Asian Journal of Chemistry Vol. 21, No. 8 (2009), 6596-6598

NOTE

RP-HPLC Determination of Pantoprazole Sodium in Tablets

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A precise reverse phase HPLC method has been developed for the determination of pantoprazole sodium in its tablet dosage forms. The chromatography was carried out on an ODS column using a mixture of acetonitrile and phosphate buffer (32:68 v/v) as the mobile phase at a flow rate of 1.0 mL/min. The detection of the drug in the eluent was done at 280 nm. The retention time of the drug was found to be 11.38 min. The method produced linear responses in the concentration range of 0.5-50 µg/mL of pantoprazole sodium. The method was found to be applicable for determination of the drug in tablets with an average per cent recovery of 99.85.

Key Words: Pantoprazole, Estimation, Tablets, RP-HPLC.

Pantoprazole, 5-difluoromethoxy benzimidazole-2-yl 3,4-dimethoxy-2-pyridyl methyl sulfoxide, is an irreversible proton pump inhibitor which decreases acid secretion from gastric parietal cells. Different analytical methods have been reported for the determination of pantoprazole in dosage forms and in biological fluids. The methods are based on spectrophotometry[1-3], fluorimetry[4], TLC[5], HPTLC[6,7], capillary electrophoresis[8] and polarography[9]. The authors propose a new validated, sensitive and reproducible HPLC method for the determination of pantoprazole.

A working standard sample of pantoprazole obtained from Nosch laboratories and two commercial samples of tablets containing the drug namely Pantin (Genx) and Pantocid (Sun) were employed in the study. HPLC grade acetonitrile (Qualigens), A.R grade potassium dihydrogen phosphate and sodium hydroxide (Qualigens) were used for preparing the mobile phase.

Chromatographic conditions: A Shimadzu LC-2010 CHT high-pressure liquid chromatographic instrument provided with a Kromacil ODS reverse phase column (25 cm × 4.6 mm) and a 25 µL Hamilton syringe were employed in the study. A freshly prepared 32:68 (v/v) mixture of acetonitrile and phosphate buffer (7.4 pH) was used as the mobile phase. Both acetonitrile and phosphate buffer were filtered through a 0.45 µm membrane filter and sonicated before use. The flow rate of the mobile phase was maintained at 1.0 mL/min. The detection was carried out at 280 nm.

Estimation of pantoprazole sodium: About 100 mg of pantoprazole sodium was weighed accurately and transferred into a 100 mL volumetric flask and dissolved

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in 25 mL of the mobile phase. The solution was sonicated for 15 min and then the volume made up with a further quantity of the mobile phase to get a 1 mg/mL solution. From this solution further dilutions ranging from 0.5-50 µg/mL were prepared in 50 mL volumetric flasks with the mobile phase. 20 µL of the solution was injected each time into the column. Each of the dilutions was injected five times into the column and the corresponding chromatograms were obtained. From these chromatograms, the retention times and the areas under the peaks of the drug were noted and the relevant calibration curve was constructed. The regression equation of the curve was computed. This equation was later used to estimate the amount of pantoprozole sodium in tablet dosage forms.

To check the intra-day and inter-day variation of the method, solutions containing 4, 8 and 12 µg/mL of pantoprazole sodium were subjected to the proposed HPLC method of analysis and the recoveries obtained were noted.

Estimation of the drug in tablet dosage forms: Ten tablets were taken and their coloured coats were removed with methanol and then they were air dried and powdered. A quantity of the powder equivalent to 100 mg of pantoprazole was accurately weighed and dissolved in 50 mL of the mobile phase in a 100 mL volumetric flask. The solution was shaken well and allowed to stand for 15 min with intermittent sonication to ensure complete solubility of the drug. The mixture was then thoroughly mixed and made upto the mark with the mobile phase and filtered through a 0.45 µ membrane filter. From this filtrate different aliquots were taken in separate 10 mL volumetric flasks. The contents of the flasks were made upto the volume with the mobile phase and mixed well. 20 µL of each of these solutions was then injected into the column. All the determinations were conducted 5 times. From the peak area ratios, the drug content in the tablets was quantified using the regression equation obtained from the pure sample.

The present study was aimed to develop a more sensitive, precise and accurate HPLC method for the analysis of pantoprazole sodium in tablet dosage forms. For this, a binary mixture of acetonitrile and phosphate buffer in the ratio 32:68 (v/v) was found to be the most suitable mobile phase as the chromatographic peaks obtained with this system were better defined and resolved and were almost free from tailing. Under the above mentioned conditions (Table-1), the retention time obtained for pantoprazole sodium was 11.38 min.

A good linear relationship ($r = 0.9995$) was observed between the concentrations of pantoprazole and the corresponding peak areas. The regression of pantoprazole concentration over its peak area was found to be $Y = 141174x + 14149$ (where Y is the peak area and x is the concentration of pantoprazole sodium). The intra-day and inter-day drug variation studies by the proposed method showed low coefficient of variation as shown in Table-2. The drug content in the tablets was quantified using the proposed method of analysis. The mean amount of pantoprazole obtained in tablet dosage forms is shown in Table-3. This reveals that the method is quite precise. The absence of additional peaks in the chromatogram indicated no interference of the common excipients used in the tablets.

TABLE-1
CALIBRATION OF THE PROPOSED METHOD

Concentration of pantoprazole sodium (µg/mL)	Peak area
0.5	70740
1.0	141482
2.0	282965
4.0	565930
8.0	1131858
10.0	1414824
20.0	2929648
30.0	4344325
40.0	5549837
50.0	7074122

TABLE-2
INTRA-AND INTER-DAY PRECISION OF THE PROPOSED METHOD

Concentration of pantoprazole sodium (µg/mL)	Observed concentration of pantoprazole sodium (µg/mL)			
	Intra-day		Inter-day	
	Mean (n = 5)	RSD (%)	Mean (n = 5)	RSD (%)
4	4.96	0.07	4.97	0.050
8	7.95	0.07	7.97	0.050
12	11.96	0.05	11.98	0.047

TABLE-3
DETERMINATION OF PANTOPRAZOLE SODIUM IN TABLET DOSAGE FORMS

Brand name of the tablet	Labelled amount of drug (mg)	Mean (± SD) amount found by the proposed method (n = 5)	Mean (± SD) % Labelled amount
Pantin	40	39.94 ± 0.07	99.85 ± 0.18
Pantocid	40	39.95 ± 0.07	99.88 ± 0.17

It can be concluded that the proposed HPLC method is sensitive and reproducible for analysis of pantoprazole sodium in tablet dosage forms in a short analysis time. The method was duly validated by evaluation of the required parameters.

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(*Received*: 3 December 2008; *Accepted*: 16 June 2009) AJC-7657