INTERNATIONAL JOURNAL OF PHARMACY AND ANALYTICAL RESEARCH

ISSN:2320-2831

IJPAR |Vol.7 | Issue 2 | Apr - Jun -2018
Journal Home page: www.ijpar.com

Research article *Open Access*

Analytical method development and validation of pantaprazole in tablet dosage form by using UV spectroscopic method as per ICH guidelines

V.Shirisha[1], Mahendar Boddupally[2], K.Rajeswar Dutt[3], M.bhavana[4], B.Mounika[5], CH.Asha[6], Sk.Basheer[7]

Nalanda College of Pharmacy, Nalgonda, Telengana, India.

Corresponding Author: V.Shirisha

ABSTRACT

A simple, accurate, precise and economic spectrophotometric method has been developed for the determination of Pantaprazole in their pharmaceutical dosage form. Pantaprazole showed maximum absorbance at 290 nm with Methanol as solvent. Beer's law was obeyed in the concentration range 10-60 µg/ml with regression coefficient of 0.999. The concentration of active component were then determined from the calibration curve obtained by measuring the amplitude at 290 nm for Pantaprazole. Accuracy and precision of the developed methods have been tested in addition recovery studies have been carried out in order to confirm their accuracy. The method was validated in terms of linearity, precision, accuracy (100.1-100.13%w/w) and specificity. This method is simple, precise, accurate, sensitive and reproducible and can be used for the routine quality control testing of the marketed formulations.

Keywords: Pantaprazole, Methanol, UV spectrophotometric estimation, Method development, Validation

INTRODUCTION

Pantaprazole is a Antiulcer (Proton pump inhibitor), molecular formula $C_{16}H_{15}F_2$, N_3O_4S, IUPAC name6- (difluro methoxy) Panthazol -2-[(3) 4- dimethoxy pyridine – 2 –y 1) methylsulfinyl] -1H, 1-3 benzodiazole. Mechanasim action of drug involves proton pump inhibitors irreversibly inhibit the gastric H^+, K^+-ATP ase Proton pump which is the final common pathway for acid secretion in responses to all stimuli all proton pump inhibitors are acid labile & the tablet should be swallowed unbroken / uncrushed, should orally, undergo little First pass metabolism, the bioavailability in 77%Pantaprazole extensively metabolized in liver through cytochrome P-450 system, excreted through urine.

According to literature review [1-8] there are very few method reported for the determination of Pantaprazole in different Instrumental techniques, out of these methods only 2 methods were reported in Single Drug by using UV spectroscopic method.

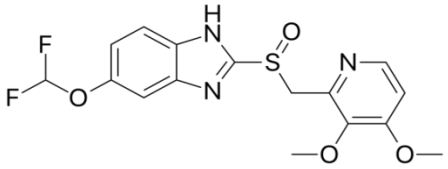

Figure 1: Structure of Pantaprazole

EXPERIMENTAL SECTION

Standard drugs

Pantaprazole was procured from the HETERO Pharma.

Chemicals and reagents

Methanol (FINER chemical LTD), Purified water (Rankem chemicals).

Instruments

UV (SHIMADZU), UV (Elico SL-196), Sonicator (Analytical technologies).

Determination of absorption maxima by UV/Visible Spectrophotometry

Accurately weigh 100 mg of drug in to 100 ml volumetric flask. To this add 75 ml of diluent Methanol and sonicate it and further make up the volume with diluent. From this take 3 ml and make up to10ml. The solutions were scanned in the range of 200-400 nm in 1cm cell against blank

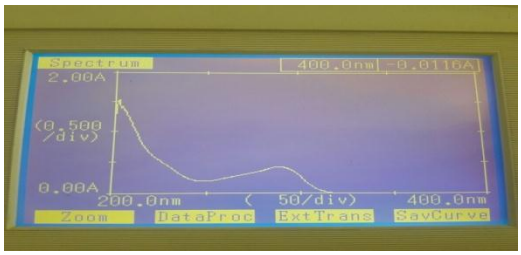

Figure: 2. Shows UV spectrum of Pantaprazole

Preparation of mobile phase

Accurately measured 100 ml of Methanol, were degassed in an ultrasonic water bath for 10minutes and then filtered through 0.45 µ nylon filter under vacuum filtration.

