DEVELOPMENT AND VALIDATION OF UV SPECTROPHOTOMETRIC METHODS FOR SIMULTANEOUS ESTIMATION OF BILASTINE AND MONTELUKAST SODIUM IN PURE AND TABLET DOSAGE FORM

Prof. (Dr.) Abhijit .N. Merekar [1], Prof. (Dr.) Smita. A. Merekar [2], Prof.Mahesh D.Dokhe [3], Mr.Harshad.B.Vitnor[4], Miss. Pooja.P.Darekar[4]

Associate Professor Department of Pharmaceutics,

Dr. Vithalrao Vikhe Patil Foundation's',

Dr. Vithalrao Vikhe Patil College of Pharmacy, Vilad Ghat, Ahmednagar-414111

Associate Professor, Department of Medicinal Chemistry,

Dr. Vithalrao Vikhe Patil Foundation's',

Dr. Vithalrao Vikhe Patil College of Pharmacy, Vilad Ghat, Ahmednagar-414111

Assistant Professor, Department of Quality Assurance Techniques,

Dr. Vithalrao Vikhe Patil Foundation's',

Dr. Vithalrao Vikhe Patil College of Pharmacy, Vilad Ghat, Ahmednagar-414111

Department of Pharmaceutics,

Dr. Vithalrao Vikhe Patil Foundation's',

Dr. Vithalrao Vikhe Patil College of Pharmacy, Vilad Ghat, Ahmednagar-414111

Corresponding Author: Prof.Dr.Abhijit N. Merekar

anmerekar@yahoo.co.in, parjanesmita23@gmail.com, **mddmedical27@gmail.com**

ABSTRACT:

Using the concept of the simultaneous equation approach, a precise, accurate, and economical method for estimating Montelukast sodium and Bilastine simultaneously in multiple tablet definite volumes has been developed. The methodology is based on measurements of bilastine at 282 nm and montelukast sodium at 287 nm in methanol. Numerous analytical parameters, such as linearity, precision, accuracy, and toughness, were established in accordance with ICH guidelines. The linearity of montelukast and bilastine at their respective wavelengths is demonstrated by their concentration ranges of 2–12 g/ml and 4–24 g/ml, respectively. Utilising statistics, the validity of the method was examined. The results of the montelukast sodium and bilastine analysis formulation, both 101.83% and 99.79% of label claims, were found to be true when expressed as a percentage.

Keywords: Simultaneous estimation, Bilastine, Montelukast sodium, linearity**.**

INTRODUCTION :

Chemically, Montelukast Sodium (MONT) (S, E 2-((1-((1-((1- ((1-((1-((1-(3-(2-(7-chloroquinolin-2-yl) vinyl) phenyl) 2-(2- hydroxypropan-2-yl) phenylpropylthio) methyl cyclopropyl acetic acid) LTRA is used to treat asthma in a consistent state and to lessen the symptoms of seasonal allergies. According to a review of the literature, montelukast sodium is recognised as an assay in both tablet and bulk form by the Indian Pharmacopoeia 2010. Chemically speaking, bilastine (BILA) is 2-[4-[2-[4-[1-(2-ethoxyethyl) benzimidazol-2-yl] piperidin-1- yl] ethyl] phenyl]. acid 2-methylpropanoic. It is a second-generation H1-antihistamine that is effective in treating chronic urticaria and allergic rhinitis symptoms. A literature review revealed that montelukast in pharmaceutical dosage forms could be assessed using analytical techniques like the UV spectrophotometer. UV spectrophotometry is the analytical method reported for the measurement of MONT and BILA alone and in combination with other medications. This work aimed to develop and test a spectrophotometric analytical technique for measuring both medications because a thorough review of the literature revealed that there is no known spectrometric method for detecting montelukast sodium and bilastine in the preparation of pharmaceuticals. The suggested approach has been optimised and validated in accordance with the ICH criteria. This study successfully attempted to measure both medications simultaneously using a UV spectrophotometer and the Simultaneous Equation approach. This study aims to support ongoing quality control of sodium montelukast sodium and bilastine in pharmaceutical formulations.

