



## Research Article

### ABSORPTION MAXIMA AND UV-SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF IVABRADINE HYDROCHLORIDE

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Article Received on: 02/08/18 Approved for publication: 20/09/18

DOI: 10.7897/2230-8407.099205

#### ABSTRACT

Ivabradine hydrochloride is a new drug approved recently by United State's Food and drug administration for treatment of chronic stable angina pectoris in coronary artery disease. As there is no reported simple UV spectrophotometric method for estimation of ivabradine hydrochloride, the aim of the present work was to develop simple, accurate and precise UV spectrophotometric method for estimation of ivabradine hydrochloride by absorption maxima method. pH 6.8 phosphate buffer was used as a solvent for ivabradine hydrochloride as it is freely soluble. 10 µg/ml solution of ivabradine hydrochloride was used as working standard solution. The solution was scanned in the wavelength range of 200-400 nm against the reagent blank to obtain the absorption maxima using UV-visible Spectrophotometer. Clear peak absorbance appeared at 286 nm was considered as absorption maxima,  $\lambda_{max}$ . Calibration curve was constructed at 286 nm for dilutions containing 10, 20, 30, 40 and 50 µg/ml of ivabradine hydrochloride. The curve was obtained with 'r' value of 0.9984 indicating positive correlation between concentrations of Ivabradine hydrochloride and the corresponding absorbance values. The method obeys Beer's law in the range of 10-60 µg/ml. Low values of standard deviation (0.11) and standard error (0.034) indicated precision and accuracy of the method respectively.

**Keywords:** Ivabradine hydrochloride, newly approved, UV method, absorption maxima method, Spectrophotometric.

#### INTRODUCTION

Ivabradine hydrochloride is a new drug approved by the United State Food and Drug Administration (USFDA) in april 2015 for treatment of chronic stable angina pectoris in coronary artery disease<sup>1,2</sup>. It blocks hyperpolarization-activated current through sodium channels present in SA node. Chemically it is 3-[3-((7S)-3,4-dimethoxybicyclo[4.2.0]octa-1,3,5-trien-7-yl)methyl)(methylamino)propyl]-7,8-dimethoxy-2,3,4,5-tetrahydro-1H-3-benzazepin-2-one. Recent research suggests that it targets mainly on reducing the heart rate by decreasing myocardial oxygen demand. Hence it is such that this drug had a wide scope of formulations to be developed for the effective treatment of chronic stable angina pectoris.

Literature revealed that, there is no reported UV method for its estimation till now. Hence present research work was aimed at development of accurate, precise UV-spectrophotometric method<sup>3,4</sup> for estimation of ivabradine hydrochloride.

#### MATERIALS AND METHODS

UV visible spectrophotometer, SHIMADZU, Electronic balance SHIMADZU, sonicator etc. Ivabradine hydrochloride is obtained as a gift sample from Mylan Laboratories Ltd., Hyderabad.

##### Spectroscopic Method<sup>5,6</sup>

##### Standard solution

Ivabradine hydrochloride, 100 mg was weighed accurately and transferred into the 100 mL standard flask. A small amount of pH

6.8 phosphate buffer was added to dissolve the drug. The volume was made up to 100 mL with buffer.

##### Working standard solution

From the above standard solution, 10µg/mL concentration was prepared by diluting with pH 6.8 phosphate buffer.

##### Scanning of absorption maxima

Working standard solution of 10 µg/ml of ivabradine hydrochloride was scanned in the wavelength range of 200-400 nm against the reagent blank to obtain the absorption maxima using UV-visible Spectrophotometer (Shimadzu). The scanning spectrum is shown in Fig. 1. Clear peak absorbance is appeared at 286 nm. Hence 286 nm was considered as absorption maxima,  $\lambda_{max}$  and the calibration curve to estimate ivabradine hydrochloride was constructed at 286 nm.

##### Construction of calibration curve

Standard solution of ivabradine hydrochloride was diluted with phosphate buffer to get dilutions containing 10, 20, 30, 40 and 50 µg/ml of ivabradine hydrochloride. The absorbencies of these diluted solutions were measured using at 286 nm against reagent blank. Each sample was estimated in triplicate, and the average values reported Table 1. The standard graph for estimation ivabradine hydrochloride was plotted and is shown in Fig. 2. The value of correlation coefficient (R) for the curve was calculated.