Diluent

Mobile phase is used as diluent

Sample preparation

Accurately weigh 25 mg of Pantaprazole powder and transfer in to 25ml volumetric flask. Add about 10ml of solvent mixture sonicate to dissolve. Cool the solution to room temperature and dilute to volume with solvent mixture. Transfer 3ml of above solution in to a 10ml volumetric flask and make up the volume with diluent.

Standard preparation

Accurately weigh 25 mg of Pantaprazole and transfer in to 25ml volumetric flask. Add about 10ml of solvent mixture sonicate to dissolve. Cool the solution to room temperature and dilute to volume with solvent mixture. Transfer 3ml of above solution in to a 10ml volumetric flask and make up the volume with diluent.

Optimized chromatographic conditions

- **Wavelength** - 290nm
- **Solvent** - methanol

Method validation

The following parameters were considered for the analytical method validation of Pantaprazole in tablet dosage form.

System Suitability

Chromatograph the standard preparations (6 replicate concentrations) and measure the absorbance evaluate the system suitability parameters as directed.

Accuracy

For accuracy determination, three different concentrations were prepared separately 50%, 100% and 150% for the concentration of absorbance values are recorded.

Precision

The standard solution was placed into cuvettes for six times and measured for all six concentrations absorbance values by using max in UV. The %RSD for the area of six replicate concentrations was found to be within the specified limits.

Robustness

As part of the Robustness, deliberate variations in method parameters and provides an indication of its reliability during normal usage. Wavelength was varied between plus or minus to. the solutions were made in triplicates and were analyzed the %RSD is determined.

Linearity and range

Linearity of the analytical method for assay by placing the linearity solutions prepared in the range of 10µg to 60µg of test concentration, into the cuvettes, covering minimum 6 different concentrations.

RESULTS AND DISCUSSION

Standard preparation

Accurately weigh 25 mg of Pantaprazole and transfer in to 25ml volumetric flask. Add about 10ml of solvent mixture sonicate to dissolve. Cool the solution to room temperature and dilute to volume with solvent mixture. Transfer 3ml of above solution in to a 10ml volumetric flask and make up the volume with diluent.

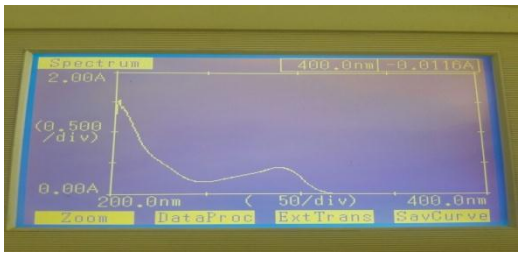

Figure: 3. Shows UV absorption spectrum of Pantaprazole standard

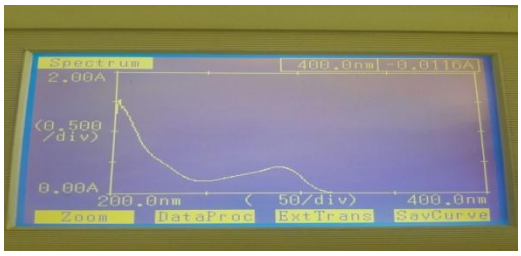

Figure: 4. Shows UV absorption spectrum of Pantaprazole sample Validation

Accuracy

Average recoveries of Pantaprazole are 100.9%, 100.1%, 100.2%, at 50%, 100% & 150% concentrations level respectively. The percentage recoveries of the drug is within the limits 98-100%. So the method is accurate, accuracy data for Pantaprazole are presented in;

Table 1: Accuracy results of Pantaprazole

Concentration level	Amount added (mg)	Amount found(mg)	%recovery	Average % recovery
50%	12.5mg	12.5mg	100.25%	100.33%
	12.5mg	12.5mg	100.25%	
	12.5mg	12.6mg	100.5%	
100%	25mg	25..25mg	100.22%	100.20%
	25mg	25.02mg	100.1%	
	25mg	25.07mg	100.3%	
150%	37.5mg	37.6mg	100.3%	100.13%
	37.5mg	37.5mg	100.09%	
	37.5mg	37.5mg	100.01%	

RESULT

The accuracy for the average of triplicate in each concentration samples are within the limit.