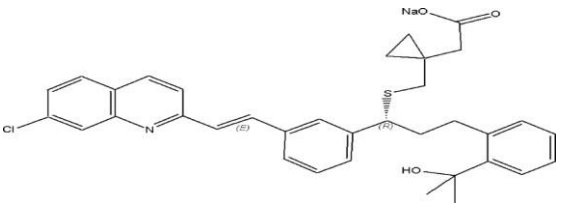


Fig 1: Montelukast Structure

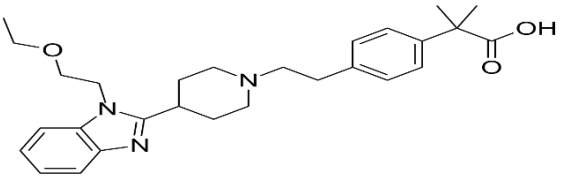


Fig 2: Bilastine Structure

MATERIALS AND METHOD:

Instrument

A UV-VIS double beam spectrophotometer UV-1700 from Shimadzu Corp. with a 1 cm quartz cell was used to record the absorption spectra. Weighing the medications and other items was done using a Shimadzu electronic balance.

Chemical agents and Components

Infinite biotech institute of research and analytics sangli provides free samples of the analytically pure drugs bilastine and montelukast sodium. The tablet formulation used in the trial was called ALLERBLIS M Tablet and was produced by TROIKAA PHARMACEUTICALS LTD in India. It contained the prescribed dosages of 20 mg Bilastine and 10 mg Montelukast Sodium. Methanol was used as the solvent.

Preparation of standard stock solution

The stock solutions were supplemented with two different 100 ml volumetric flasks, each containing 10 mg of MONT and BILA. The flasks were stirred to dissolve solids inside of them. The amounts were increased to the necessary level using methanol, producing 100 g/ml of each medication.

Selection of Analytical Wavelength

The wavelength maxima of both medications must be considered when designing the simultaneous equation method. The overlapping spectra of MONT and BILA (10 g/ml) show that the wavelength maxima of MONT are at 344 nm and 282 nm, respectively. We used 344 nm and 282 nm wavelengths to construct a simultaneous equation.

