ejpmr, 2020,7(4), 604-607

SJIF Impact Factor 6.222

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Research Article

ISSN 2394-3211

EJPMR

A NOVEL METHOD DEVELOPMENT AND VALIDATION OF PANTOPRAZOLE IN PURE AND CAPSULE DOSAGE FORMS BY USING UV- SPECTROPHOTOMETRIC METHOD

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Article Received on 09/02/2020 **Article Revised on 29/02/2020** **Article Accepted on 20/03/2020**

ABSTACT

A Novel, simple, accurate, and precise Area under curve spectroscopic method was developed and validated for the estimation of Pantoprazole in Pure and Capsule dosage forms and has an absorption maximum between 288-298nm in 0.1N Sodium hydroxide. The stock solution was made to produce 1000 µg/ml with 0.1N Sodium hydroxide. The linearity was found in the concentration range of 3-18 µg/ml. The correlation coefficient was found to be 0.9999. The regression equation was found to be Y=0.031x+0.0025. The method was validated for linearity, accuracy, precision, limit of detection, limit of quantitation and ruggedness. The limit of detection and limit of quantitation for estimation of Pantoprazole was found to be 0.03632µg/ml and 0.3632µg/ml, respectively. Recovery of Pantoprazole was found to be in the range of 99.29% - 99.92%. The %RSD values were less than 2. The method has been validated according to ICH guidelines. The Proposed method was successfully applied for the quantitative determination of Pantoprazole in Capsule dosage forms.

KEYWORDS: Pantoprazole, Area under Curve Spectroscopy, 0.1N Sodium hydroxide, accuracy.

INTODUCTION

Pantoprazole is a Proton Pump inhibitors used in the treatment of ulcer. Pantoprazole is chemically described as, 5-(difluromethoxy)-2-[(3,4-dimethoxypyridin-2-yl)methylsulfinyl]-3H-benzoimadazole.

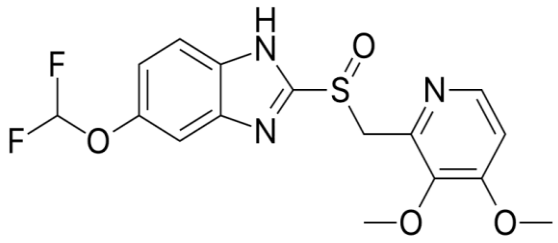

Figure 1: Chemical structure of Pantoprazole.

It has a molecular formula of $C_{16}H_{15}F_2N_3O_4S$and molecular weight of 383.371 g/mol. It has the structural formula (Fig.1). Pantoprazole is a white to Off White crystalline powder which is freely soluble in water.[1,2,3]

Literature Survey revealed that the drug has been estimated by Few methods such as UV Spectrophotometric methods[4, 5, 6]HPLC[7,8, 9, 10,11,12] and Simultaneous estimation by Derivative Spectroscopy[13, 14] methods has been reported so far.

The aim of present work was to develop and validate a novel, simple, accurate and precise Area under curve Spectrophotometric method for estimation of Pantoprazole in its Pure and Capsule dosage form.

MATERIALS AND METHOD

Instrument

UV-Visible double beam spectrophotometer, SHIMADZU (model UV-1800) with UV probe software. All weights were taken on analytical balance.

Chemicals

Pantoprazole was given as a gift sample by Cipla Pharma Limited, Hyderabad. Capsules of Pantoprazole were procured from local market.

Solvent

0.1 N NaOH

Selection of analytical wavelength

Appropriate dilutions were prepared for drug from the standard stock solution and the solution was scanned in the wavelength range of 200-400 nm. The absorption spectra thus obtained was showing the absorption maxima at 293nm and Area under curve in absorption spectra were measured between the wavelength range of 288-298nm which illustrated in Fig.2.

