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Solvents effect on Spectrophotometric estimation of Bilastine

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Abstract

Bilastine is an anti-histamine used to treat Allergic reactions Two simple UV spectrophotometric methods have been developed for the estimation of Bilastine in bulk and pharmaceutical dosage forms. The absorption maxima (λmax) of Bilastine was found to be 280 nm in Methanol and in 0.1 N Acetic acid observed at 271 nm and Beer-Lambert's law was obeyed over the concentration range 5-30µg/ml.LOD and LOQ values of Bilastine was found to be 0.102 µg/ml, 0.3097 µg/ml and 0.136 µg/ml, 0.411µg/ml in Methanol and 0.1N Acetic acid respectively. The validation parameters were treated statistically with 't' test and significant differences were observed. The study clearly revealed that the solvents influence the determination of Bilastine. The methods developed were rapid and easy can be applied for the estimation of Bilastine in bulk and pharmaceutical formulations.

Keywords: Bilastine; Methanol; Acetic acid; UV Spectrophotometry

1. Introduction

Bilastine is an antihistamine that is used to relieve the symptoms of allergic rhino conjunctivitis (sneezing, itchy nose, nasal secretion, nasal congestion and red, streaming eyes) and other forms of allergic rhinitis. It can also be used to treat itchy skin rashes (wheals or urticaria). It is a second-generation antihistamine and takes effect by selectively inhibiting the histamine H_1 receptor, preventing these allergic reactions. Bilastine has effectiveness similar to Cetirizine, Fexofenadine, and Desloratadine. Bilastine is most quickly absorbed with the absence of food, and reaches a mean peak plasma concentration of 220 ng/mL approximately 1 h after both single and multiple dosing. Absorption is reduced by a high-fat breakfast or fruit juice, and the estimated global oral bioavailability is approximately 60%. Bilastine has linear pharmacokinetics in the 2.5–220 mg dose range in healthy adult subjects without evidence of accumulation after 14 days of treatment. Bilastine, chemically,2-[4-(2-{4-[1-(2-Ethoxyethyl)-1H-benzimidazol-2-yl]-1-piperidinyl}ethyl)phenyl]-2-methylpropanoicacid.The molecular formula of Bilastine is $C_{28}H_{37}N_3O_3$ and its molecular weight is 463.622 g·mol^{-1}. Choice of solvent can shift peaks to shorter or longer λ depends on their nature of the interaction of the particular solvent with the environment of the chromophore in the excited state of the molecule. Solvents can affect the fine structure of absorption curves as well as the intensities and wavelengths of maxima. There are various methods are available for the estimation of Bilastine. Among these methods High performance liquid chromatography (HPLC), spectrophotometric methods and LC/MS reported for the quantification of Bilastine. The effect of solvents for the determination of Bilastine has not been reported .In the present study two UV spectrophotometric methods were developed for estimation of Bilastine in bulk and pharmaceutical formulations among these the sensitive one can be confirmed by calculating limit of detection (LOD)and limit of quantification (LOQ) as per ICH guidelines.

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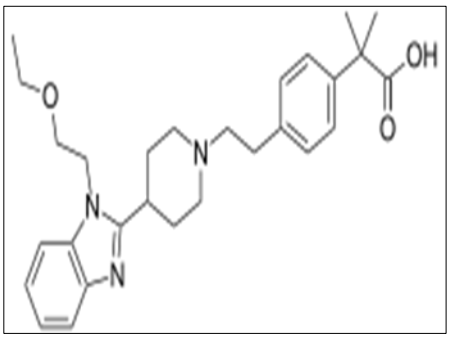

Figure 1 Structure of Bilastine

2. Material and methods

Absorbance measurements were made on double beam UV-Visible spectrophotometer with spectral band width of 0.5nm and wavelength accuracy of **±** 0.3nm with 10 mm matched quartz cuvettes (ELICO SL 244) were employed. Bilastine reference standard was gifted by Micro Molecules Pvt .Ltd, Hyderabad. Acetic acid used was of analytical grade purchased from National scientific Laboratories Vijayawada. Methanol –Govt supply.

2.1. Preparation of standard stock solutions of Bilastine

25mg of Bilastine pharmaceutical grade was accurately weighed two times separately and transferred into two different 25ml volumetric flasks and dissolved in Methanol, Acetic acid volume was made up to the mark with the same solvents the stock solution obtained was 1000ppm(1mg/ml).

2.2. Determination of λmax

The two different stock solutions were suitably diluted with Methanol and Acetic acid to get a concentration of10 ppm (10µg/ml) and scanned in the UV region ranges from 200nm-400nm. The wave length at which maximum absorbance observed was noted. The absorbance of the standard solutions containing the Methanol and Acetic acid were observed at 280nm and 271 nm respectively.

2.2.1. Beer's Lambert law

The two different stock solutions were suitably diluted to get concentration range from 5-30µg/ml and their absorbances were measured at λmax 280 nm against methanol as blank and λmax 271 nm against acetic acid as blank.. Calibration curve constructed for Bilastine different solvents by taking concentration (µg/ml)on x-axis and their absorbances on y-axis.

