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Review

A review on analytical method development and validation of pantaprazole in bulk and tablet formulation by using Uv- spectrophotometry

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Abstract

Pantoprazole (Protonix) is an irreversible proton pump inhibitor (PPI) that reduces gastric acid secretion. in conjunction with a pair of antimicrobial medicines, most frequently amoxicillin, clarithromycin, or metronidazole. Analysis can be done by various methods. Most commonly used solvents are HCl, NaOH, Methanol, Water. Various parameters are collected including LOD, LOQ, Correlation Coefficient and linearity range, accuracy, Ruggedness.

Keywords: Pantoprazole, Methanol, UV Spectrophotometry

INTRODUCTION

Pantaprazole 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. 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%. Pantaprazole 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.

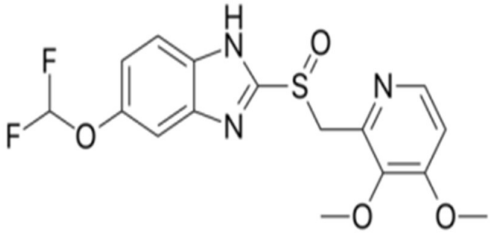

Fig 1: Structure of Pantoprazole

Literature review

S.NO	AUTHOR NAME	JOURNAL NAME	TITLE NMAE	ANALYTICAL CONDITIONS
1	RajnishKumaret al.2011[1]	Journal of Chemical and Pharmaceutical Research	Development of UV Spectrophotometric method for estimation of Pantoprazole in pharmaceutical dosage forms	Solvent- 0.1M HCl and 0.1M NaOH λ max – 292nm Beer's law limit- 5-70µg /mL Molar absorptivity, L mol-1 cm-1 1.52x104 Regression equation Slope (m) 0.399 Intercept (c) 0.01547 Correlation coefficient 0.9998
2	B. Shrestha et al.2019[2]	Research of Journal of Life Sciences, Bioinformatics, Pharmaceutical Sciences	A Novel Difference Spectrophotometric Method or the determination of Pantoprazole in tablet Dosage form	Solvent-Water λ max-284nm,295nm Linearity- 5-50 µg/mL Accuracy- 98.3-102.4%
3	V. Shirisha et al.2018[3]	International Journal of pharmacy and Analytical Research	Analytical Method Development and validation of pantaprazole in tablet dosage form by using UV Spectroscopic method as per ICH Guidelines	Solvent-Methanol λ max-290nm %recovery 92-102% LOD - 0.1583(µg/ml) LOQ - 0.3333(µg/ml) Linearity range (µg/ml) - 10-60(µg/ml) Correlation Coefficient NLT- 0.999 Robustness- 0.174 Precision - 0.055 Intermediate Precision- 0.14
4	P. Ravi Kumar et al.2006[4]	E-Journal of Chemistry	Simultaneous Estimation of Domperidone and Pantoprazole in Solid Dosage Form by UV Spectrophotometry	Solvent- Methanol λ max-216nm, 287nm, 290nm Linearity- 0-50 mcg/mL
5	Basavaiah et al.2009[5]	Iranian Journal of chemical and Engineering	Spectrophotometric Determination of Pantoprazole Sodium in pharmaceuticals using N-Bromosuccinimide Methyl Orange and	Solvent- Water λ max- 520-610nm Beer's law limits, µg mL-1 0.1 - 2.0, 0.5 - 6.0 Sandell sensitivity, µg cm^{-2} 0.003 - 0.01

			Indigo Carmine as Reagents	LOD - 0.02- 0.06µg/ml LOQ-0.07-0.19 µg/ml
6	M. Purusotham Reddy et al.2014[6]	Chemical Science Transactions	A Simple Spectrophotometric Determination of Pantoprazole Pharmaceutical Formulations	Solvent- Methanol λ max- 420nm Recovery-100.22, 99.9,100.1
7	Shamkant S. Patil et al.2008[7]	International Journal of Chemical Sciences	Spectrophotometric Estimation of pantoprazole in tablet dosage form	Solvent- Methanol λmax - 290, 282, 286-296nm Beers-Lambert's range (µg/mL) 5-35 10-100 5-40 Coefficient of correlation -0.999934, 0.999973, 0.99996 LOD- 0.15,0.35,0.1 LOQ- 0.45,1.05,0.30
8	Siddhartha et al.2013[8]	Research Journal of Pharmaceutical dosage forms and Technology	Development and Validation of UV–Spectrophotometric Method of Pantoprazole in bulk and pharmaceutical dosage form	Solvent- 0.1 NaOH λmax-2955nm Beer's law limit- 1-20(µg/mL) Absorptivity- 0.640 x 10^4 Sandell's sensitivity-0.0156 correlation coefficient 0.999 LOD- 0.083µg/ml LOQ- 0.250µg/ml Precision(%RSD)-0.001
9	Gaur A et al. 2018[9]	International Journal of Pharmaceutical Quality Assurance	Development and Validation of UV Spectroscopic Method for Simultaneous Estimation of Pantoprazole and Cinitapride in Bulk and in Capsule Dosage Form	λmax-289 nm, 267.2 nm Beer's law Concentration 13-65µg/ml and 1-5 µg/ml Accuracy- 101.32 %,98.9 % Accuracy (% Recovery) 100.153 99.25 Repeatability (% RSD) 1.417 1.003 Intraday analysis (% RSD) 0.360 0.243 Intraday analysis (% RSD) 0.305 0.300 LOD (µg/ml) - 0.0820 0.1092 LOQ (µg/ml) - 0.247 0.331
10	KaveriChandrakantDulange et al.2019[10]	Asian Journal of Pharmaceutical Analysis and Medicinal Chemistry	Development and Validation of UV Spectrophotometric Method for Simultaneous Estimation of Domperidone and Pantoprazole Sodium in bulk and	Solvent- Methanol λmax -288nm,291nm Beer's Law limit - 5-25 µg/ml, 5-25 µg/ml LOD (µg/ml)- 0.045, 0.01 LOQ (µg/ml)- 0.122 0.059 Robustness (%RSD)-0.13, 0.191

