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Original Article

Force degradation study of butenafine hydrochloride in bulk and cream formulation

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ABSTRACT

Simple specific, accurate and precise UV-Spectrophotometric method is developed for Butenafine hydrochloride in bulk and cream formulation. The method has been validated for the linearity, accuracy, precision, robustness and ruggedness as per ICH guideline. The solvent used was methanol and the λ max or the absorption maxima of the drug was found to be 252 nm. The linearity for butenafine hydrochloride was found to be in the range of 10-60 µg/ml with the regression coefficient of 0.999. Stability of butenafine hydrochloride was carried out by force degradation study. The stress degradation studies showed that Butenafine hydrochloride undergoes degradation in acidic, alkaline, dry heat, oxidation and photolytic conditions. This method can be used for the determination of Butenafine hydrochloride in quality control of formulation without interference of the excipients. All the above factors lead to the conclusion that the proposed method is accurate, precise, simple, sensitive, robust and cost effective and can be applied successfully for the estimation of butenafine hydrochloride in bulk and pharmaceutical formulation. The proposed method is also useful for determination of butenafine hydrochloride stability in sample of pharmaceutical dosage forms.

Key Words: UV Spectrophotometry, Butenafine, Force Degradation

INTRODUCTION

Butenafine is chemically [(4-tert-butylphenyl) methyl] (methyl) (napthalene-l- yl methyl) amine **[1].** Butenafine is used for topical treatment as an antifungal treatment of athlet's foot (TinePedis), ringworm (Tinea corporis), and jock itch (Tinea cruris). **Fig.1** Shows the structure of butenafine HCL [2,3] Like the allylamine antifungals, butenafine works by inhibiting the synthesis of ergosterol by inhibiting squalene epoxidase, an enzyme responsible for the creation of sterols needed in fungal cell membranes. Lacking ergosterol, the cell membranes increase in permeability, allowing their contents to leak out. Literature survey reveals that simple UV method, HPLC [5, 6] method has been reported for determination of butenafine in bulk and dosage forms. Literature servey also indicates that no Stability indicating UV spectrophotometric method has been reported for Butenafine in bulk Pharmaceutical Formulation. The aim of this work is to develope and validate an analytical method by using UV-VIS spectrophotometry for the estimation of Butenafine in bulk and pharmaceutical dosage forms and also perform stress degradation studies on the drug as per ICH Guidelines using the developed method [9,10].

EXPERIMENTAL

Material and method: Butenafine hydrochloride was kindly gifted by Glenmark Pvt.Ltd. Nashik. Methanol (AR grade) solvent was purchased from Finar chemicals Ltd. The commercial cream formulation FINTOP cream was purchased from local market. Instrument used UV-Visible Spectrophotometer 1800 (Schzimadzu)

Experimental Work:
Preparation of stock solution: [8,9] Standard Stock solution of butenafine hydrochloride was prepared by dissolving 10 mg of sample into 50 ml of methanol was added to the volumetric flak. Finally, volume was adjusted up to the mark with methanol to get 100µg/ml. Solution of 100µg/ml was scanned in the wavelength range of 200-400 nm. λ max of butenafine 252nm. **Fig.2.** The Linearity was obtained in the concentration range of 10-60 µg/ml. **Fig.3**

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Analysis of marketed formulation: A quantity of cream equivalent to (10 mg) of butenafine Hydrochloride was taken and dissolved in 50 ml methanol. The solution was ultrasonicate for 20 min. The volume was made up to the 100 ml, then filtered through whatsman filter paper. The final solution has conc.10 µg/ml of Butenafine Hydrochloride. The developed method was validated for limit of detection (LOD), limit of quantitation (LOQ) precision (Intraday and Interday), recovery (80%.100%.120%), specificity, robustness, ruggedness as per the guidance provided by ICH guideline. [1]

Method Validation: [7, 8, 9]

Validation is a process of establishing documented evidences a high degree of assurance that specific activity will constantly produce a desire result or product meeting its predetermine specifications and quality characteristics. The method was validated for different parameters such as,

***Linearity*:** Various stock solutions were prepared from the 100µg/ml in the concentration range 10-60µg/ml and scanned by UV- Spectrophometer and linearity range found to be in 10-60µg/ml.

