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DEVELOPMENT AND VALIDATION OF STABILITY INDICATING UV SPECTROPHOTOMETRIC METHOD FOR THE ESTIMATION OF BENZYDAMINE HYDROCHLORIDE IN BULK AND IN PHARMACEUTICAL DOSAGE FORM: A NOVEL ANALYTICAL TECHNIQUE FOR CONDUCTING *IN-VITRO* QUALITY CONTROL TESTS

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Benzydamine Hydrochloride,
Correlation coefficient (r^2), UV
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ABSTRACT: The objective of the present study is to develop and validate a novel stability indicating UV spectrophotometric method for estimation of Benzydamine Hydrochloride (BNZ) in pharmaceutical dosage form as not a single UV spectrophotometric method has been reported for the estimation of Benzydamine Hydrochloride, which makes the present work novel. In the present research work, UV spectrophotometric determination was carried out at an absorption maximum of 305.6 nm in pH 6.8 phosphate buffer. The proposed method was validated statistically for linearity, accuracy, precision, repeatability, ruggedness, sensitivity as per International Conference on Harmonization guidelines. The drug substance was exposed to acid hydrolysis, alkaline hydrolysis, oxidative degradation, photolytic degradation, and thermal degradation and the stressed samples were analyzed by the proposed method to demonstrate the specificity of the method. The application of developed method was established by performing the assay of pharmaceutical formulation. The proposed method obeyed Beer Lambert's law in the concentration range of 5 - 50 $\mu\text{g ml}^{-1}$ with correlation coefficient (r^2) of 0.999. Percentage relative standard deviation associated with all the validation parameters were $\leq 2\%$. There were no significant changes in absorbance after performing the forced degradation studies and the % drug recovery was found to be 98.53% and 98.53% for film and gel respectively. The proposed method was found to be novel, simple, rapid, precise, selective, reproducible economical and stability indicating can be successfully applied to the determination of Benzydamine Hydrochloride in bulk and in pharmaceutical dosage form.

INTRODUCTION: Benzydamine Hydrochloride (BNZ) is a tertiary amine indazole derivative having IUPAC Name *i.e.* 3- (1-benzylindazol-3-yl)oxy) propyldimethylamine hydrochloride. It is available as Benzydamine cream, Benzydamine Gel, Benzydamine Mouthwash, Benzydamine or omucosal spray.

It is an official drug in British Pharmacopoeia¹. It is a unique non-steroidal anti-inflammatory drug (NSAID) with local anaesthetic and analgesic properties. It provides beneficial effects after both topical and systemic administration.

By acting locally it inhibits the release as well as the response of inflammatory mediators *i.e.* mainly thromboxanes². The action of Benzydamine is believed to be mediated by the prostaglandin system. The drug may affect formation of thromboxanes and alter the rate of prostaglandin produced, inhibiting platelet aggregation and stabilizing cell membranes.

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The primary site of metabolism is the liver; derivatives and free Benzydamine are excreted by the kidney and in the bile³. The Empirical Formula of Benzydamine Hydrochloride is C₁₉H₂₃N₃O.HCl. Physically it is a white crystalline powder with a molecular weight of 345.9. It is very soluble in water; freely soluble in ethanol (96%); practically insoluble in ether⁴. The structure is given in Fig. 1.

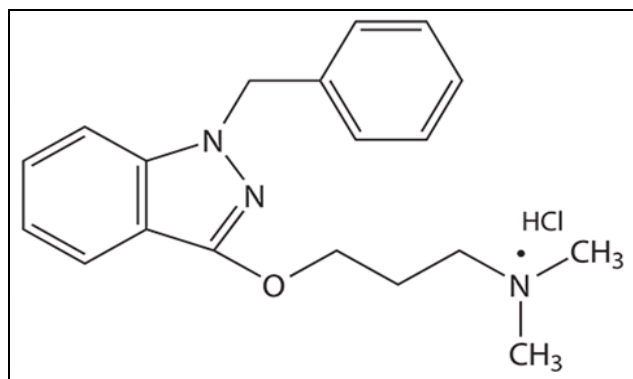


FIG. 1: CHEMICAL STRUCTURE OF BENZYDAMINE HYDROCHLORIDE

Literature survey revealed that very few analytical methods have been reported on Benzydamine Hydrochloride. Benson HAE *et al.*, described a RP-HPLC method for determination of Benzydamine Hydrochloride in topical pharmaceutical preparation⁵. Wang J *et al.*, studied the photo-degradation of Benzydamine in pharmaceutical formulations by HPLC with diode array detection². Carlucci G *et al.*, performed the HPLC for the determination of 1-Benzyl-1H-indazol-3-ol in Benzydamine in pharmaceutical formulations⁶.

