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# Application of area under curve technique for UV-spctrophotometric determination of benazepril in bulk and tablet formulation

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## ABSTRACT

Novel, accurate, precise and economical UV- spectrophometric method has been developed for estimation of Benazepril hydrochloride in bulk and tablets using area under curve (AUC) technique. The method is based on calculation of area under curve for analysis of Benazepril hydrochloride in the wavelength range of 228.40 - 252.20 nm. Methanol was used as solvent for preparation of standard and sample solutions. Calibration curves were plotted by using instrumental response at selected wavelength and concentrations of analyte in the solution. The drug obeyed Beer's law in the concentration range of 2 - 12 µg/mL. The proposed methodcan be used for routine analysis since it is rapid, simple, accurate and also sensitive. The results obtained are reproducible with a % relative standard deviation less than 2%. This method was validated for accuracy, precision, repeatability, sensitivity and ruggedness as per ICHguidelines.



## KEYWORDS

Benazepril hydrochloride;
UV- spectrophotometry;
Area under curve.

## INTRODUCTION

Benazepril hydrochloride (BZP), (3S)-3-[[(1S)-1-Carbethoxy-3-phenylpropyl]amino]-2,3,4,5-tetrahydro-2-oxo-1H-1-benzazepine-1-acetic acid, hydrochloride is an angiotensin-converting enzyme (ACE) inhibitor andused in the treatment of hypertension and heart failure[1].

Literature survey revealed several analytical methods such as GC-MS[2] HPLC[3,4], and UV – spectrophotometry[5,6] have been reported in bulk, pharmaceutical dosage form and in biological fluids for determination of BZP.

To our notice, so far no UV- spectrophotometric method using Area Under Curve(AUC) has been reported for the determination of BZP in bulk and tablets.

Hence an attempt has been made to develop new UV- spectrophotometry (AUC) method for estimation of BZP in bulk andpharmaceutical formulations with good accuracysimplicity, precision and economy.

## MATERIALS AND METHODS

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## Chemicals and reagents

Benazepril hydrochloride working standards were obtained as generous gifts from Wockhardt Pharm., Aurangabad, India. Methanol (A.R. Grade) was purchased from Merck Ltd., Worli, Mumbai, India. Tablets (BENACE) was purchased from local market, containing BZP 10 mg per tablet.

## Instrumentation

For proposed spectrophtometric method, UV-Visible spectrophotometer (Shimadzu 2450 with UV Probe 2.21 software) and a pair of 1 cm matched quartz cells were used.

## Preparation of standard and sample solutions

Stock solution of 100 µg/ml of BZP was prepared in methanol. The standard solutions were prepared by dilution of the stock solution with methanol in a concentration range of 2-12 µg/ml with methanol.

## Area under curve UV-spectrophotometric method

For the selection of analytical wavelength range, 6 µg/ml solution of BZP was prepared and scanned in the spectrum mode from 200 nm to 400 nm. From the spectrum of BZP, AUC in the wavelength range of 228.40 - 252.20 nm was selected for the analysis. The calibration curve was prepared in the concentration range of 2-12 µg/ml. Concentrations of sample solution were determined using calibration curve.

## Analysis of tablet formulation

For analysis of commercial formulation; twenty tablets were weighed, average weight calculated and crushed into fine powder. An accurately weighed quantity of powder equivalent to 10 mg of BZP was transferred into 100 mL volumetric flask containing 50 mL methanol, shaken manually for 10 min, volume was adjusted to mark with same solvent and filtered through Whatmann filter paper no. 41. An appropriate aliquot was transferred to 10 mL volumetric flask; volume was adjusted to the mark and used for estimation of BZP. The analysis was repeated for six times.

# RESULTS AND DISCUSSION

Benazepril hydrochlorides being soluble in methanol, the solutions were prepared in methanol. The solutions of different concentrations were prepared and scanned in UV range 200-400 nm. From the spectrum of BZP, AUC in the wavelength range of 228.40 - 252.20nm was selected for the analysis (Figure 1). The proposed method has been validated according to ICH guidelines[6].