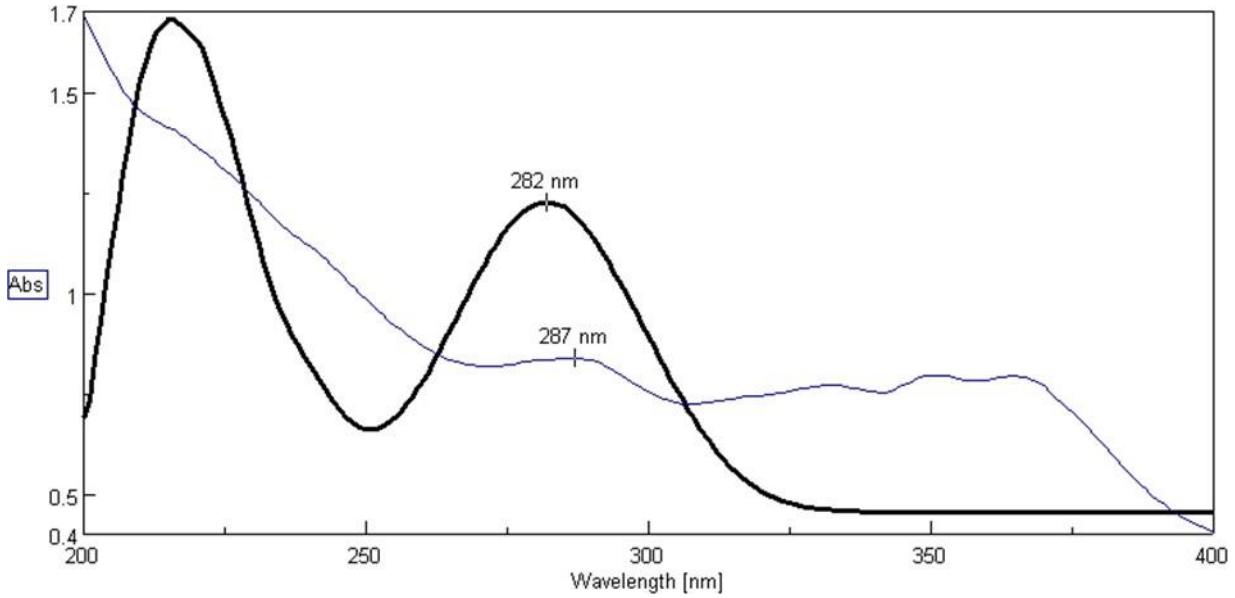


FIG 3: OVERLAY OF BILASTINE AND MONTELUKAST

Standard Curves for MONT AND BILA

To achieve final concentrations of 2, 4, 6, 8, 10, and 12 g/ml of Montelukast Sodium and 4, 8, 12, 16, 20 and 24 g/ml of Bilastine, respectively, the working standard solutions of MONT and BILA were appropriately diluted with methanol. We looked at the solution spectra between 200 and 400 nm, and a correlation between absorbance and concentration was discovered by measuring solutions at wavelengths of 287 nm and 282 nm, respectively.

FIG 4 : UV SPECTRA OF MONTELUKAST

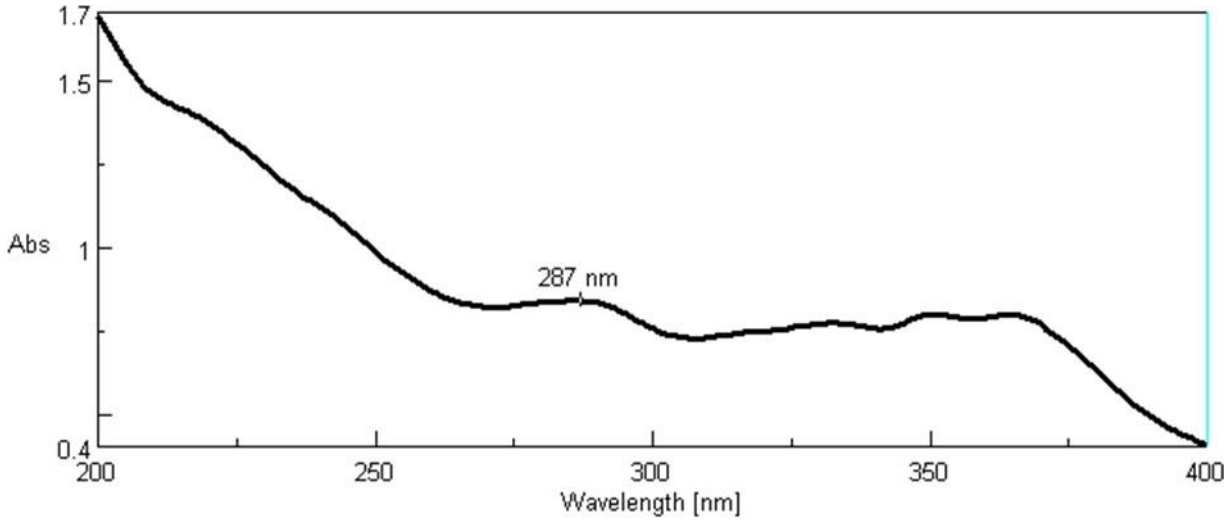
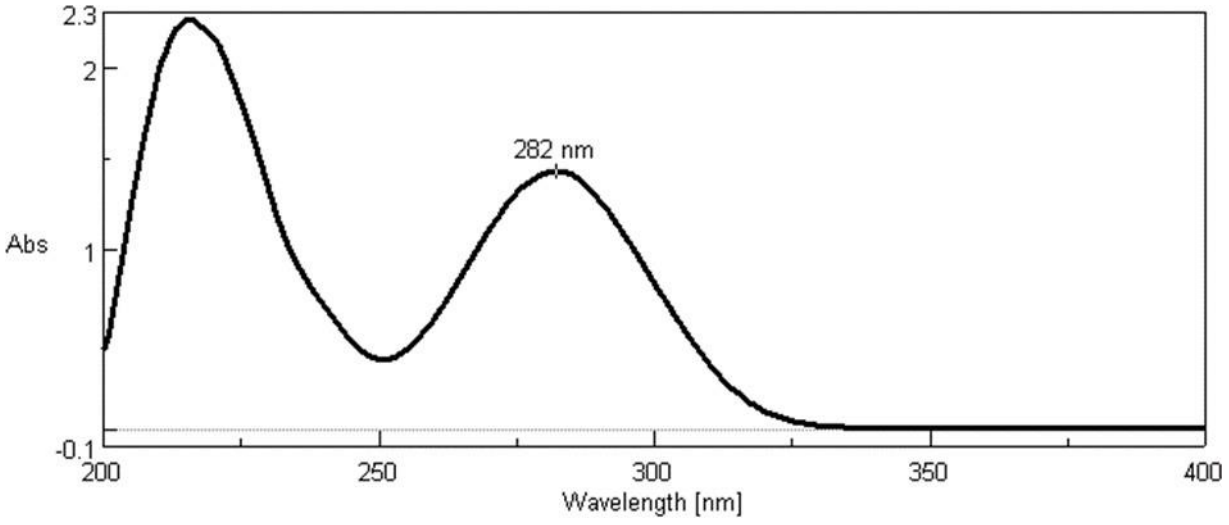