Li *et al.*, developed an ion-selective piezoelectric sensor method for the determination of Benzydamine in serum and urine⁷. De Jesus *et al.*, reported an amperometric biosensor method for Benzydamine determination in pharmaceuticals⁸. Carlucci G *et al.*, described a RP-HPLC method for the determination of Benzydamine Hydrochloride and its impurities in oral collutory⁹. However, not a single UV - Spectrophotometric method has been reported for the estimation of Benzydamine Hydrochloride, which makes the present work novel.

Among the various methods available for the determination of drugs, spectrophotometry continues to be very popular, because of their simplicity, specificity and low cost. The UV spectrophotometric method has the various advantages

over RP-HPLC method *i.e.* the UV spectrophotometric method is cost effective as well as less time consuming method than RP-HPLC method. The present study describes a novel, rapid, simple, precise, selective, reproducible, economical and stability indicating UV spectrophotometric method for the determination of Benzydamine Hydrochloride in bulk and pharmaceutical formulations.

MATERIALS AND METHODS:

Apparatus: A double beam UV Spectrophotometer (Systronics), model UV-2201 (India) with a spectral bandwidth of 1nm, wavelength accuracy of ± 0.5 nm and a pair of 1 cm quartz cells were used to measure absorbance of the resulting solutions.

Chemicals and Reagents: The Benzydamine Hydrochloride was obtained as a gift sample from Harika Drugs Pvt. Ltd., Telangana, India. Other chemicals used were HPMC K100M (Colorcon Asia Pvt. Ltd. Goa), potassium dihydrogen phosphate, sodium hydroxide *etc.* All other chemicals or reagents used were of analytical grade. Double distilled water was used throughout the experiment.

Selection and Preparation of Common Solvent:

The phosphate buffer (pH 6.8) was selected as common solvent. The selection of common solvent was based on the good solubility of BNZ in this solvent. Place 125 ml of 0.2 M Potassium dihydrogen phosphate in a 500 ml volumetric flask, add the 56 ml of 0.2 M sodium hydroxide and then add water to volume to prepare phosphate buffer of pH 6.8.

- (a) **Preparation of 0.2 M Potassium Dihydrogen Phosphate Solution:** 27.218 g of potassium dihydrogen phosphate was dissolved in double distilled water and was diluted double distilled with water to 1000 ml.
- (b) **Preparation of 0.2 M Sodium Hydroxide:** 8 g of NaOH was dissolved in double distilled water and was diluted with double distilled water up to 1000 ml¹⁰.

Preparation of Standard Stock Solution and Working Solution: 100 mg of BNZ was weighed accurately and transferred into a 100 ml volumetric

flask and dissolved in phosphate buffer of pH 6.8. Then the solution was diluted up to the mark with phosphate buffer (pH 6.8) to obtain the solution having strength of $1000 \mu\text{g ml}^{-1}$ (Standard Stock Solution). 10 ml of this solution was taken into a 100 ml volumetric flask was diluted up to 100 ml to get the solution of $100 \mu\text{g ml}^{-1}$ concentration (working Solution) ¹¹.

Determination of Absorption Maxima (λ_{max}):

The absorbance of the working solution was scanned in the range of 200 - 400 nm on UV spectrophotometer ¹¹.

Validation of the Proposed Method: The method was validated in terms of linearity, accuracy, precision, repeatability, robustness, ruggedness, sensitivity and forced degradation study.

Linearity: Different aliquots of BNZ in the range 0.5-5 ml of working solution ($100 \mu\text{g ml}^{-1}$) were transferred into series of 10 ml volumetric flasks, and the volume was made up to the mark with double distilled water to get concentrations 5, 10, 15, 20, 25, 30, 35, 40, 45 and $50 \mu\text{g ml}^{-1}$, respectively. The solutions were scanned on a spectrophotometer in the UV range 200 - 400 nm. The spectrum was recorded at 305.6 nm. The calibration plot was constructed as concentration vs. absorbance ¹¹.