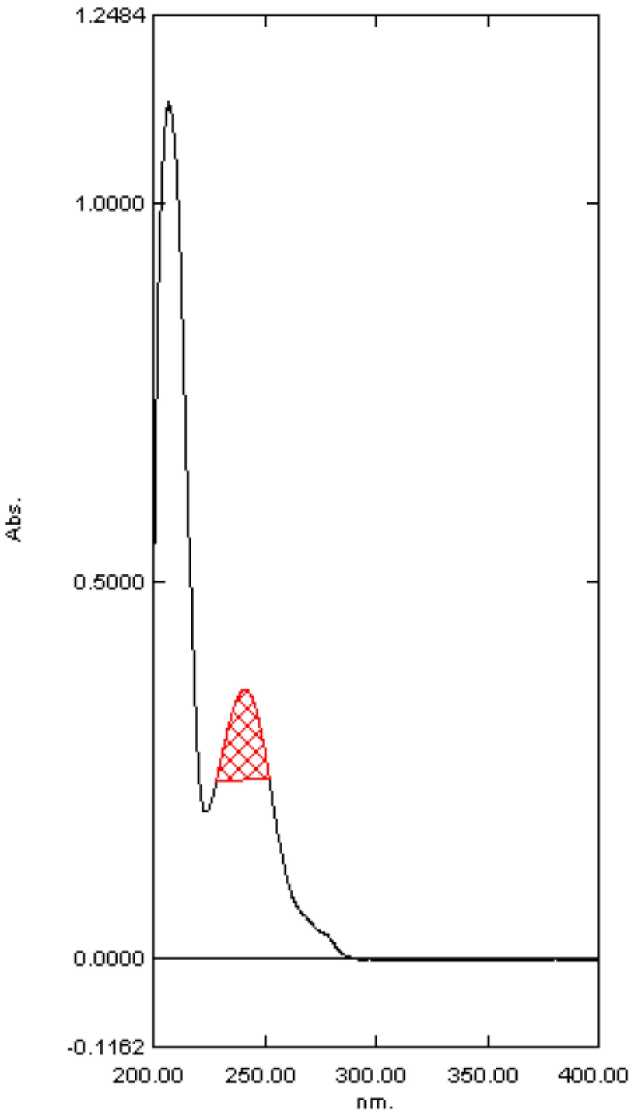


**Figure 1 : UV-Spectrum of BZP in methanol showing selection of wavelength for determination of BZP**

## Linearity

The linearity was evaluated by analyzing different concentrations of standard solution of BZP. The drug was found to be obeyed Beer- Lambert's law in the concentration range of 2-12 µg/ mL for method. Regression analysis was done for the slope, intercept and correlation coefficient values. The regression equation of calibration curve was Y = 0.181x +

0.048with $r^2$>0.99 TABLE 1.

**TABLE 1 : Optical characteristics and statistical data of the regression equations**

| Parameters | AUC method |
|---|---|
| Wavelength range | 228.40 - 252.20 nm |
| Linearity range | 2-12 µg/mL |
| Regression equation | Y = 0.181x + 0.048 |
| Intercept | 0.048 |
| Slope | 0.181 |
| Coefficient of correlation | $r^2$ = 0.998 |

## Method precision (Repeatability)

The precision of the methods was assessed by repeated scanning and measurement of the absorbance and thereby area under curve of solutions (n = 6) of BZP (4µg/ml) without changing the parameters for the method. The repeatability was expressed in terms of relative standard deviation (% RSD).

## Intermediate precision (Reproducibility)

The intra-day and inter-day precision of theproposed method was done by analyzing thecorresponding responses three times on the same dayand on three different days over a period of one weekfor three different concentrations of standard solutions of BZP (4, 6and 8µg/ml). The results were reported in termsof relative standard deviation (% RSD).Results are shown in TABLE 2

**TABLE 2 : Validation parameters**

| Parameters | BZP |
|---|---|
| Precision(%RSD) | |
| Inter-day [n = 3] | 0.48 - 1.24 |
| Intra-day [n = 3] | 0.62 - 1.08 |
| Repeatability [n = 6] | 0.94 |
| Ruggedness (%RSD) | |
| Analyst I [n = 6] | 1.57 |
| Analyst II [ n= 6] | 1.78 |
| % Recovery (n = 3) | 99.22 - 100.32 |
| %RSD | 0.42 -1.64 |

**n= number of estimations**

## Accuracy (% Recovery)

The accuracy of the method was performed bycalculating % recovery of BZP by thestandard addition method. Known amounts ofstandard solutions of BZP were added at 80, 100 and 120% levels to pre-quantified samplesolutions of BZP (4 µg/ml). At each levelof the amount three determinations were performed. The amount of BZP was estimated byapplying obtained values to regression equation.The results pointed that method is accurate.

## Sensitivity

The limit of detection (LOD) and limit of quantification (LOQ) were calculated by using the equations

LOD = 3 x σ / S and

LOQ = 10 x σ /S,

where σ is the standard deviation of intercept, S is the slope.

The LOD and LOQ of BZPwere found to be 0.19 µg and 0.58 µg,respectively.

## Ruggedness

Ruggedness of the developed method was determined by analysis of aliquots from homogenous slot by two analysts keeping same operational and environmental conditions.Results were interpreted by calculating the %RSD value and found to be within range.

Result of all validation parameters shown in TABLE 2

## Analysis of the marketed tablets

There was no interference from the excipients commonly present in the tablets. The percent drug content ± S.D. was found to be 99.60 ± 1.23 for developed area under the curve spectrophotometric method. The low % R.S.D. value indicated the suitability of this method for routine analysis of BZP in pharmaceutical dosage form. Results are shown in TABLE 3

**TABLE 3 : Analysis of tablets**

| Drug | Label claim (mg/tablet) | % amount found | %RSD |
|---|---|---|---|
| BZP | 10 | 99.60 ± 1.23 | 1.234 |

## CONCLUSION

The method that was developed for the determination of Benazepril hydrochloride is based on

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Area Under Curve technique. The method was validated and found to be simple, sensitive, accurate, and precise. Hence, it can be used successfully for routine analysis of pharmaceutical dosage forms of Benazepril hydrochloride.

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