The proposed methods are validated for the following parameters

- Linearity

Linearity ranges of the proposed UV methods were found out. In order to find out the linearity range of proposed UV methods a curve was constructed by plotting absorbance obtained for the analyte against its concentrations in Methanol and Acetic acid. A series of 5(µg/ml), 10(µg/ml), 15(µg/ml), 20(µg/ml), 25(µg/ml), and 30(µg/ml) were prepared for standard calibration curve and absorbance were observed. The results were subjected to regression analysis by the least squares method to calculate slope (m),intercept(c) and regression coefficient (R^2).

- Precision

Precision of method was determined in terms of repeatability (within run precision), intermediate precision and reproducibility(between run precision).

- Repeatability

Repeatability of the method was determined by analyzing three samples of 10(µg/ml),15(µg/ml),20(µg/ml) concentration in two different solvents and the %RSD and SE were calculated.

2.3. Intermediate precision

2.3.1. Intraday precision

It was calculated by analyzing six test samples of Bilastine on the same day ,and the intra day precision of the method was determined by evaluating the samples of Bilastine on different days or and on two different spectrophotometers in the same laboratory.

2.3.2. Reproducibility

The sample solutions were prepared and analyzed in different labs.

2.3.3. Sensitivity

The sensitivity of the proposed UV method was measured interms of limit of detection (LOD)and limit of quantification (LOQ).The LOD and LOQ were calculated using formula:

$$LOD=3.3\sigma/s \& LOQ=10\sigma/s$$

Where
σ=standard deviation of Y-intercepts of regression lines.
S=slope of the calibration curve.

2.3.4. Sandell's sensitivity and Molar absorption coefficient

It is calculated by using the following formula

$$S=\epsilon. p$$

Where
S=sandell's sensitivity
ϵ=specific extinction coefficient
P=concentration of substance in mg/liter.

2.3.5. Robustness

To determine the robustness of the method, the experimental conditions were altered and assay was evaluated. Sample solutions were prepared and absorbance were observed at ± 5nm from absorption maxima.

2.3.6. Accuracy

Accuracy of the methods were confirmed by studying recovery at three different concentrations for 80, 100, 120% of these expected, in accordance with ICH guidelines by replicate analysis, Standard drug solutions were added to a pre-analyzed sample solution and %drug content was measured.

2.3.7. Analysis of tablet formulations

Twenty tablets from each brand were weighed and grained into a fine powder using a Pestle and Mortar. An amount of tablet powder equivalent to 25 mg of BLS was taken and dilutions were made with respective solvents, filtered using Whatmann No.42 filter. Analyze these solutions by using proposed UV methods.

2.3.8. Recovery study

To further ascertain the accuracy and reliability of the proposed methods, recovery experiments were performed via standard-addition procedure. Pre-analyzed tablet powder was spiked with pure BLS at three different levels and the total was found by the proposed methods. Each determination was repeated three times. The percent recovery of pure BLS added was within the permissible limits indicating the absence of inactive ingredients in the assay. These results are depictedin Table.No.6

3. Results and discussion

The wavelength maxima obtained for Bilastine in two different solvents were 280 nm in Methanol and in Acetic acid observed at 271 nm . The developed UV spectrophotometric methods followed beer's law in the range of 5-30µg/ml. The relative standard deviation values were observed less than '1' indicates precision of the method, the lower standard error value indicates the accuracy of the method. The molar extinction coefficient, sandell's sensitivity, and LOD & LOQ values were calculated as per ICH guide lines, the values are depicted in table No.5. Based on LOD and LOQ values, the solvents were ranked Methanol > Acetic acid. The study clearly revealed the sensitivity of the method improved in the presence of Methanol than in Acetic acid. Methanol was found to be more sensitive as it offered lowest LOD and LOQ values. LOD and LOQ values are subjected to statistically and data shown in Table.No:3&4. Significant differences were observed between the solvents used for the determination of drug. Lowest LOD and LOQ values were observed with the solvent i.e. Methanol. The LOD and LOQ values of Bilastine in Methanol and Acetic acid were subjected to t-test. The calculated 't value compared with t- table value, the observed value was greater than the table value indicated that the significant differences between the LOD and LOQ values of Bilastine in two different solvents.

Table 1 Linearity of Bilastine in Methanol

Sr.No.	Concentration(ppm)	Absorbance
1.	5	0.120
2.	10	0.259
3.	15	0.369
4.	20	0.494
5.	25	0.612
6.	30	0.728