Accuracy (Percentage Recovery): Accuracy is the percentage of analyte recovered by assay from known added amount. Solutions were prepared in triplicate at levels of 50%, 100% and 150% of $20 \mu\text{g ml}^{-1}$ test concentration of the sample solution using working Standard solution as per the test method and taken absorbance of each solution in triplicate ¹³.

Precision: Precision is the degree of repeatability of an analytical method under the normal operation conditions. The precision was determined with standard quality control samples prepared in triplicate at different concentration levels covering the entire linearity range. The precision of assay was determined by repeatability (intra-day), intermediate precision (inter-day) and reported as % RSD for a statistically significant number of replicate measurements. The intermediate precision was studied by comparing the assay on three

different days and the results were documented as standard deviation and % RSD ¹⁴.

Repeatability: Repeatability of the method was determined by analyzing six samples of same concentrations of drug ($20 \mu\text{g ml}^{-1}$). From the resulting absorbance the standard deviation and relative standard deviation were calculated ¹⁵.

Robustness: The robustness of an analytical method is the measure of its capacity to remain unaffected by small, but deliberate variations in method parameters and provides an indication of its reliability during normal usage. Robustness was tested by varying detection wavelength (± 2 nm) of optimized conditions from the standard detection wavelength (305.6 nm) ¹⁶.

Ruggedness: Ruggedness of the method was determined by analysing repeatedly for six times the standard solution having $30 \mu\text{g ml}^{-1}$ of BNZ by two different analysts using the same experimental and environmental conditions ¹⁷.

Sensitivity: Sensitivity of an instrument can analysed by determining the two parameters as follow:

- ✓ Limit of Detection (LOD)
- ✓ Limit of Quantification (LOQ)

The limit of detection (LOD) is the lowest amount of analyte in a sample that can be detected, but not necessarily quantified, under the stated experimental conditions. The Limit of Quantification (LOQ) is lowest amount of analyte in a sample which can be quantitatively determined. LOD and LOQ were calculated by using standard deviation (δ) and slope value (s) obtained from calibration curve.

Equations:

$$\text{LOD} = \frac{3.3 \delta}{s}$$

$$\text{LOQ} = \frac{10 \delta}{s}$$

The LOD and LOQ were based on the third approach and were calculated according to the $3.3 \sigma/S$ and $10\sigma/S$ criteria, respectively, where σ is the standard deviation of the y-intercepts of the regression lines and s is the slope of the calibration curve ¹⁸.

Forced Degradation Study (Stress Conditions):

A 2 ml of the standard stock solution ($1000 \mu\text{gml}^{-1}$) of BNZ was taken as four replicates in four different volumetric flasks of 100 ml and mixed with 10ml of following (1 - 3) solutions. Then, all the flasks were set aside for 1 hour at room temperature. Solution was diluted up to mark with double distilled water.

- 0.1N HCl for acid hydrolysis.
- 0.1N NaOH for alkaline hydrolysis.
- 5% H_2O_2 for oxidative degradation.
- For photolytic degradation, a solution of drug ($20 \mu\text{g ml}^{-1}$) was exposed to UV radiation of wavelength 254 nm and of 1.4 flux intensity for 24 hours in a UV chamber.
- For thermal degradation solid pure drug was kept in an oven at 100°C for 24 hours. After cooling to room temperature $20 \mu\text{g ml}^{-1}$ solution was prepared.
- Absorbance of all the solutions from acid hydrolysis, alkaline hydrolysis, oxidative degradation, photolytic degradation, and thermal degradation were measured at 305.6 nm against respective solvent as blank in each case¹⁹.

Preparation of Mucoadhesive film and gel formulation: HPMC K100M was used for the preparation of Mucoadhesive film ($1 \text{ cm}^2 \times 1 \text{ cm}^2$) and gel formulation. For the preparation of mucoadhesive film solvent casting method is used in which the polymer (1% w/v) first dissolved in distilled water followed by addition of plasticizer polyethylene glycol (50% w/v of polymer) on a magnetic stirrer. After that the calculated amount of drug was added in such a way that each film contains 3 mg of drug and stirred the solution for 6 hours.

