INTERNATIONAL JOURNAL OF PHARMACY AND ANALYTICAL RESEARCH

IJPAR |Vol.10 | Issue 4 | Oct - Dec -2021
www.ijpar.com

ISSN: 2320-2831

Research article Open Access

Stability indicating stress degradation studies for bilastine

M.Sarbudeen [1], Dr.K.Padmalatha [2]

[1]*Research scholar, Krishna University, Machilipatnam, Andhrapradesh, India.*
[2]*Professor & Principal, Vijaya Institute of Pharmaceutical sciences, Vijayawada, Andhrapradesh, India.*

***Corresponding author: M. Sarbudeen**

ABSTRACT

Studies on forced degradation involve the breakdown of novel pharmacological substances. These investigations demonstrate the molecule's chemical stability, which makes it easier to prepare stable formulations with proper storage conditions. Since the chemistry of each substance differ, the experimental technique for carrying out forced degradation experiments will rely on the active components and formulation involved. It is generally advised to aim for degradation rate of 20% or less. According to ICH recommendations, some factors might cause degradation, such as UV light, oxidation, dry heat, acidic or basic conditions, Humidity, etc. The forced deterioration experiments are clearly illustrated by ICH Q1A, QIB, and Q2B. The mobile phase, which was Buffer (2.72 g Potassium dihydrogen orthophosphate dissolved in 1000 mL water adjust pH 2.40 with OPA) : Acetonitrile (600: 400) was delivered through the C-18 column in a gradient mode.

Keywords: HPLC, Stress degradation, ICH, Bilastine.

INTRODUCTION

The shelf life of pharmaceuticals can be determined with the use of stability tests of drug substances. Pharmaceutical stability testing takes a lot of money, time, and scientific knowledge to produce safe, high-quality, and effective drug formulations. Over stressing a molecule results in degradation profiles that are not indicative of actual storage circumstances. Some compounds may not degrade appreciably even after prolonged exposure to stressful situations, according to studies. Studies on degrading are significant for creating stability-indicating techniques that will be applied on clinical trials.

MATERIALS AND METHODS

Final Concentration of the Standard & Sample

Transfer 50 mg of BILASTINE WS, adequately weighed, into such a 100-ml volumetric flask. Mix after dissolving and dilution with methanol to make the volume. Stir mobile phase to the 5.0 ml of this solution from 100- ml VF to make 25.0 ml, mix well (100 mcg).

Sample Preparation

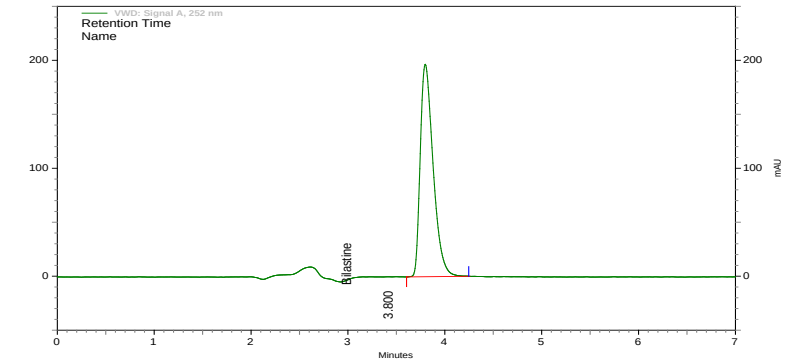
Precisely weigh 20 tablets, transfer a precisely weighed amount of tablets that have been finely powdered to meet 20 mg of Bilastine into a volumetric flask about 100 –ml and dilute with methanol. Filter through 0.45µ filter. Discard first few ml of filtrate and use the remaining solution. Further 10.0 ml of this solution to 20.0 ml with mobile phase and mix properly (100 **mcg).**