Accuracy: **A**ccuracy is calculating the percent recovery and it carried out at three different concentrations as 80%, 100% and 120% in which amount of marketed formulation is kept constant 10 µg/ml and amount of pure drug added is varied to 80%,100%,120% and accuracy was indicated by % recovery.

Precision: Method was demonstrated by intraday and interday studies. In intraday study six different solutions of same concentration is analyzed three times in a day by taking its absorbance. The result was indicated by % RSD. In interday different solutions of six different concentrations were analyzed for three consecutive days by taking its absorbance. The result was indicated by % RSD.

Specificity: Specificity was carried out by spiking butenafine different exipients at the different concentrations and results were noted by taking its absorbance.

***Robustness*:** Robustness was carried out by two different wavelengths (± 2nm) i.e.250 nm and 254nm.The respective absorbance is noted and result was noted in % RSD.

Ruggedness: Ruggedness was carried by two different analysts. Respective absorbance is noted and result is noted in % R.S.D.

Stress Degradation Study [7, 8, 9]

The stress degradation studies of the Butenafine hydrochloride carried out at acidic, alkaline, oxidation, dry heat and photolytic condition. For acidic and alkaline degradation study 1ml 0.1 N HCL and 0.1 N NaOH added in to 1ml of stock (100 µg/ml) and make-up the volume 10ml with solvent while oxidative degradation carried out by adding 6%H_2O_2.For dry heat sample is kept in oven at 55^0c for 2 hrs and for photolytic study sample solution is kept in sunlight for 2hrs.

***Acidic and Alkaline Degradation*:** For acidic and alkaline degradation study 1ml 0.1 N HCL and 0.1 N NaOH added in to 1ml of stock (100 µg/ml) and make-up the volume 10ml with solvent. This dilution kept for 60 minutes and absorbance was measured and percentage of degradation was calculated.

***Oxidative degradation*:** Oxidative degradation carried out by adding 1 ml of 6% H_2O_2 in to 1 ml of stock solution and kept for 60 minutes. Absorbance was measured and percent purity calculated.

***Dry Heat degradation*:** For thermal degradation specified amount of sample was kept in oven at 55^0c for 2 hrs then 1 ml stoke solution diluted up to the 10 ml. Absorbance was measured and percent purity was calculated.

***Photolytic Study*:** For photolytic study sample solution is kept in sunlight for 2hrs. Absorbance was measured and percent purity was calculated. Summary of stress degradation study given in **Table 2**

RESULT AND DISCUSSION

The developed method found to be precise. The linearity was found to in the range 10-60 (µg/ml) with correlation coefficient values 0.999. The value of correlation coefficient greater than 0.999 indicate good linearity response in the above mentioned range. The LOD 1.236 & LOQ 3.106 for BTF. Accuracy of the method was determined by recovery study, carried out at 80, 100, 120 % level and % recovery for BTF was found to be 0.998-1.256. The percent recovery obtained indicates non-interference from the excipients used in the formulation. The proposed method was applied for pharmaceutical formulation and % label claim for BTF was found to be 99.56 %. The amount of drug estimated by proposed method was in good agreement with the label claim. The method was found to be precise as indicated by the inter-day, intra-day and repeatability analysis, robustness and ruggedness study; low % RSD less than 2. The % RSD values less than 2 indicative of accuracy of the method. Stability of BFT was determined by forced degradation study. The sample degraded with acid, base, hydrogen

peroxide, dry heat and light. Degradation was observed in acid, alkali, hydrogen peroxide, dry heat and photo light which indicates the drug is not stable at above conditions. Summary of results of force degradation study of Butenafine are shown in the **(Table 2)** .

CONCLUSION

The proposed method is accurate, precise, simple, sensitive, robust and cost effective and can be applied successfully for the estimation of Butenafine in bulk and pharmaceutical formulation. The proposed method is also useful for determination of butenafine stability in sample of pharmaceutical dosage forms.