Allowed the solution to stand overnight for 24 hours for removal of all bubbles in the solution. Then the resulting solution was poured into the petridish and allowed to dry at room temperature for 24 hours²⁰. For gel formulation, 1% w/w of HPMC K 100M was taken into 100 ml beaker and was allowed to wetting for 24 Hrs. After that the volume was made up to 100 ml using double distilled water. The polymer was dissolved completely using magnetic stirrer. Then BNZ and methyl paraben were added (0.15% w/w of both) in the above solution and was mixed well²¹.

Assay of BNZ in Mucoadhesive Film and Gel

Formulation: To determine the drug content uniformity three films containing (3 mg of drug) were taken in separate 100 ml volumetric flask. 100 ml of pH 6.8 phosphate buffer was added and continuously stirred for 24 hrs. The solutions were filtered and analyzed at 305.6 nm by UV Spectrophotometer. The average of drug contents of three films was taken as final reading²². 100 mg of prepared gel (equivalent to 1.5 mg of BNZ) was weighed accurately and it was dissolved in 100 ml of phosphate buffer of pH 6.8. The conical flask containing gel was shaken for 2 hrs on mechanical shaker in order to get complete solubility of BNZ. The resulting solution is filtered through whatmann filter paper, the BNZ content was analyzed spectrophotometrically at 305.6 nm using an UV spectrophotometer (Systronics, India). The measurement was carried out in triplicate and the average BNZ content in the topical gel was calculated²³.

RESULTS AND DISCUSSION:

Determination of Absorption Maxima (λ_{max}): The standard stock solution ($100 \mu\text{g ml}^{-1}$) of Benzydamine Hydrochloride showed absorbance maximum (λ_{max}) at 305.6 nm (**Fig. 2**), and this wavelength is selected for constructing the calibration plot as well as for further analysis of drug.

Linearity: The drug was found to be linear in the concentration range of $5 - 50 \mu\text{g ml}^{-1}$ (**Fig. 3**). The Correlation co-efficient (r^2) value was found to be 0.999. From the calibration curve as well as from overlap spectra (**Fig. 4**) of different concentration of BNZ shows that the drug obeys Beer's law limit within $5 - 50 \mu\text{g ml}^{-1}$ concentration range.

Accuracy (Percentage Recovery): The accuracy of the proposed method was calculated from the slope and Y-intercept of the calibration curve. The % age recovery for this method for all the three concentration levels ranged between 98.80% to 100.08% with mean % age RSD of 0.360. The mean value of % age accuracy study was found to be greater than 99.0% demonstrate the high accuracy of the proposed method. The recovery data for accuracy studies are given in **Table 1**.

Precision: The mean % RSD values for intra-day as well as for inter-day were found to be 0.411 and

0.371 as given in **Table 2**. The measured % RSD values were found to be within the acceptance limit of $\leq 2\%$ indicated good precision of the developed method.

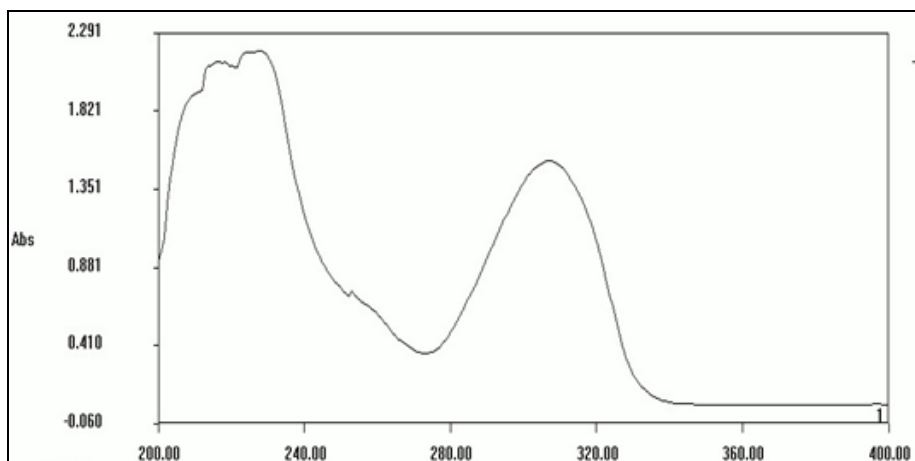


FIG. 2: UV SPECTRA OF BNZ IN PHOSPHATE BUFFER (pH 6.8)