Table 2: Percentage Recovery of Pantaprazole

Amount added (mg)	Amount found (mg)	Average % recovery
25 mg	25.2mg	100.22%

Precision

Precision are summarized in **Table No: 3**, respectively. The %RSD values for Precision was less than 2.0%, which indicates that the proposed method is precise.

Table 3: Precision Results of Pantaprazole

Concentration (µg/ml)	Absorbance of pantaprazole
30	0.970
30	0.970
30	0.970
30	0.969
30	0.969
30	0.970
Mean	**0.969666**
Standard deviation	**0.00051**
%RSD	**0.0525954**

Linearity

The response was found linear over a concentration range of 10-60 µg/mL of Linearity. The correlation co-efficient were found to be 0.999 for Linearity**.** So the method is linear, data is presented in

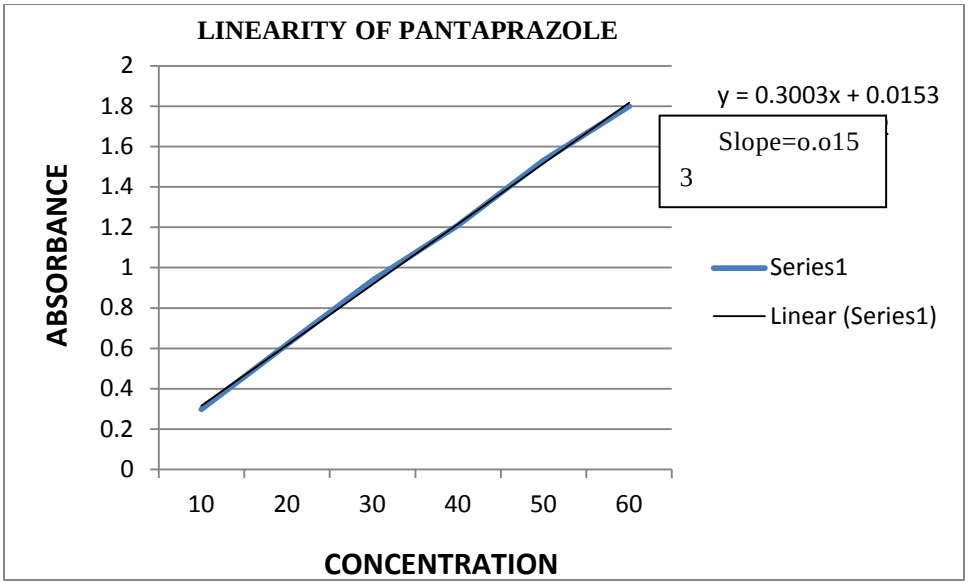

Figure 5: Linearity curve of Linearity is given in.

Table 4: linearity results of Pantaprazole

S.no	Linearity level	Concentration	Area
1	I	10µg	0.299
2	II	20µg	0.62
3	III	30µg	0.938
4	IV	40µg	1.21
5	V	50µg	1.531
6	VI	60µg	1.8
Correlation coefficient			0.999
Intercept			Y=0.3003X+0.0153
Slope			0.0153

Robustness

The Robustness of the method was determined by making slight changes in the experimental conditions such as change in the wavelength.

Table 5: Results of Robustness

S.NO	**Parameter name**	**Average results obtained in 6 units**		
		Mean	Pantaprazole drug in mg	Pantaprazole drug in %
1	Robust wavelength 288 nm	0.930	97.72	100.3
2	Robust wavelength 289nm	0.931	98.24	100.5
3	Robust wavelength 290 nm	0.933	100	100.01
4	Robust wavelength 291nm	0.931	98.24	100.3
5	Robust wavelength 292nm	0.928	97.13	100.25
Mean				100.27
Standard deviation				0.17512
%RSD				0.174

