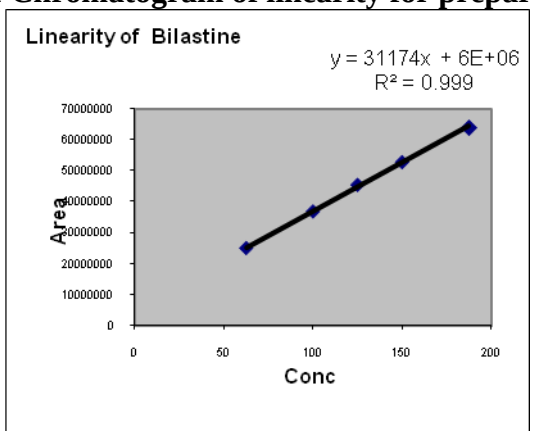

Fig-2 Graph for Linearity data of Bilastine

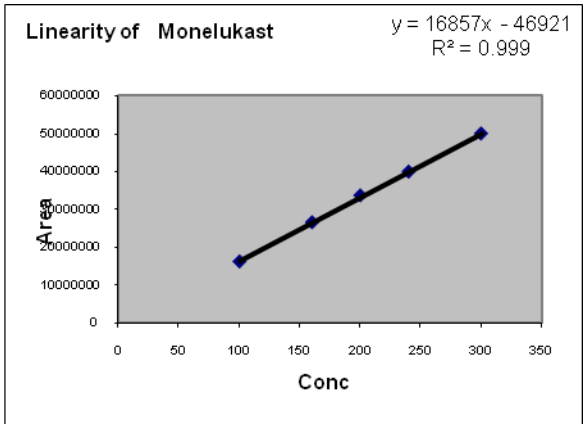

Fig-3 Graph for Linearity data of Montelukast

The % mean recovery of Bilastineand Montelukastwas founded between 98.0 to 102.0(Table-5 and 6).

Table-5 Results for Recovery of Bilastine

%Recovery	Amount present (µg/mL)	Amount found (µg/mL)*	Percent Recovery *	% Mean Recovery
50%	62.50	**62.66**	100.3	99.9
100%	125.0	**123.75**	99.4	
150%	188.5	**188.17**	100.4	

Table-6 Results for Recovery of Montelukast

%Recovery	Amount present (µg/mL)	Amount found (µg/mL)*	Percent Recovery *	% Mean Recovery
50%	100	100.94	99.1	99.8
100%	200	198.58	100.7	
150%	300	300.95	99.7	

The proposed methods were validated. The accuracy of the methods was assessed by recovery studies at three different levels. Recovery experiments indicated the absence of interference from commonly encountered pharmaceutical additives. The method was found to be precise as indicated by the repeatability analysis, showing %RSD less than 2. All statistical data proves validity of the methods and can be used for routine analysis of pharmaceutical dosage form.

CONCLUSION

From the above experimental results and parameters it was concluded that, this newly developed method for the simultaneous estimation Bilastine and montelukastwas found to be simple, precise, accurate and high resolution and shorter retention time makes this method more acceptable and cost effective and it can be effectively applied for routine analysis in research institutions, quality control department in meant in industries, approved testing laboratories studies in near future.

REFERENCES

1. Chatwal**,** R**.** G**.;** Anand**,** K**.** S**.** High performance liquid chromatography**.***Instrumental methods of chemical analysis***,** 5th ed**.;** Himalaya publishers**:** Mumbai, 2010**;** 2.570-2.629**.**
2. Sharma**,** B**.** K**.** High performance liquid chromatography**.***Instrumental methods of chemical analysis***,** 24th ed**.;** Goel publishers**:** Meerut**,** 2005**;** 295 - 300**.**
3. Dong,W. M. HPLC instrumentation and trends. *Modern HPLC for practicing scientists*, USA, 2006; 5-10, 78-110.
4. Swartz,M. E.; Ira Krull, S, Analytical method development. *Analytical method development and*

validation, 1st ed.; Marcel Dekker, Inc: New York, 2009; 17-80.
5. ICH, *Text on Validation of Analytical Procedures*, ICH – Q2A, International Conference on Harmonisation, IFPMA, Geneva, 1995, 2-3, A–1 to A–3.
6. ICH, *Validation of Analytical Procedures: Methodology*, ICH – Q2B, International Conference on Harmonisation, 1996, 1-3.
7. ICH Guidelines, Q2 (R1) - Validation of Analytical Procedures: Text and Methodology,2005, 1-6.
8.