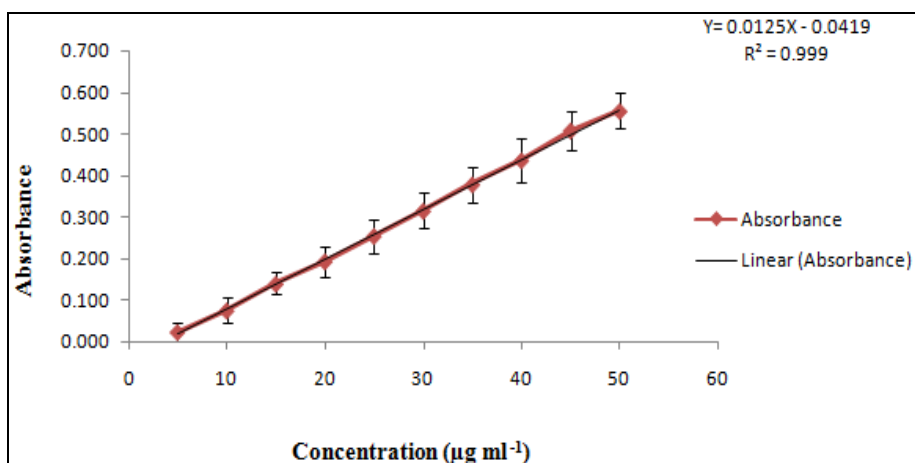


FIG. 3: CALIBRATION CURVE OF BNZ IN PHOSPHATE BUFFER (pH 6.8)

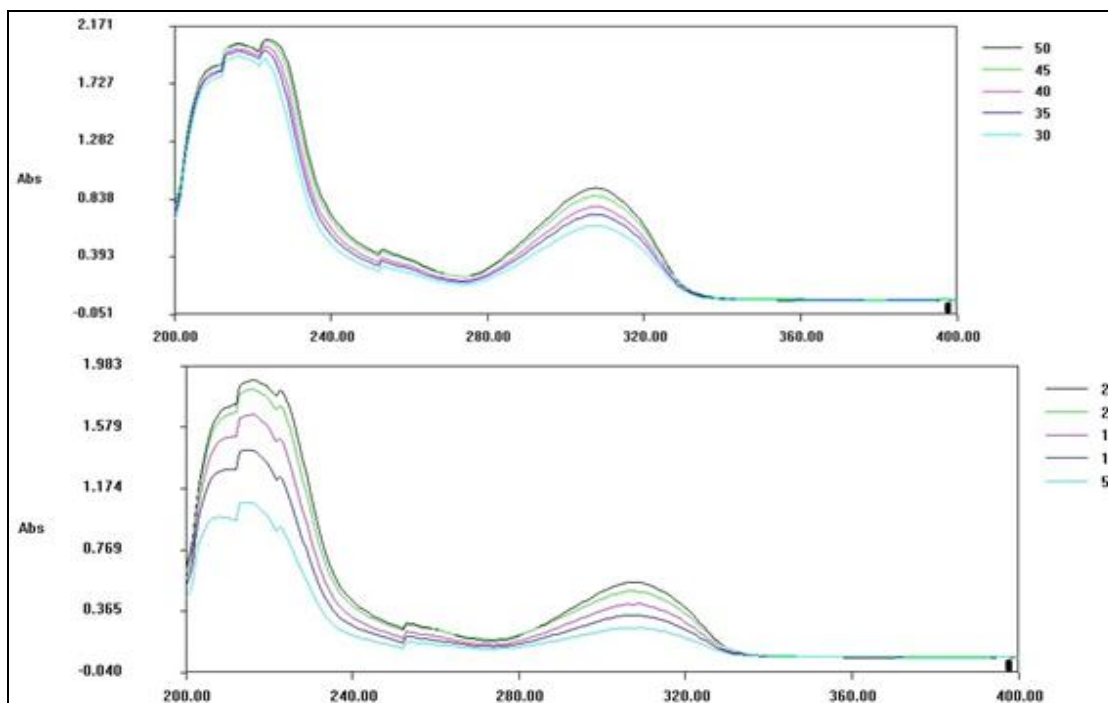


FIG. 4: OVERLAIN SPECTRA OF TEN DIFFERENT CONCENTRATIONS (5 - 50 µg ml⁻¹)