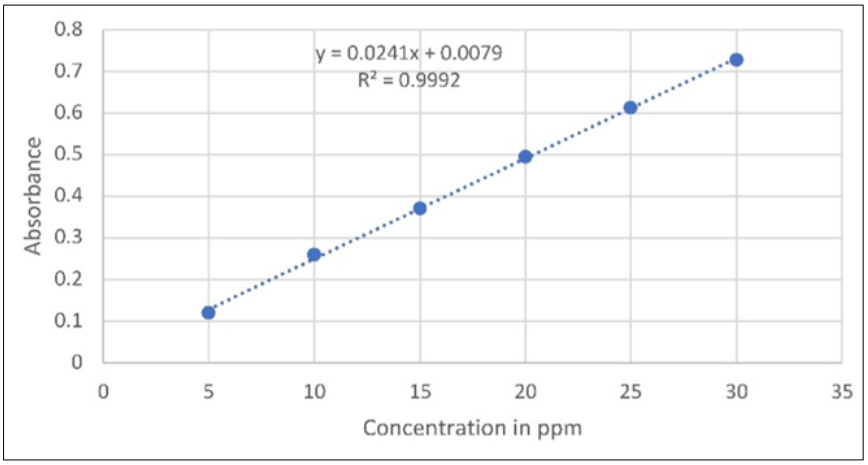

Figure 2 Calibration Curve of Bilastine in Methanol

Table 2 Linearity of Bilastine in Acetic acid

Sr.No.	Concentration(ppm)	Absorbance
1.	5	0.122
2.	10	0.245
3.	15	0.367
4.	20	0.491
5.	25	0.587
6.	30	0.718

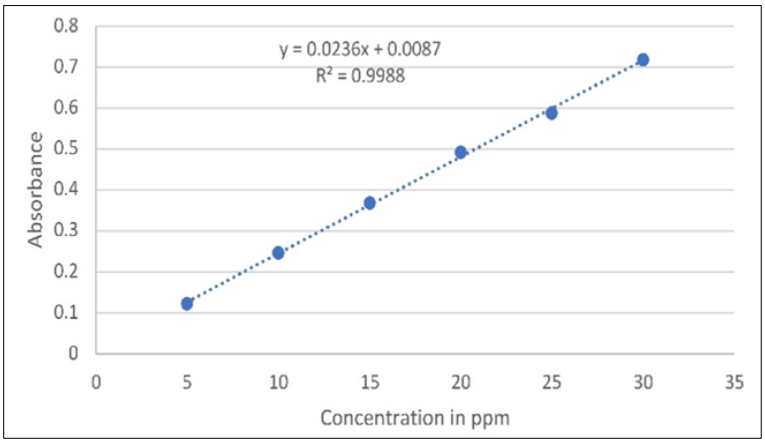

Figure 3 Calibration Curve of Bilastine in Acetic acid

Table 3 Limit of Detection (LOD)

S.No	Methanol. LOD±S.D(n=6)	Acetic acid LOD±S.D(n=6)	tCal	tTab	D.F
1.	$0.102\pm2.15X10^{-4}$	$0.136\pm3.27X10^{-4}$	4.78	2.228	10

D.F=Degrees of freedom, tCal-Calculated t value, tTab–t table value

Table 4 Limit of Quantification (LOQ)

S. No	Methanol, LOQ±S.D(n=6)	Acetic acid LOQ±S.D(n=6)	tCal	tTab	D.F
1.	$0.3097\pm4.01X10^{-4}$	$0.411\pm2.66X10^{-4}$	12.64	2.228	10

D.F=Degrees of freedom, tCal-Calculated t value, tTab–t table value

Table 5 Validation Parameters of Proposed UV methods

S.No	Parameters	Methanol	Acetic Acid
1.	λmax	280 nm	271 nm
2.	Range	5-30µg/ml	5-30µg/ml
3.	Regression equation	Y=0.0241X+0.0079	Y=0.0236X+0.0087
4.	Slope	0.0241	0.0236
5.	Intercept	0.0079	0.0087
6.	$A^{1\%}_{1cm}$	247	242
7.	R^2	0.9992	0.9988
8.	Molar absorption coefficient(litre/mole.cm-1)	1.142×10^4	$1,123X10^4$
9.	LOD	0.102µg/ml	0.136µg/ml
10.	LOQ	0.3097µg/ml	0.411µg/ml
11.	Sandell's sensitivity(µg/cm2/0.001absorbanceunit)	0.4424	0.4566

Table 6 Results of recovery study by standard addition method

Brad Name of Tablets	Methanol				Acetic acid			
	BLS in tablets (µg/ml)	Pure BLS added (µg/ml)	Total Found (µg/ml)	Pure BLS recovered percent ±S.D(n=3)	BLS in tablets (µg/ml)	Pure BLS added(µg/ml)	Total found (µg/ml)	Pure BLS recovered percent ±S.D(n=3)
Ubil-20	10	3	12.79	98.38± 1.23	10	3	12.77	98.23±1.33
	10	6	16.03	100.2±1.25	10	6	15.99	99.93±1.35
	10	9	18.84	99.2±1.16	10	9	19.09	100.5±0.81
Beltas-20	20	3	23.08	100.3±0.89	20	3	22.86	99.39±0.98
	20	6	25.98	99.92±0.96	20	6	26.11	100.4±0.89
	20	9	29.14	100.5±1.02	20	9	28.92	99.72±1.63

Mean value of three determinations, BLS: Bilastine, S.D: Standard deviation

4. Conclusion

The proposed methods were easy to perform and applicable for estimation of Bilastine in bulk and pharmaceutical formulations in Quality control laboratories.

Compliance with ethical standards

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Disclosure of conflict of interest

The authors declare that there are no conflicts of interest regarding the publication of this paper

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