FIG 5: UV SPECTRA OF BILASTINE

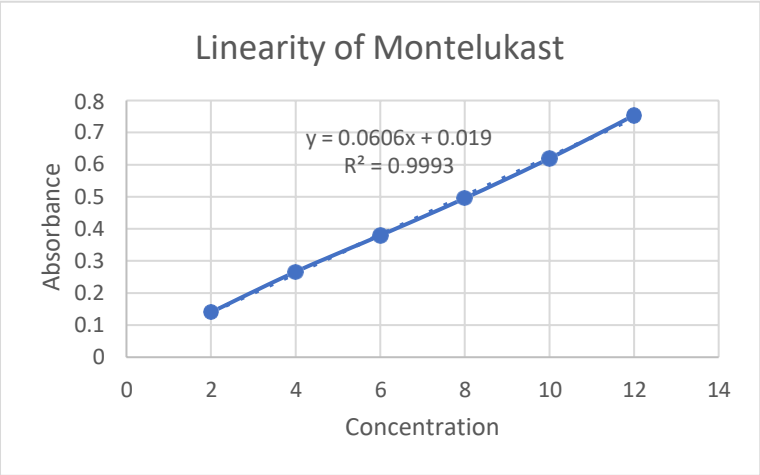


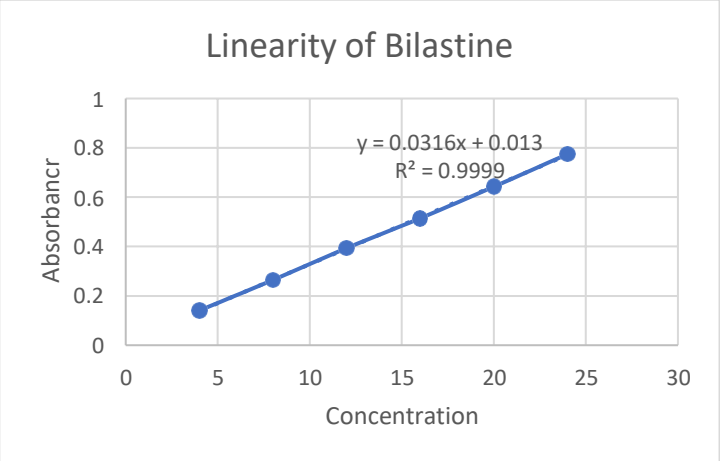
VALIDATION

Linearity

The linearity of these medications was examined by statistically calculating the response of the analyte and the concentration. Results must be expressed as correlation coefficients.

For first-order derivatives, spectrophotometric methods, the calibration curve regression equations for Montelukast sodium and Bilastine were y= 0.0606x+0.019 (r2 = 0.999) at 287nm and y= 0.0316x+0.013 (r2 = 0.999) at 282 nm, respectively. The calibration curve was plotted as shown below using concentration ranges of 2–12 ug/ml for Montelukast sodium and 4-24 ug/ml for Bilastine.





Accuracy

By measuring absorbance three times on the same day and three times on three different days for three different concentrations of MONT (6, 8, and 10 g/ml) and BILA (12, 16, and 20 g/ml), the proposed technique's intraday and interday accuracy was assessed. RSD was used to display the outcomes. Without changing any of the parameters of the suggested Spectrophotometry technique, the instrument's accuracy was evaluated by repeatedly scanning and measuring the absorbance of solutions (n = 6) for MONT (6 g/ml) and BILA (12 g/ml).