TABLE 1: RESULTS OF ACCURACY STUDIES OF BNZ

Recovery Level	Initial Conc. ($\mu\text{g ml}^{-1}$)	Conc. of standard drug added ($\mu\text{g ml}^{-1}$) (*n = 3)	Amount recovered ($\mu\text{g ml}^{-1}$) (*n = 3)	% age Recovery (*n = 3)	% RSD
50%	10	5	15.013	100.08	0.619
100%	10	10	19.983	99.91	0.200
150%	10	15	24.700	98.80	0.263
Mean				99.59	0.360

*Each value is the average of three determinations; RSD: Relative Standard deviation.

TABLE 2: INTRA-DAY PRECISION AND INTER-DAY PRECISION DATA FOR BNZ

Intra-day Precision			Inter-day Precision		
Conc. taken ($\mu\text{g ml}^{-1}$)	Mean Conc. found ($\mu\text{g ml}^{-1}$) \pm SD (*n = 3)	% RSD	Conc. taken ($\mu\text{g ml}^{-1}$)	Mean Conc. found ($\mu\text{g ml}^{-1}$) \pm SD (*n = 3)	% RSD
10	10.449 \pm 0.046	0.440	10	9.806 \pm 0.058	0.591
15	13.984 \pm 0.047	0.336	15	13.777 \pm 0.037	0.268
20	18.715 \pm 0.086	0.459	20	18.385 \pm 0.047	0.255
Mean		0.411			0.371

*Each value is the average of three determinations; SD: Standard deviation; RSD: Relative Standard deviation

Repeatability: The repeatability of the instrument was validated by taking the absorbance of six samples of the same concentration ($20 \mu\text{g ml}^{-1}$). The mean concentration found was $19.78 \mu\text{g ml}^{-1}$.

The SD and the % RSD were in the given limits ($\leq 2\%$) indicates that the proposed method is repeatable as shown in **Table 3**.

TABLE 3: RESULTS OF REPEATABILITY STUDIES

Conc. taken ($\mu\text{g ml}^{-1}$)	Conc. found ($\mu\text{g ml}^{-1}$)
20	19.95
20	19.85
20	19.75
20	19.75
20	19.65
20	19.75
Mean	19.78 \pm 0.103, % RSD = 0.521

SD: Standard deviation; RSD: Relative Standard deviation.

Robustness: Robustness studies assumed that the small variations in any of the variables did not significantly affect the results as given in **Table 4**.

This provided an indication for their liability of the proposed method during routine analysis.

TABLE 4: RESULTS OF ROBUSTNESS STUDIES

At 303.6 nm			At 307.6 nm		
Conc. ($\mu\text{g ml}^{-1}$)	Conc. found ($\mu\text{g ml}^{-1}$)	Statistical analysis	Conc. ($\mu\text{g ml}^{-1}$)	Conc. found ($\mu\text{g ml}^{-1}$)	Statistical analysis
30	30.24	Mean = 31.30 SD = 0.540 % RSD = 1.72	30	32.22	Mean = 32.42 SD = 0.228 % RSD = 0.703
30	31.53		30	32.12	
30	31.43		30	32.42	
30	31.43		30	32.42	
30	31.53		30	32.72	
30	31.63		30	32.62	

SD: Standard deviation; RSD: Relative Standard deviation.

Ruggedness: The results did not show any major statistical difference between operators suggesting

that method developed was rugged as given in **Table 5**.

TABLE 5: RESULTS OF RUGGEDNESS STUDIES

Analyst 1			Analyst 2		
Conc. ($\mu\text{g ml}^{-1}$)	Conc. found ($\mu\text{g ml}^{-1}$)	Statistical analysis	Conc. ($\mu\text{g ml}^{-1}$)	Conc. found ($\mu\text{g ml}^{-1}$)	Statistical analysis
30	32.92		30	32.22	

30	33.31	Mean = 33.72	30	32.12	Mean = 32.72
30	33.81		30	32.72	
30	34.00	SD = 0.400	30	32.82	SD = 0.116
30	33.51		30	32.82	
30	33.81	% RSD = 1.23	30	32.72	% RSD = 0.350

SD: Standard deviation; RSD: Relative Standard deviation.