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Table1. Summary of Validation of Butenafine HCL

Parameter	UV-spectrophotometry
Wavelength	252nm
Linearity Range	10-60
Reggration Equation	Y=0.012×-0.113
Slope (m)	0.012
Y intercept(c)	0.113
Correlation Coefficient (r^2)	0.999
%Recovery(n=3)	101.1
LOD (µg/ml)	1.236
LOQ (µg/ml)	3.106
Precision(% R.S.D)	
Intra Day(n=6)	0.196
Inter Day(n=6)	0.188
Specificity(% R.S.D)	
Impurity-1 (n=3)	0.202
Impurity-2 (n=3)	0.226
Ruggedness(% R.S.D)	
Analyst1st(n=3)	0.968
Analyst2nd(n=3	0.689
Robustness(% R.S.D)	
Wavelength 1 (±2(n=3)	1.256
Wavelength 2 (±2) (n=3)	1.306

Table 2. Summary of force Degradation Study

Condition	Time	% Degradation
Acidic degradation(0.1N HCL)	60 minutes	96.10%
Alkaline degradation(0.1NNaOH)	60 minutes	74.89%
Photolytic degradation	2 hrs	7.92%
Oxidative degradation (6% H_2O_2)	60 minutes	88.06%
Thermal degradation	2 hrs	14.20%

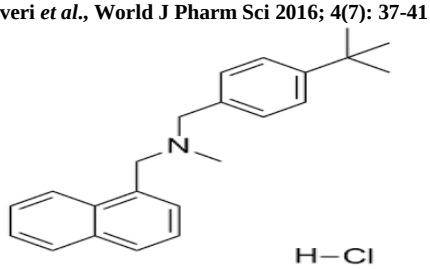

Fig.1 Structure of Butenafine HCL.

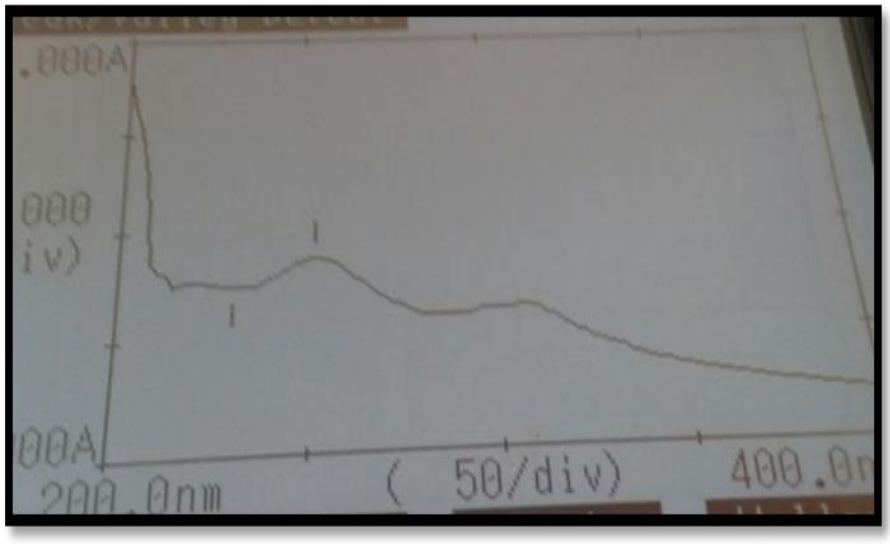

Fig.2: UV- Spectrum of Butenafine Hydrochloride at 252nm. (100 µg/ml)