			pharmaceutical dosage form	Ruggedness(%RSD)- 0.137, 0.1 Accuracy - 99-100%, 98-99%
11	BarriSwathi et al. 2019[11]	Indo American Journal of Pharmaceutical Research	Development and validation of new Analytical method for the Simultaneous Estimation Pantoprazole and Domperidone by UV Spectrophotometry	Solvent- Methanol λmax-290nm,287nm Linearity- 1-15 µg/ml, 1-50 µg/ml Recovery- 99 -103%
12	IncilaySuslu et al. 2004[12]	Fabad Journal of Pharmaceutical Sciences	Determination of pantoprazole in tablet dosage forms by two different spectrophotometric methods	Solvent-Methanol, Water λmax-295-305nm Correlation coefficient (r) 0.999 0.999 LOQ- 2.31 0.5 µg/ml LOD- 0.69 0.15 µg/ml Linearity range (µg mL-1) 2.50 - 80.00 ,0.5 – 70
13	Nejal M. Bhatt et al. 2014[13]	The Scientific World Journal	Manipulating Ratio Spectra for the Spectrophotometric Analysis of Diclofenac Sodium and Pantoprazole Sodium in Laboratory Mixtures and Tablet Formulation	Solvent-Methanol λmax-251-318 Linearity- 2.0–24.0 µg/mL, 2.0–20.0 µg/mL Accuracy-99.25% Precision-101.05%
14	Dimal A. Shah et al.2013[14]	Hindawi Publishing Corporation	Simultaneous Estimation of Pantoprazole Sodium and Levosulpiride in Capsule Dosage Form by Simultaneous Equation Spectrophotometric Method	Solvent- Methanol λmax- 290 ,232 nm Linearity- 4–12 µg/mL, 8–20 µg/mL % recovery-100.23–100.99%,100.51–100.94% Robustness 98.45–100.48% 99.12–100.65%
15	Jigar Pandya et al.2012[15]	Journal of Pharmaceutical Science and Bioscientific Research	Development and Validation of Differential Spectrophotometric method for Determination of Pantoprazole in Tablet Dosage Form	Solvent -Water λmax- 296 ,319 nm Linearity- 5-25 µg/ml Precision (RSD)%- 0.5-0.9 LOD- 0.0954 LOQ 0.2891 Correlation Coefficient- 0.997 % Recovery- 99.06%
16	Suresha D. Net al.2002[16]	European Journal of Pharmaceutical and Medical Research	A Novel Method Development and Validation of Pantoprazole in Pure and Capsule Dosage Forms by using UV-Spectrophotometric Method	Solvent - 0.1 N NaOH λmax- 288- 298nm Linearity- 3-18 µg/ml correlation coefficient- 0.9999 regression equation- Y=0.031x+0.0025 Sandell's Sensitivity 0.0023

				%Recovery - 99.29% - 99.92%
17	SmitaMujbaile et al.2012[17]	IOSR Journal of Pharmacy and Biological Sciences	Simultaneous Estimation of Ondansetron and Pantoprazole in Solid Dosage Form by First Derivative Spectroscopy Method	Solvent- Water λmax- 288.5- 310 nm concentration range- 0.5-2.5ug/ml, 5-25ug/ml Regression equation- y=0.001x-0.0011, y=0.0118x+0.0117.
18	Abdel-Aziz M. Wahbi et al.2002[18]	Journal of Pharmaceutical and Biomedical Analysis	Spectrophotometric determination of omeprazole, lansoprazole and pantoprazole in pharmaceutical formulations	Solvent- NaOH λmax- 306.2, 292.4, 295.4nm Linearity-0.5 / 3.5 mg/ml $^{-1}$ Repeatability-0.3-0.5%

CONCLUSION

According to this review spectroscopic and chromatographic methods for pantoprazole are available for single and combination analysis. Methanol is the typical solvent used in the majority of spectroscopic techniques. The majority of the techniques used were UV absorbance detection because they provide the highest levels of precision, repeatability, reliability, and also it is simple, rapid and robust quantitative analytical method.

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