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Analytical Method Development and Validation of Pantoprazole in Tablet and Bulk Formulation by Uv Spectrophotometry

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ABSTRACT
A Simple and selective UV method is described for the determination of Pantoprazole.0.01N NaOH is the solvent utilized, and the detection wavelength is 250 nm. For pantoprazole, linearity was seen in the 10–50 µg/ml range (r2 = 0.9987) for medications assessed using the suggested method, which was in good accord with the label claim. Pantoprazole has been shown to be a straightforward, accurate, precise, and high-resolution method. Its shorter retention time also contributes to its acceptability and cost-effectiveness. As such, it can be used for routine analysis in research facilities, industry quality control departments, approved testing laboratories, biopharmaceutical companies, and bioequivalence studies.

KEYWORDS: Pantoprazole, Ultraviolet Spectroscopy.

I. INTRODUCTION

Pantoprazole is an Antiulcer (Proton pump inhibitor), molecular formula $C_{16}H_{15}F_2$, N_3O_4S, IUPAC name is (difluoromethoxy) Panthazol -2-[(3)4-dimethoxy pyridine–2–y1) methyl sulfinyl] -1H, 1-3 benzo diazole. It is a white to off-white crystalline powder. It is freely soluble in water, very slightly soluble in phosphate buffer at pH 7.4, and practically insoluble in n- hexane. The Melting point of drug is 139-140^{0}c and the Molecular weight is383.4 g/mol

Mechanism action of drug involves proton pump inhibitors irreversibly inhibit the gastric H^+ K^+ ATPase Proton pump is the final universal mechanism for acid secretion in response to all stimuli. All proton pump inhibitors are acid labile, and the tablet should be eaten unbroken / uncrushed, orally, undergo little first pass metabolism, with a bioavailability of 77%. Pantoprazole is extensively processed in the liver by the Cytochrome P-450 system and eliminated into the urine.

The serum concentration of Pantoprazole can be increased when it is combined with Apalutamide. Pantoprazole may decrease the excretion rate of Apixaban which could result in a higher serum level. The metabolism of Pantoprazole can be increased when combined with Apremilast.[1]

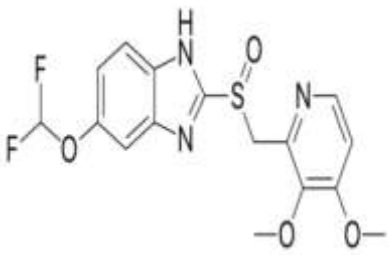

Fig 1: Structure of Pantoprazole

II. METHODOLOGY

Preparation of stock solution

Standard stock solution was prepared by accurately weighing 10 mg of pantoprazole and transferred in to 10 ml of volumetric flask and then dissolved in few ml of 0.01N NaOH until it solubilizes and the volume was made up to the mark with 0.01N NaOH to obtain the concentration of 1mg/ml or 1000 µg/ml (standard stock solution-1). From stock 1 solution pipette out 5 ml and transfer to 50 ml volumetric flask and made up to the mark with sodium hydroxide, to obtain the concentration of 100 µg/ml (standard stock solution-2).[2-7]

Selection of wavelength for analysis pantoprazole

Accurately measured 1 ml of standard stock solution-2 was transferred into 10 ml volumetric flask and diluted to 10 ml with sodium hydroxide to give the concentration of 10 µg/ml and it was used for initial spectral scan in the UV range of 200-400 nm to detect the maximum wavelength and further dilutions for linearity were prepared from the stock solution. [2-7]

Preparation of serial dilutions

The serial dilutions were prepared from the standard stock-2 solution to get a respective

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concentration of 10 µg/ml, 20 µg/ml, 30 µg/ml, 40 µg/ml, & 50 µg/ml absorbance of all the solution was measured at 250 nm. [2-7]

Linearity

Calibration curve was plotted by taking absorbance on x-axis and concentration on y-axis.

Precision

Precision of the method was determined by repeatability (intraday precision) and intermediate precision (interday precision) for standard solution (10 µg/ml) by six replicate measurements from the homogenous solution. For the precision of the method, three replicate were injected in to the system on same day and % RSD was calculated the result were expressed as % RSD of the measurement. [2-7]

LOD and LOQ

The detection limit of an individual's analytical procedure is the lowest amount of analyte in a sample which can be detected but not necessarily quantified as an exact value. Quantification limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be quantitatively determined with suitable precision and accuracy. [2-7]

Robustness

Robustness of this method was determined by analysing the pantoprazole standard solution of 10 µg/ml at different max (i.e. ±1) of actual max. Absorbance was measured. [2-7]

Accuracy

Accuracy was determined by standard addition method. To the sample solution, a known amount of standard solution was added at three different levels i.e, 80%, 100%, 120% of triplicate and the solution were analysed and % recovery was calculated. [2-7]

Assay

The pantoprazole content in its marketed formulation (Pantop 40 mg) was estimated using pre-validated UV Spectrophotometric method. 10 tablets were accurately weighed, and average weight was calculated, they were crushed to fine powder. The powder equivalent to 100 mg pantoprazole was dissolved in 0.01M NaOH with the help of sonication and volume was made up using 0.01M NaOH solution up to the mark of 100 ml volumetric flask gives the concentration of 1000 µg/ml. The stock solution was filtered using Whatman filter paper and the solution was further diluted with acetate buffer solution to give 20 µg/ml. Measure the absorbance of the solution at 250 nm and the % Assay was calculated.

III. RESULTS AND DISCUSSION

Linearity

The linearity concentration lies for Pantoprazole lies in between 10-50 µg/ml. Calibration curve and linearity data was shown in Table:1 and Fig-8. The correlation coefficient, intercept and slope were calculated for pantoprazole and results were shown in Table:2.