Validity

Recovery studies confirmed the accuracy of the method. The previously reviewed formulation was amended to include known amounts of the raw materials, bilastine and montelukast sodium. The process was then carried out per the formulation analysis. The quantity of each medication discovered was calculated. This process was repeated three times for each concentration, and the% RSD was computed.

Detection Limit

Limit of Detection:

After calculating the standard deviation (SD) of the intercepts from six calibration curves, the LOD was calculated using the formula.

LOD equals (3.3 * SD)/Slope

The six calibration curves' Y-intercept standard deviation is abbreviated as SD. The slope is the average slope of the six calibration curves.

Limit of Quantitation

The technique was used to calculate the LOQ after six calibration curve runs and measurement of the standard deviation (SD) of the intercepts.

LOQ = Slope / (10*SD)

The six calibration curves' Y-intercept standard deviation is abbreviated as SD. The slope is the average slope of the six calibration curves.

Evaluation of tablet formulation

The next step is to finely powder the 20 tabs before measuring them. Powder precisely measured to equal 10 mg of MONT and 20 mg of BILA was added to a 100 ml volumetric flask. As mentioned above, a small amount (50 ml) of methanol was added to the flask before it was subjected to five minutes of sonication. The solution was filtered into a second 100 ml volumetric flask using Whatman filter paper and the same solvent. The necessary amount was increased using methanol after the proper percentage was added to a 10 ml volumetric flask to synthesise 8 g/ml of MONT and 16 g/ml of BILA. At 282 and 287 nm, the absorbance of the solution was calculated after studying the solution's spectra between 400 and 200 nm.

RESULT AND ANALYSIS:

Table 1: Optical Characteristics and Precision

Sr.No.	Parameter	Bilastine	Montelukast Sodium
1	**Λ Range**	**200-400**	**200-400**
2	**Regression Equation (y=mx +c)**	**Y=0.0606x+0.019**	**Y=0.0316x+0.013**
3	**Measured Wavelength**	**287**	**282**
4	**Linearity Range**	**2-12**	**4-24**
5	**Slope**	**0.0606**	**0.0316**
6	**Intercept**	**0.019**	**0.013**
7	**Correlation Coefficient(R^2)**	**0.999**	**0.999**
8	**Limit of Detection(LOD) ug/ml**	**0.84**	**0.71**
9	**Limit of Quantitation(LOQ)ug/ml**	**2.56**	**2.17**

The recommended methods received approval in accordance with ICH recommendations. It was found that when the absorbances of MONT and BILA were plotted against theirrespective concentrations, the graphs were linear in the concentration ranges of 2–12 g/ml and 4–24 g/ml, respectively. The correlation coefficients for the two medications using the simultaneous equation method were 0.999 At 287 nm and 0.999 At 282nm. For both of the medications listed in

Table 1

TABLE 2: Analysis data of tablet formulation

MONT: Montelukast Sodium, BILA: Bilastine S.D.: Standard Deviation, SE: Standard Error, CV: Coefficient of Variation, * Average of three estimations of tablet formulation.

Table 3: Results of Recovery Studies

Method	**Recovery level (Added amount)**	**Percent recovery ± SD**	
		MONT	**BILA**
Simultaneous Equation	80 %	99.09	99.72
	100 %	101.2	100.9
	120 %	99.45	100.7
Absorbance Ratio	80 %	100.0	100.1
	100 %	99.62	99.83
	120 %	100.4	101.2

Method	**Drug**	**Label claim (Mg/tab)**	**Label Claim (%)**	**SD.**	**CV.**
Simultaneous Equation	MONT	10	100.66	0.015	0.999
	BILA	20	101.26	0.006	0.999
Absorbance Ratio	MONT	10	99.28	0.672	0.999
	BILA	20	99.68	0.3958	0.999

MONT: Montelukast Sodium, BILA: Bilastine S.D.: Standard deviation, * Average of three estimations of tablet formulations.

CONCLUSION:

Based on the results obtained, it is found that the proposed methods are accurate, precise, reproducible and economical and can be employed for routine quality control of Montelukast Sodium and Bilastine in combined dose tablet formulation.

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