Limit of Detection (LOD) & LOQ

The detection limit is determined by the analysis of samples with known concentration of analyte and by establishing that minimum level at which the analyte can reliably detected **,** The LOD are calculated from the calibration curve by formula LOD = 3.3 x SD/ b The quantification limit is generally determined by the analysis of sample with known concentrations of analyte and by establishing the minimum level at which the analyte can be quantified with acceptable accuracy and precision, The LOQ are calculated from the calibration curve by formula LOQ = 10 x SD/

Table 6: LOD & LOQ results of Pantaprazole

Parameters	Pantaprazole
LOD	2.97µg/ml
LOQ	9ug/ml

Table 7: Validation parameters

S.NO	Parameter	Acceptance criteria	UV
1	%recovery	92-102%	100.22
2	Linearity range (µg/ml)	-	10-60(µg/ml)
3	Correlation Coefficient	NLT 0.999	0.999
4	Precision	%RSD(NMT 2%)	0.05
5	Intermediate Precision	%RSD(NMT 2%)	0.14
6	Robustness	%RSD(NMT 2%)	0.174
7	LOD	-	0.1583(µg/ml)
8	LOQ	-	0.3333(µg/ml)

CONCLUSION

Method development & validation of Pantaprazole was done by Uv-Visible spectroscopic method. The estimation was done by using mobile phase as methanol. The linearity range of Pantaprazole was found to be 10-60 µg/ml. Correlation coefficient value was 0.999, values of % RSD was 0.05 which is within the limit. These results show the method is accurate, precise& sensitive. The spectroscopic method is more rapid. The proposed method is successfully applied to tablet dosage form. The method was found to be having suitable application in routine laboratory analysis with high degree of accuracy and precision.

REFERENCES

[1]. Available at: https://www.drugbank.ca>drugs.

[2]. https://en.m.wikepedia.org>wiki>pantoprazole.

[3]. Prateek Kumar Mishra, Savita Upadhyay, Avinash C. Tripathi, Shailendra K. Saraf, Stability Indicating HPLC-UV Method for Simultaneous Estimation of Pantoprazole Domperidone and Drotaverine, International Journal of Pharma Tech Research 8(5), 2015, 912-923.

[4]. J. Subba Rao, S. Vidyadhara, A. Ramu, B. Venkateswara Rao and Vanaja, A novel RP-HPLC method development and validation for the simultaneous estimation of domperidone and pantoprazole in bulkand pharmaceutical formulations, Journal of Chemical and Pharmaceutical Research 7(12), 2015, 640-646.

[5]. Byendla Mahendar Amarnath and Medidi Srinivas, Method Development and Validation of RP-HPLC Method for the Simultaneous Estimation of Pantoprazole and Ondansetron Hydrochloride in Bulk and in a Synthetic Mixture, International Journal of PharmTech Research 6(6), 2014, 1794 – 1802.

[6]. Lakshmidurga k, ram mohan reddy t, ajitha a and uma maheswar rao v, Analytical Method Development & Validation for Simultaneous Estimation of Pantoprazole and Mosapride in Pharmaceutical Dosage form by RP-HPLC Method, Journal of Pharmacy and Chemistry 8(4), 2014, 14-20.

[7]. B. Siddartha and I. Sudheer Babu , Analytical method development and method validation for the estimation of pantoprazole in tablet dosage form by RP-HPLC, Der Pharma Chemica 5(4), (2013), 99-104.

[8]. Jigar Pandya , Mr. Sagar Solanki, Dr. Mandev Patel, Development and Validation of Differential Spectrophotometric method for Determination of Pantoprazole in Tablet Dosage Form, Journal of pharmaceutical sciences and bioscientific research 2(1), 2012, 1-4.

[9]. J.sunil, m.sanjith nath, u.samba moorthy, development and validation of an rp-hplc method for simultaneous determination of pantoprazole and cinitapride in antiulcer formulation, International Journal of Pharmacy and Pharmaceutical Sciences 4(4), 2012, 657-659.

[10]. Rajnish Kumar*, Harinder Singh and Pinderjit Singh, Development of UV Spectrophotometric method for estimation of Pantoprazole in pharmaceutical dosage forms, Journal of Chemical and Pharmaceutical Research 3(2), 2011, 113-117.