Table:1Linearity data of Pantoprazole

S.NO.	CONCENTRATION(µG/ML)	ABSORBANCE
1	10	0.136
2	20	0.246
3	30	0.382
4	40	0.499
5	50	0.611

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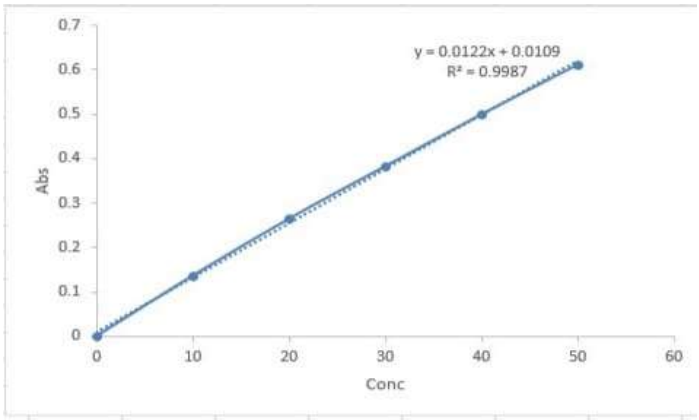

Fig. 2 Calibration curve of pantoprazole at 250 nm

Table:-2Optical characteristics of pantoprazole

PARAMETERS	PANTOPRAZOLE
λmax	250nm
Slope	0.0122
Linearity	10 to 50 µg/ml
Correlation coefficient	0.9987
Intercept	0.0109

Discussion: Calibration curve was plotted and correlation coefficient was found to be 0.9987. So, there was a good correlation between absorbance and concentration.

Precision: Intraday and Interday precision data was shown in Table:3 and 4 respectively.

Table: -3 Intraday Precision data of Pantoprazole

CONCENTRATION(µG/ML)	ABSORBANCE
10	0.190
10	0.198
10	0.199
10	0.195
10	0.196
Mean	0.195
Stdev	0.00350
%RSD	1.7

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Table:-4 Interday Precision data of Pantoprazole

CONCENTRATION(µG/ML)	INTRADAY ABSORBANCE DAY-1	INTERDAY ABSORBANCE DAY-2
10	0.190	0.228
10	0.198	0.235
10	0.199	0.235
10	0.195	0.235
10	0.196	0.228
Mean	0.195	0.232
Stdev	0.00350	0.003834
%RSD	1.7	1.6

Discussion: The %RSD for intraday and interday precision was found to be <2%. It indicates that the method was precise.

Limit of detection and Limit of quantification:

LOD and LOQ was calculated and shown in Table:5.

Table: 5 LOD and LOQ data

PARAMETERS	PANTOPRAZOLE
LOD	0.973 µg/ml
LOQ	2.95 µg/ml

Discussion:LOD and LOQ values for pantoprazole was found to be 0.97 µg/ml and 2.95 µg/ml.

Accuracy: Recovery studies were carried out by spiking the samples solution with standard solution 80%, 100%, and 120% for three replicates data was shown in Table:6.

Table: 6 Accuracy data of Pantoprazole

SAMPLE (% LEVEL)	AMOUNT TAKEN	AMOUNT ADDED	AMOUNT RECOVERED	% RECOVERY	AVERAGE
80 80 80	15 15 15	12 12 12	26.89 26.97 27.05	99.2 % 99.8 % 100.3 %	99.7 %
100 100 100	15 15 15	15 15 15	29.84 30.0 29.92	98.6 % 100.0 % 99.4 %	99.3 %
120 120 120	15 15 15	18 18 18	32.95 33.04 33.12	99.6 % 100.2 % 100.8 %	100.2 %

Discussion: The average % recovery of Pantoprazole was found to be in between 99-101%.

Robustness: Robustness data was shown in Table:7

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Table: 7Robustness data of pantoprazole

S.NO.	WAVELENGTH	ABSORBANCE
1	249	0.109
2	250	0.105
3	251	0.103

Discussion: There was no much variation in the absorbance with change in wavelength.

Assay:

Assay data of pantoprazole was shown in Table:8.

Table:8 Assay of pantoprazole

LABEL CLAIM	AMOUNT FOUND	% ASSAY
40mg	39.5mg	98.7%

Discussion: The % assay of pantoprazole was found to be 98.7%. It shows that UV- Spectroscopic method developed was successful in determining pantoprazole from tablet dosage form.

IV. SUMMARY

PARAMETERS	RESULTS	LIMITS
Linearity range (µg/ml)	10 to 50 µg/ml	
Regression coefficient	0.9987	R^2 <1
Slope (m)	0.0122	
Intercept (c)	0.0109	
Regression equation (y=mx+c)	y = 0.0122x + 0.0109	
Assay	98.7 %	90-110%
Precision %RSD		
Intraday precision	1.7	NMT 2.0%
Interday precision	1.6	
Accuracy % recovery		
80%	99.7 %	
100%	99.3 %	98-103%
120%	100.2 %	
LOD	0.973 µg/ml	NMT 3
LOQ	2.95 µg/ml	NMT 10

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V. CONCLUSION

From the above experimental results and parameters, it was concluded that, this developed UV- Spectroscopy method for the estimation of pantoprazole was found to be simple, precise, accurate, robust, economic and rapid makes this method more acceptable and cost effective and it can be effectively applied for routine analysis in research institutions and quality control department.The results for various parameters were found within the limits. The Linearity was found to be in range of 10 to 50 µg/ml. The %RSD for Intraday and Interday precision studies was found to be 1.7 and 1.6 respectively. The % assay was found to be 103.4%. The average % recovery of pantoprazole was found to be in between 99-101 %. LOD and LOQ was found to be 0.973 µg/ml and 2.95 µg/ml respectively.

VI. ACKNOWLEDGEMENT

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