**Precision and accuracy of the method**

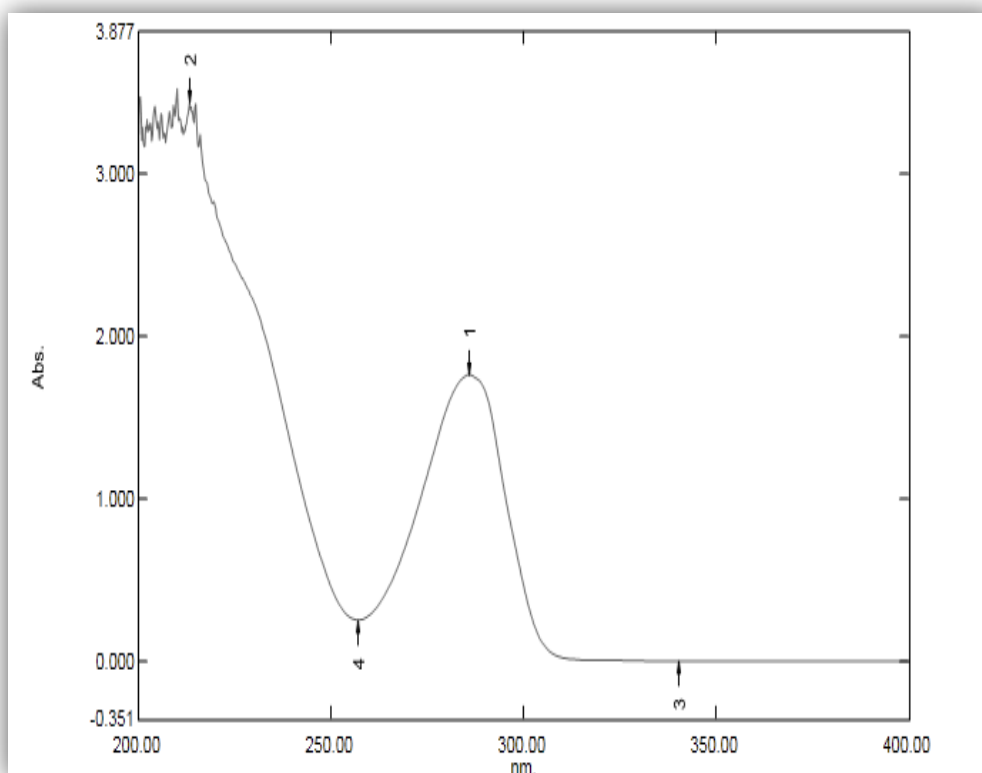
Precision is a measure of the agreement among the values obtained when the same solution is repeatedly assayed. While accuracy is the agreement between the estimated value and true value standard error and standard deviation (s.d.) are the measures of precision and accuracy respectively. Therefore, a dilution containing 50 µg of ivabradine hydrochloride was assayed repeatedly (n=10) by the proposed method and standard error and standard deviation (s.d.) of the results are calculated and are given in are given in Table 2.

**RESULTS AND DISCUSSION**

pH 6.8 phosphate buffer phosphate buffer was used as a solvent for ivabradine hydrochloride as it is freely soluble in it and it is an ideal simulated gastric fluid for its formulations of ivabradine hydrochloride.

The spectrum of 10 µg/ml of ivabradine hydrochloride shown in Fig. 1 indicated peak absorbance at 286 nm. Hence 286 nm was considered as absorption maxima, λ<sub>max</sub> for estimation of ivabradine hydrochloride.

Based on the results shown in the Table 1 and Fig. 2, it is such that, the calibration curve is obtained with 'r' value of 0.9984, which indicates a positive correlation between concentrations of ivabradine hydrochloride and the corresponding absorbance values. The method obeys Beer's law in the range of 10-60 µg/ml. Low values of standard deviation (0.11) and standard error (0.034) in Table 2 indicates precision and accuracy of the method respectively. Therefore, this method is suitable for estimation of ivabradine hydrochloride in various formulations and in *in-vitro* dissolution studies.



**Fig. 1: UV absorption spectrum of 10µg/ml of ivabradine hydrochloride**

**Table 1: Concentration Vs absorbance values of ivabradine hydrochloride**

Concentration(µg/ml)	Absorbance±SD
0	0
10	0.197±0.57
20	0.381±0.27
30	0.549±0.39
40	0.721±0.33
50	0.913±0.90

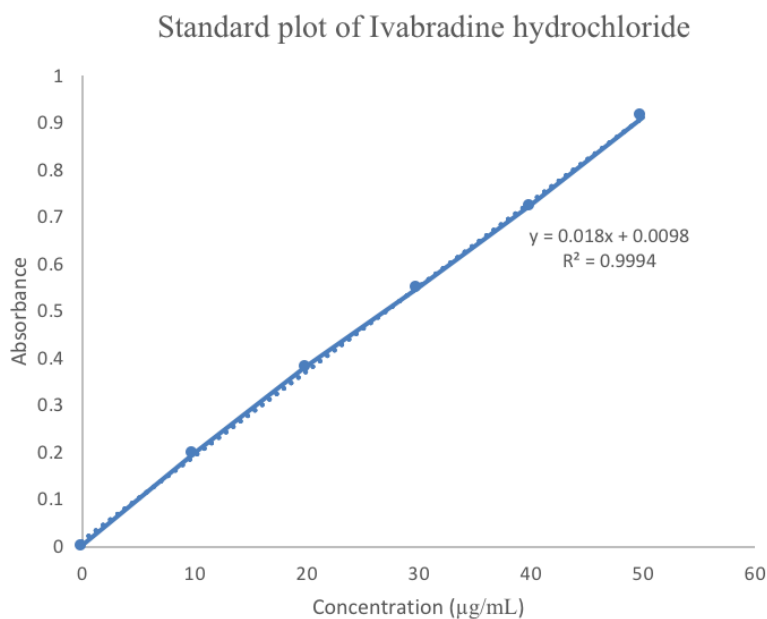


Fig. 2: Calibration curve for estimation of ivabradine hydrochloride

Table 2: Precision and accuracy data

True amount (µg)	Amount estimated (µg)	Mean (µg)	Standard deviation	Standard error
50	50.12, 50.1, 49.89, 49.95, 50.24, 49.87, 50, 49.97, 50.06, 49.94	50.014	0.11	0.034

## CONCLUSION

An absorption maximum for estimation of ivabradine hydrochloride by UV spectroscopic method is 286 nm. Calibration curve to estimate ivabradine hydrochloride has positive correlation with 'r' value of 0.9984 with Beer-Lambert's law obeyed in the concentration range of 10-60 µg/ml. Hence this method can be used for estimation of ivabradine hydrochloride.

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### Cite this article as:

Jeevana Jyothi B and Navya B. Absorption maxima and UV-spectrophotometric method for estimation of Ivabradine hydrochloride. *Int. Res. J. Pharm.* 2018;9(9):158-160 <http://dx.doi.org/10.7897/2230-8407.099205>

Source of support: Nil, Conflict of interest: None Declared

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