Sensitivity: LOD and LOQ of the drug were calculated as per ICH guideline. LOD and LOQ values for BNZ were found to be $1.00 \mu\text{g ml}^{-1}$ and $3.04 \mu\text{g ml}^{-1}$ respectively.

Forced Degradation Study: From the result given in **Table 6**, it was found that there were no significant changes in absorbances after performing

acid hydrolysis, alkaline hydrolysis, photolytic degradation, and thermal degradation. But there is significant change in absorbance value after performing oxidative hydrolysis confirming that drug is susceptible to oxidative hydrolysis having % age degradation of 87.90 %.

TABLE 6: RESULTS FOR STABILITY OF DRUG UNDER FORCED DEGRADATION STUDY

Parameter studied	Concentration taken ($\mu\text{g ml}^{-1}$)	Concentration found ($\mu\text{g ml}^{-1}$)	% age Degradation	% age Recovery
Acid Hydrolysis	20	18.51	7.45	92.55
Alkaline Hydrolysis	20	18.73	6.35	93.65
Oxidative Degradation	20	2.42	87.90	12.10
Thermal Degradation	20	19.82	0.9	99.10
UV Degradation	20	19.89	0.55	99.45

*Each value is the average of three determinations.

Assay of BNZ in gel formulation: The validated UV spectrophotometric method was applied to the direct estimation of BNZ HCl in mucoadhesive film and gel formulation using calibration curve

method. From the absorbance value, the drug content was calculated. The results were found as shown in **Table 7**.

TABLE 7: RESULTS OF THE ASSAY OF PHARMACEUTICAL FORMULATION

Formulation	Amount Taken Equivalent to ($\mu\text{g ml}^{-1}$)	UV Spectrophotometric Method		
		Amount Recovered ($\mu\text{g ml}^{-1}$) \pm S. D.*	% Drug Recovered	% RSD
Mucoadhesive Films (3 mg of Drug)	30	29.65 \pm 0.018	98.83	0.061
Mucoadhesive Gel (0.15% w/w)	15	14.78 \pm 0.015	98.53	0.101

*Each value is the mean of three values; SD: Standard deviation; RSD: Relative Standard deviation.

All the validation parameters are summarized in **Table 8**, showed that proposed UV spectrophotometric method was found to be novel, rapid,

simple, precise, selective, reproducible and economical.

TABLE 8: SUMMARY OF ALL THE VALIDATION PARAMETERS

Validation Parameters	Result
Absorption maxima (λ_{max})	305.6 nm
Linearity Range	5 – 50 $\mu\text{g ml}^{-1}$
Standard Regression Equation	$Y = 0.0125X - 0.0419$
Slope (m)	0.0125
Intercept	0.0419
Correlation Co-efficient (r^2)	0.999
% Recovery (n = 3)	99.59 %
% RSD for Intra-day (n = 3) Precision	0.411
% RSD for Inter-day (n = 3) Precision	0.371
Repeatability (% RSD)	0.521
Robustness (% RSD)	At 303.6 nm
	At 307.6 nm
Ruggedness (% RSD)	Analyst 1
	1.72
	0.70
	1.23

	Analyst 2	0.35
LOD		1.00 $\mu\text{g ml}^{-1}$
LOQ		3.04 $\mu\text{g ml}^{-1}$
% Drug Recovered (Assay)	Film	98.83 %
	Gel	98.53 %

CONCLUSION: The developed UV spectrophotometric method was found to be novel, rapid, simple, precise, selective, reproducible and economical. The results reveal that the proposed UV spectrophotometric method can be successfully applied for the routine quality control analysis of Benzydamine Hydrochloride in bulk and in pharmaceutical dosage form and cost of analysis is less and do not require sophisticated instrumentation as compared to reported methods.

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CONFLICT OF INTEREST: The authors declare that there is no conflict of interests regarding the publication of this paper.

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