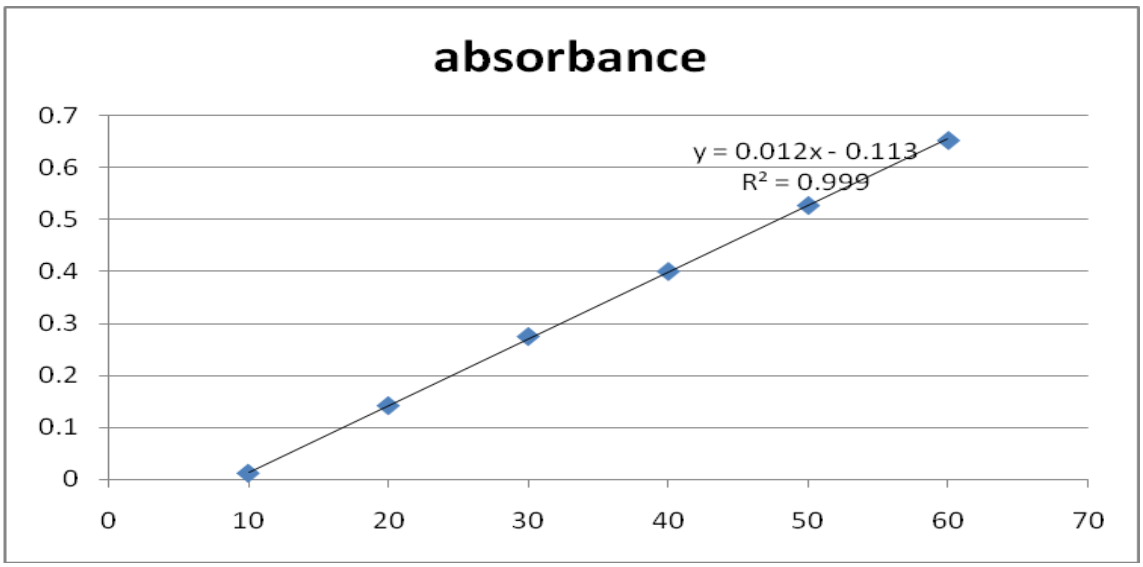

Fig.3 Linearity of Butenafine HCL

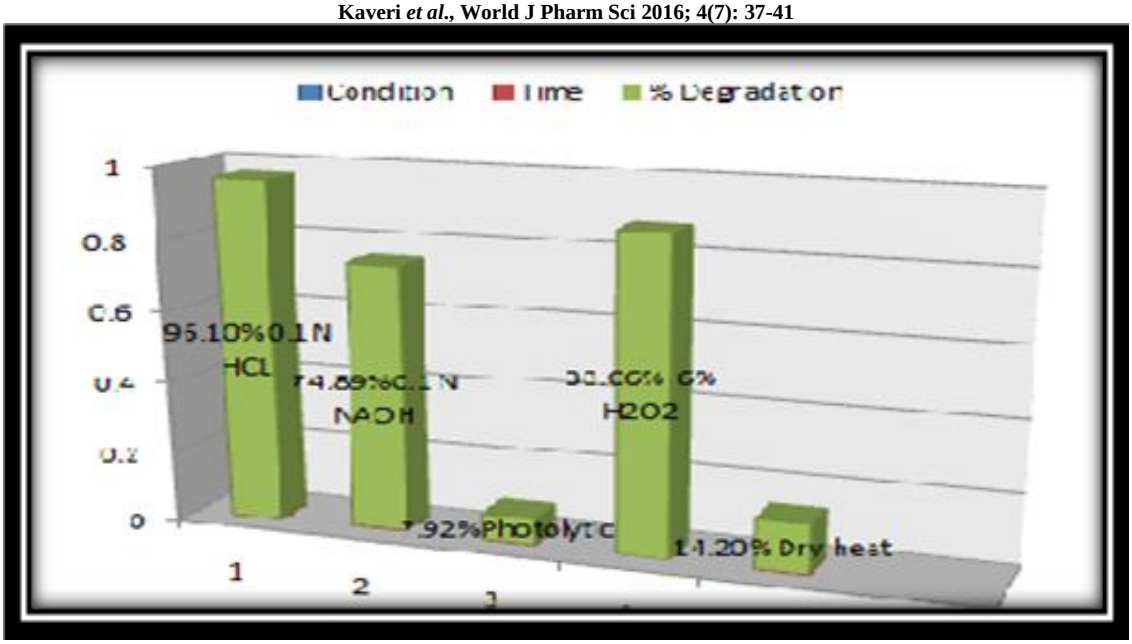

Fig.4. Force Degradation Study

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