1. **Acid Stressed- (5ml of 2N Hcl stay for 30 min)**
   The powder equivalent of 100 mcg of bilastine was combined with 5 ml of 2 N HCl in a 100 ml volumetric flask for acidic stressed hydrolysis, and the mixture was let to stand for 30 minutes. Make up the volume up to mark with mobile phase.
2. **Base Stressed-(5ml of 2N NaOH stay for 30 min)**
   The powder equivalent of 100 mcg of bilastine was combined with 5 ml of 2N NaOH in a 100 ml volumetric flask for base induced hydrolysis and the mixture was

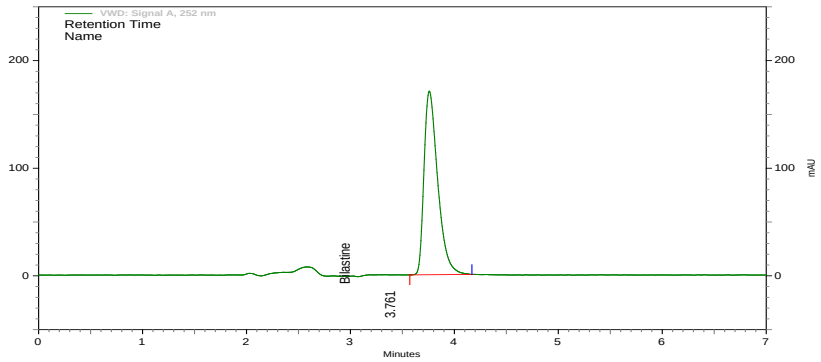
let to stand for 30 minutes. Make up the volume upto mark with mobile phase.

3. **Peroxide Stressed- (5ml of 2% H2O2 stay for 30 min)**
Bilastine powder equivalent to 100 mcg was combined with 5 ml of 2% H2O2 (v/v) in a 100 ml volumetric flask to execute oxidative degradation. The resulting solution was then sonicated for 30 minutes. The solution was diluted with mobile phase till the desired strength after oxidation.
4. **UV Stressed - (2 days)**
In order to conduct photo degradation testing, sample powder containing 100 mcg of bilastine was exposed to the sun light directly for two days. The photo-degraded sample was added to and thoroughly mixed in a 100 ml volumetric flask with mobile phase. The flask's capacity was adjusted using mobile phase with desire concentration.
5. **Thermal Stressed - (105ºC for 12 Hours)**
By placing sample powder containing 100 mcg of bilastine in an oven set at 105 °C for 12 hours, dry heating was accomplished. In a 100 ml volumetric flask, 30 ml of mobile phase was used to dissolve the treated material. The flask's contents were thoroughly combined and diluted with mobile phase to the appropriate level.
6. **Humidity Stressed -(75% RH for 12 hours)**
By placing sample powder containing 100 mcg of bilastine in humidity chamber at 75% RH for 12 hours. In a 100 ml volumetric flask, 30 ml of mobile phase was used to dissolve the treated material. The flask's contents were thoroughly combined and diluted with mobile phase to the appropriate level.

