www.sphinxsai.com

PharmTech

International Journal of PharmTech Research
CODEN (USA): IJPRIF ISSN : 0974-4304
Vol.1, No.4, pp 1094-1096, Oct-Dec 2009

Estimation of pantoprazole from multiparticulate dosage form by new HPLC method

V. Saini *and V.B. Gupta
B.R. Nahata College of Pharmacy, Mhow Neemuch Road, Mandsaur (M.P.) 458001
Present address:H-26/27, Saini Colony, Sodala Suvej Farm,Ram Nagar Extension-2, Jaipur (Rajasthan) India.

Corres author: singhvipins31@rediffmail.com
Mob. No. 09929215268, 0141-2291148

Abstract: A straightforward, specific, accurate, reasonably priced and reproducible high pressure liquid chromatography method has been developed for estimation of pantoprazole from multiparticulate dosage form. An octa decyl silane (ODS) C18 column from shimadzu in gradient mode, with mobile phase HPLC grade acetonitrile and methanol in the ratios of 50:50 was used in present research work. The following method obeyed the Beer's-Lambert law in the concentration range of 5-25 µg /ml. The result of analysis were validated both for statistically and by recovery studies. The statistical analysis of data indicated a high level of accuracy for the proposed method as evidenced by low standard deviation (SD) values. This method has been successfully used to analyze commercial solid dosage form containing 40 mg of pantoprazole .
Key words: Pantoprazole, HPLC and multiple unit tablet of pantoprazole

Introduction

Pantoprazole is the third proton pump inhibitor to be marketed in the UK; it is mainly used to treat too much acid secretions in the stomach, duodenal ulcer, benign gastric ulcer and gastro-esophageal reflux diseases (GERD) and reflux oesophagitis.Pantoprazole has several advantages compared to its analogus (e.g., omeprazole and lansoprazole) such as specific binding site, greater stability in neutral pH environment and longer duration of action.It is more selective inhibitor of acid secretion than other proton pump inhibitors.In case of oral administration pantoprazole drug is destroyed in acid medium (stomach),due to necessity to pass intact through the stomach for reaching to duodenum for absorption, the pantoprazole is formulated as controlled release dosage forms [1,2,3].

Pantoprazole is a proton pump inhibitor that suppress the final step in gastric acid production by forming a covalent bond to two sites of the (H^+K^+)-ATP-ase enzyme system at the secretary surface of the gastric parietal cell. This effect is dose related and leads to inhibition of both basal and stimulated gastric acid secretion irrespective of stimulus. The binding to the (H^+, K^+)-ATP-anti secretary effect that persists longer than 24 hours. Pantoprazole 40 mg is equivalent to pantoprazole sodium sesquihydrate 45.10 mg. Pantoprazole is usually administered in a dose of 40 mg given 1-2 times to maintain effective blood concentration through out the day. It is absorbed after oral administration as controlled release coated tablet with maximum plasma concentrations within 2-3 hours and with bioavailability of 77 %. Pantoprazole is freely soluble in water.The widespread use and benefit of the proton pump inhibiting class of acid suppressing drugs pantoprazole have been precious paraphernalia in the treatment of an assortment of upper gastrointestinal diseases [4,5,6].

Various solid dosage forms of pantoprazole are accessible in Indian and international market. A search of literature reveals that only a few methods have been reported for the assay of pantoprazole drug. The aim of this present work is to develop a simple, validated and cost effective and fast method for determination of pantoprazole from multiple unit controlled release tablet dosage form. The procedure was also applied successfully for the analysis of the commercial available pantoprazole tablets dosage form, purchased from the local market.

Experimental

Reagents and chemicals

Pantoprazole as pantoprazole sodium sesquihydrate drug sample was supplied by McNeil pharma, India) as a gift sample.HPLC grades acetonitrile and methanol (Merck) were used as solvent and mobile phase. All mobile

phases were filtered through whatman filter paper no.-1. Commercially tablets of pantoprazole were procured from the local market, Mandsaur (M.P.).

Instrumentation
Merck HPLC (model) with Column C-18 Lichrosphere, Pump L 710 Lachrom, Detector UV, L 7400 Lachrom, was used for separation and detection of drug. Injection volume was 10 µl.U.V. detection was done at 289 nm. Flow rate1 ml /minute were used for present HPLC analysis.

Preparation of mobile phase
HPLC grade acetonitrile and HPLC grade methanol in 50: 50 ratios are used as mobile phase in present work. The solution was then sonicated for 10 minutes and filtered through whatman filter paper no.1.

Preparation of standard solution
Accurately weighed quantities of (100 mg) of pantoprazole (pantoprazole sodium sesquihydrate) was dissolved in 100 ml solution mixtures of HPLC grade acetonitrile and HPLC grade methanol in 50: 50 ratios .One ml of this solution was diluted to 100 ml with mixture of HPLC grade acetonitrile and HPLC grade methanol in 50 : 50 ratios. The solution was further diluted to get drug solutions concentration of 5 µg /ml, 10 µg /ml, 15 µg /ml, 20 µg /ml and 25 µg /ml respectively.
The filter portion of samples (about 10 µl) was separately injected into the chromatograph and the chromatogram was recorded at 289 nm.