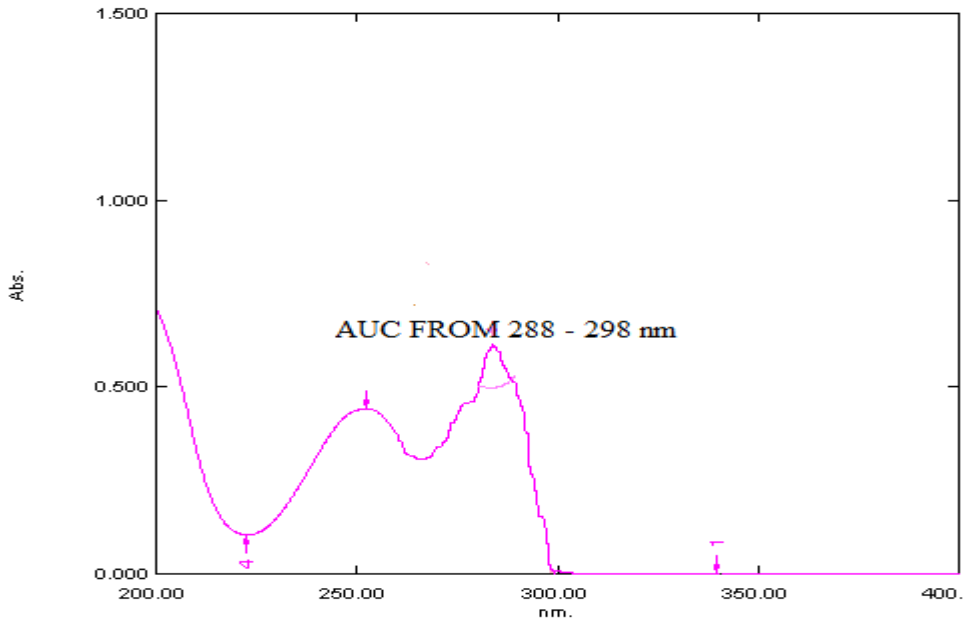

Fig. 2: Typical Zero order spectra of Pantoprazole showing AUC from 288-298nm.

Preparation of Standard stock solution

Accurately weigh 100mg of Pantoprazole was transferred into 100ml volumetric flask and diluted with 0.1 N NaOH up to the mark. From this pipette out 10ml into 100ml volumetric flask and diluted with 0.1N NaOH up to the mark, from this solution pipette out 0.3, 0.6, 0.9, 1.2, 15, and 1.8 ml into 10ml individual volumetric flask and add 0.1N NaOH up to the mark, this gives 3, 6, 9, 12, 15 and 18 µg/ml concentrations.

Preparation of Sample solution

The commercially available Pantosec contains 40 mg of Pantoprazole. From this twenty tablets were weighed and powdered. The tablets powder equivalent to 100 mg of Pantoprazole was transferred into 100 ml volumetric flask then it was diluted with 0.1N NaOH and made up to the mark and the solution was filtered through whatman filter paper NO. 41. From the above solution 10 ml was pipetted out into 100 ml volumetric flask and the volume was made up to the mark with 0.1N NaOH. The final concentration of Pantoprazole was brought to 20µg/ml.

Method validation: The method is validated according to the ICH guidelines.[15,16,17]

RESULTS AND DISCUSSION

Method: Area under curve spectroscopy

Linearity

The working standard solution were diluted serially with 0.1 N NaOH to obtain the range of 3-18µg/ml. a calibration curve for Pantoprazole was obtained by measuring the absorbance between 288nm to 298nm and absorbance values are shown in Table.1 and Calibration graph were presented in Fig.3. Statistical parameters like slope, intercept, coefficient of correlation, and Sandel's sensitivity were determined and presented in Table.2.

Table 1: Results of calibration curve for Pantoprazole by Area under curve Spectroscopy.

SL. NO	Concentration in µg/ml.	Absorbance between 288-298nm
1.	3	0.089
2.	6	0.183
3.	9	0.275
4.	12	0.37
5.	15	0.463
6.	18	0.557