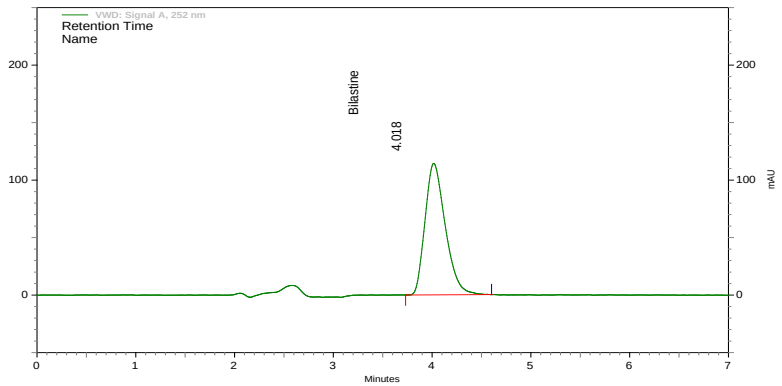
TABLE: 1



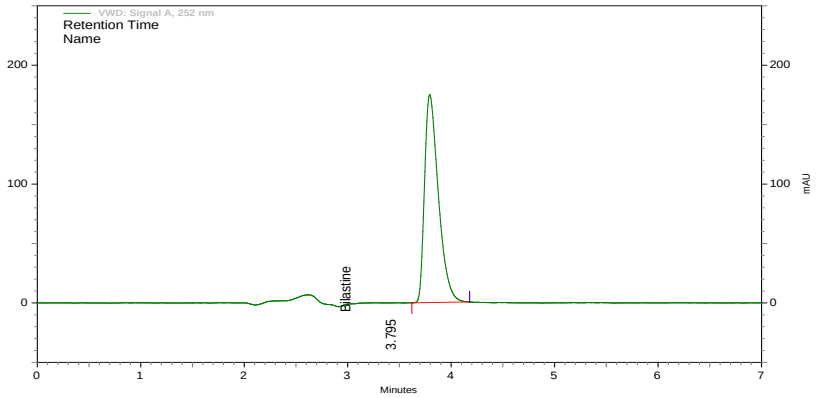
chromatogram:1- STD



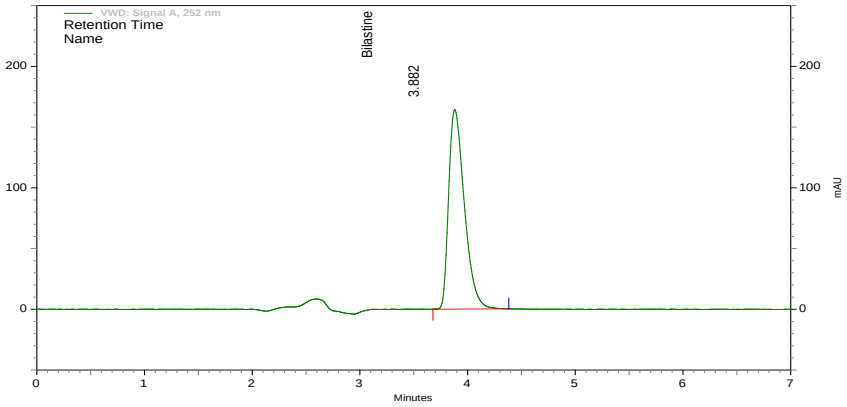
chromatogram: 2- Hcl stressed degradation



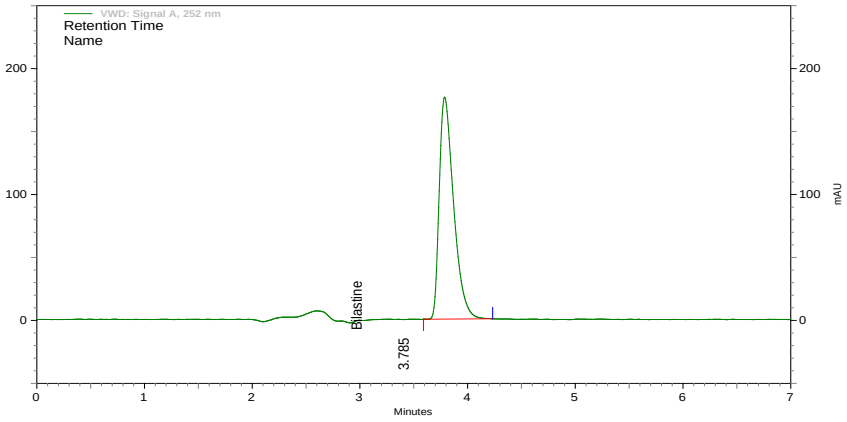
chromatogram:3- NaOH stressed degradation