Assay of formulations
Twenty multiple-unit tablets were weighed accurately and taken in a porcelain mortar and crushed to a fine powder .Powder sample equivalent to net average content 40 mg of pantoprazole (which is equivalent to pantoprazole sodium sesquihydrate 45.10 mg) weighed accurately and transferred to 100 ml volumetric flask and volume was maintained up to 100 ml with mixture of HPLC grade acetonitrile and HPLC grade methanol in 50: 50 ratios. The solution was filtered through what man filter paper no 1. One ml of the solution was taken and diluted up to 100 ml with mixture of HPLC grade acetonitrile and HPLC grade methanol in 50: 50 ratios. This stock solution was used to prepare dilutions in the range of 5 µg /ml, 10 µg /ml, 15 µg /ml, 20 µg /ml and 25 µg /ml respectively. The filter portion of samples (about 10 µl) was seperately injected into the chromatograph and the chromatogram was recorded at 289 nm [7]. Results of the analysis of the multiple-unit tablet formulation are shown in table-I

Recovery studies
The recovery of the methods was studied by accuracy experiments. To the powdered formulation containing 40 mg of pantoprazole ,the stock working standard solution were spiked at the levels of 50 %,100% and 150 % of the original drug concentration.The analysis was done as the assay experiment. Accuracy was determined from the recoveries so obtained.The results of recovery studies were found to be adequate and indicate non intervention from the excipients used in the formulation [8,9]. The results of recovery studies are listed in table-II.

Results and discussion
The applicability of the proposed method for estimation of pantoprazole multiple-unit controlled release tablet dosage forms was examined. The results of recovery studies performed at three different levels showed high degree of reproducibility and precision of the methods.The standard deviation calculated was low, indicating the suitability of the proposed method for the estimation of pantoprazole from multiple-unit controlled release tablet dosage form.

Conclusions
The above new method give consistent, corroborate and lucrative result and hence, developed validated method can be adopted in schedule analysis of pantoprazole drug in multiple-unit controlled release tablet dosage forms.

Table -1 Result of the analysis of the multiple-unit pantoprazole tablet formulation

Formulations	Label claim(mg/tab)	% label claim estimated* (Mean ± S.D.)	% Coefficient of Variation.	Standard Error
Pantoprazole multiple-unit tablet	40mg	96.21±0.604	0.6279	0.3487
Marketed tablet	40mg	94.85±0.555	0.5851	0.3204

*Average of three trials

Table -II Result of the recovery study for spiked concentration of pantoprazole
(Added to pre-analyzed tablet powder sample)

Formulations	Amount of drug in preanalyzed tablet powder(mg)	Pantoprazole drug sample added (spiked)in %	% Recovery of pantoprazole
Pantoprazole multiple-unit tablet	40 mg	50	101.90
	40 mg	100	99.37
	40 mg	150	102.23
Marketed tablet	40 mg	50	100.35
	40 mg	100	101.45
	40 mg	150	99.29

References

1. Wyeth pharmaceuticals literature, 2000
2. Raffin R.P., Colome L.M., Pohlmann A.R. and Guterres S.S., Preparation ,characterization and in vivo anti-ulcer evaluation of pantoprazole – loaded microparticles, European Journal of Pharmaceutics and Biopharmaceutics, 2006,2, 63 , 198-204.
3. Swarbrick J. and Boylan, Encyclopedia of Pharmaceutical Technology, Marcel Dekker, 1998, 3, 281.
4. Salas M., Ward A. and Caro J, Are proton pump inhibitors the first choice for acute treatment of gastric ulcers? A Meta analysis of randomized clinical study. BMC gastroenterology, 2002, 2, 17.
5. Pandey V.P., Development of tablet formulation of enteric coated pantoprazole with domperidone, The Indian Pharmacist, 2000, 5. 54.
6. Gomes N.A., vaidya V.V., Thombre V., and Chitlange SS Simultaneously assay of mosapride citrate and pantoprazole in pharmaceutical preparation using reserve phase high phase chromatography, Indian drugs, 2008,45,5, 421-425.
7. Reddy B. P. K,Reddy Y. R. and Ramachandaran D., Determination of pantoprazole sodium and lansoprazole in individual tablets dosage forms by RP-HPLC using single mobile phase, E-journal of chemistry. 2009,6,2, 489-494.
8. Battu P.S.,Simultaneously HPLC estimation of pantoprazole and domperidone from tablets, International journal of pharm.tech research ,2009,1,2,275-277
9. Bharathi D.V., Hotha H.K., Jagadeesh B., Chatki P.K. , Thriveni K., Mullangi K., Naidu A., Simultaneously estimation of four proton pump inhibitors-lansoprazole,omeprazole,pantoprazole and rabeprazole:Development of a novel generic HPLC-U.V. method and its applications to clinical pharmacokinetic studies,Biomedical chromatography,BMC,2009,9.

*****