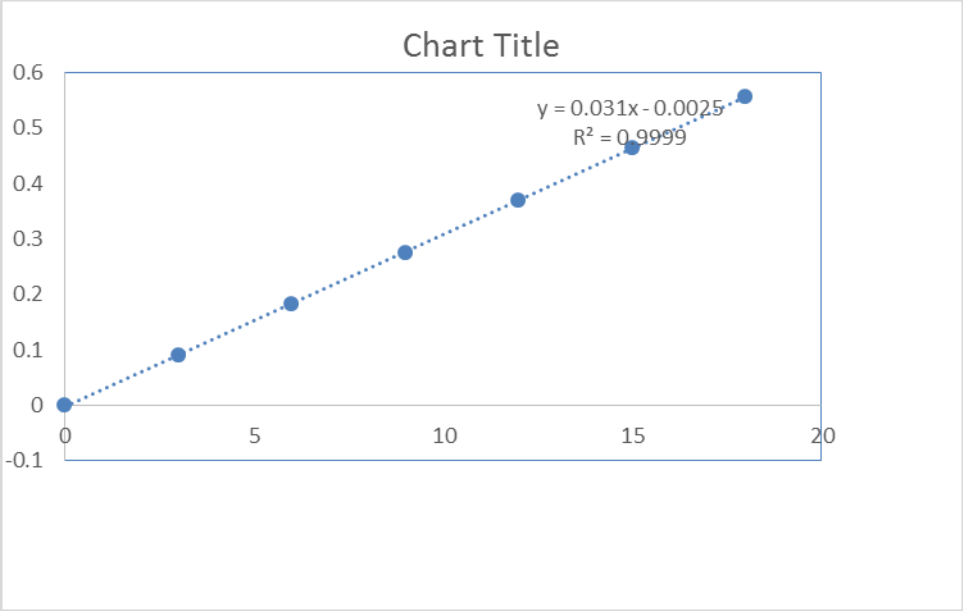

Fig 3: Calibration curve for Pantoprazole by AUC Spectroscopy.

Table no 2: Regression parameters for Pantoprazole by AUC spectroscopy.

Regression Parameters	Pantoprazole
Range	3 - 18 µg/ml
Max	288-298nm
Regression Equation	Y=0.031x+0.0025
Slope (b)	0031
Intercept(a)	0.0025
Correlation coefficient (r2)	0.9999
Sandell's Sensitivity	0.0023

Precision

Precision of the method was studied as intra-day and inter-day precision. Intra-day precision was determined by analyzing the 3, 6, 9, 12, 15, and 18 µg/ml concentration for three times in same day. Inter-day precision was determined by analyzing the same concentration of solution daily for three days. Precision results are shown in Table.3.

Table 3: Determination of precision results for Pantoprazole from 288nm to 298nm by AUC spectroscopy.

Concentration (µg/ml)	Intraday Absorbance ±SD**	% RSD	Interday Absorbance ±SD**	% RSD
3	0.089±0.001	1.12	0.087±0.0015	1.15
6	0.183±0.0015	0.83	0.179±0.0015	0.85
9	0.275±0.0015	0.55	0.276±0.0035	1.27
12	0.370±0.002	0.50	0.365±0.0032	0.87
15	0.463±0.001	0.21	0.460±0.002	0.43
18	0.557±0.001	0.17	0.553±0.0036	0.65

Accuracy

To assess the accuracy of the proposed method, recovery studies were carried out at three different levels i.e, 50%, 100% and 150%. In which the formulation concentration was kept constant and varied pure drug concentration. Accuracy results were shown in Table.4.

Table 4: Determination of accuracy results for Pantoprazole by AUC spectroscopy.

Spiked levels	Amount of sample (µg/ml)	Amount of standard (µg/ml)	Amount recovered	%Recovery ±SD**	% RSD
50	3	1.5	4.49	99.92±0.01512	0.0151
100	3	3	5.98	99.72±0.01136	0.011
150	3	4.5	7,44	99.29±0.00674	0.0067

**Average of six determinations

Ruggedness

Ruggedness was determined between different analysts. The value of %RSD was found to be less than 2 were shown in Table.5.

Table 5: Determination of Ruggedness results for Pantoprazole by AUC Spectroscopy.

Analysts	Analyst-1	Analyst-2
Mean absorbance	0.275	0.276
Standard deviation	0.001528	0.003512
%RSD	0.55	1.27

Limit of detection and Limit of Quantitation

The LOD and LOQ of the present method were calculated based on standard deviation of the Response and slope of linearity curve. LOD and LOQ values of Pantoprazole were found to be 0.03632µg/ml and 0.3632µg/ml.

CONCLUSION

Thus, the developed method was found to novel, simple, accurate and precise UV- spectrophotometric method for the routine estimation of Pantoprazole in Pure and Capsule dosage form.

ACKNOWLEDGEMENT

We like to thanks Management, Principal, teaching and non-teaching staff of Bharathi college of pharmacy for their continues co-operation and support.

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