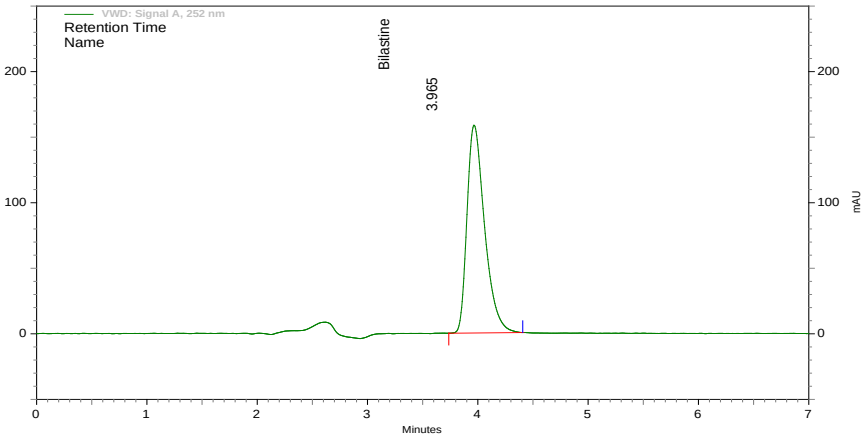
chromatogram:4- H_2O_2 stressed degradation



chromatogram:5- UV stressed degradation



chromatogram:6- Humidity stressed degradation



chromatogram:7- Temperature

RESULTS AND DISCUSSION

Table 1 : Studies On Stress Degradation And Evidence On Spectral Homogeneity

S.No	Category of stress condition	Peak response	Assay value	% Degradation of Bilastine	Interference
1.	Undegraded	27511822	100	0	**No interference of analyte peak**
2.	Acid	26220823	95.29	4.71	
3.	Base	26350177	95.64	4.36	
4.	Sunlight	25902544	94.12	5.88	
5.	Peroxide (oxidation)	27252237	99	1	
6.	Thermal	27486188	99.75	0.25	
7.	Humidity	27433643	99.67	0.33	

CONCLUSION

There was no impurity flag for bilastine for any stress degradation samples. The confirmation of peak purity shows that there is no interference from stress degradants, making it possible to accurately quantify bilastine drugs.The stress degradation test was carried out to ensure that bilastine could be isolated from the degradation products produced by the stress degradation study. The samples chromatograms following the forced degradation technique are displayed in above. The peak areas responses of the samples subjected to all deterioration conditions exhibited notable modification. No other peaks beyond bilastine were seen in any of the degradation circumstances. The proposed method can be regarded as successful. The whole data for degradation investigation studies given in table .1.

ACKNOWLEDGEMENT

Thankful to Vice chancellor and research director and Heads & faculty members from department of Chemistry and Pharmacy, Krishna University, Machilipatnam, Andhrapradesh**,** provided support for the authors to conduct their research work, for which they are grateful. Finally, the authors thank Spectrum Labs in Hyderabad, for providing research facilities and equipments.

REFERENCES

1. Terzc J, Popovic I. Application of Analytical Quality by Design concept for bilastine and its degradation impurities determination by hydrophilic interaction liquid chromatographic method. J Pharm Biomed Anal. 2016;5(125):385-93.
2. RambabuKatta, Murty N. Stability indicating method development and validation for the determination of bilastine and its impurities by UPLC method. Int J Pharm Sci Res. 2020;11(3):1312-21.
3. Analytical procedures and methods validation, chemistry, manufacturing and controls documentation. Fed Regist. 2000;65(169):52776-7.
4. Michael E, Schartz IS, Krull. Analytical method development and Validation. Lond John Wiley Sons. 2004:25-46.
5. Sharma P, Dr. Shiv Kumar Gupta, & Mr. Nishant Kumar. Method development and validation of bilastine by HPLC. Int J Adv Sci Technol. 2020;29(7):13751-8.
6. ICH guidelines Q1A. Vol. R2. Rockville: Stability of New Drug Substances and Products; 2003. p. 1-22.