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Simultaneous Estimation of Ranitidine Hydrochloride and Ondansetron Hydrochloride by Reverse Phase High Performance Liquid Chromatography

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A simple, precise, fast, reproducible and selective reverse phase HPLC method has been developed for the simultaneous estimation of ranitidine hydrochloride and ondansetron hydrochloride from tablet. This was resolved by using mobile phase (methanol and 0.05 M phosphate buffer in a ratio 60 : 40 and pH 5.8 was adjusted by triethylamine) at a flow rate of 1.0 mL/min on an isocratic HPLC system consisting of LC-10 AT liquid pump, SPD-10A UV-Vis detector, an ODS C-18 RP column (250 × 4.6 mm) at a wavelength of 310 nm. The linear dynamic range for ranitidine hydrochloride was 35.0 to 195.0 μg/mL and ondansetron hydrochloride was 1.0 to 5.0 μg/mL is obtained by this method.

Key Words: HPLC, Ranitidine hydrochloride, Ondansetron hydrochloride and Pharamaceutical dosage.

INTRODUCTION

Ranitidine hydrochloride[1] (RAN) is a histaminic H_2-receptor antagonist, used in acidity and chemotherapy-induced acidity[2]. Chemically, it is N,N-dimethyl 1-5-[2-1-methylamino-2-nitrovinylamino)ethylthiomethyl]furfurylamine hydrochloride[2–3]. Few HPLC[3–5], HPTLC[6–8] and spectrophotometric[9] methods have been reported for the estimation of ranitidine hydrochloride.

Ondansetron hydrochloride[1] (OND), is a selective 5-HT_3 receptor antagonist used as antiemetic in chemotherapy-induced emesis[2]. Chemically, it is 1,2,3,4-tetrahydro-9-methyl-3-(2-methylimdazol-1-yl methyl)-carbazol-4-one hydrochloride[2]. Few methods have been reported for estimation of ondansetron hydrochloride in pharmaceutical dosage form by HPLC[10–14] method. However, no reverse phase HPLC method has been reported for ranitidine hydrochloride and ondansetron hydrochloride in combination dosage form.

EXPERIMENTAL

Ranitidine hydrochloride and ondansetron hydrochloride were procured directly from the manufacturer. The methanol used was of HPLC grade (E. Merck) and triple distilled water was used. All other reagents (potassium dihydrogen phosphate, triethylamine) used in the study were of AR quality (E. Merck). An isocratic HPLC system (Shimadzu) consisting of LC-10 AT liquid pump, SPD-10A UV-Vis detector, an ODS C-18, RP column (250 × 4.6 mm), 25 mL Hamilton

syringe was used. The HPLC system was equipped with the software Class-VP series version 5.03 (Shimadzu).

Preparation of stock solution of ranitidine hydrochloride

About 20.0 mg of standard ranitidine hydrochloride was accurately weighed and transferred to a 100 mL volumetric flask. It was dissolved in mobile phase and volume was made up to the mark with mobile phase to give a stock solution containing 200.0 μg/mL ranitidine hydrochloride.

Preparation of stock solution of ondansetron hydrochloride

About 10.0 mg of standard ondansetron hydrochloride was accurately weighed and transferred to a 100 mL volumetric flask. It was dissolved in mobile phase and volume was made up to the mark with mobile phase to give a stock solution containing 100 μg/mL ondansetron hydrochloride.

Chromatographic conditions

Both methanol and 0.05 M potassium dihydrogen phosphate, pH 5.8 adjusted by using tri ethylamine, were filtered before use through 0.44 μ PFTE membrane filter. The flow rate of mobile phase was maintained at 1 mL/min at a ratio of 60 : 40 (methanol: 0.05 M potassium dihydrogen phosphate, pH 5.8 was adjusted with triethylamine). The concentration of drug was detected by UV detector at 310 nm. The data were acquired, stored and analyzed with the software Class-VP series version 5.03 (Shimadzu).

Procedure

Working standard solution containing different concentrations of ranitidine hydrochloride and ondansetron hydrochloride were prepared in mobile phase. 20.0 μL of each solution were injected in the HPLC system to obtain the chromatogram. The AUC of ranitidine hydrochloride and ondansetron hydrochloride were recorded. The results are shown in Table-1.

TABLE-1
LINEARITY DATA FOR ESTIMATION OF RANITIDINE HYDROCHLORIDE AND ONDANSETRON HYDROCHLORIDE

Concentration (μg/mL)		AUC	
Ranitidine hydrochloride	Ondansetron hydrochloride	Ranitidine hydrochloride	Ondansetron hydrochloride
35.0	1.0	2548288.49	60491.00
75.0	2.0	5094397.00	114595.00
115.0	3.0	7616523.85	180469.00
155.0	4.0	10000649.00	242100.00
195.0	5.0	12699866.00	302586.00
Slope (m):		63024	61170
Intercept (b):		–5.462	0.05657
Correlation cofficient (r^2):		0.9997	0.9993

Estimation of ranitidine hydrochloride and ondansetron hydrochloride in combination dosage form

Twenty tablets were weighed accurately and finely powdered. Powder equivalent to 20.0 mg ranitidine hydrochloride was transferred into a 100 mL volumetric flask and dissolved in 50 mL of mobile phase and sonicated for 15 min. The solution was filtered through 0.22 μ PFTE membrane filter and washed with mobile phase and diluted up to the mark with mobile phase to give a concentration of 2.0 μg/mL of ondansetron hydrochloride and 75.0 μg/mL of ranitidine hydrochloride. This solution was injected 5 times into the column. The mean values of peak area were calculated and the drug content in the tablet dosage form was quantified using the regression equation obtained above. The results are given in Table-2.

TABLE-2
ANALYSIS OF TABLET CONTAINING RANITIDINE HYDROCHLORIDE AND ONDANSETRON HYDROCHLORIDE

Pharmaceutical formulation	Amount (mg)			
	Ranitidine hydrochloride		Ondansetron hydrochloride	
	Labelled	Found	Labelled	Found
Tablet	150.0	149.75	4.0	4.02

Recovery studies

Recovery experiments by adding known amount of ranitidine hydrochloride and ondansetron hydrochloride to the analyzed pharmaceutical preparation were carried out and results are given in Table-3.

TABLE-3
RECOVERY STUDIES

S. No.	Conc. of added drug in final dilution (μg/mL)		% Recovery	
	RAN	OND	RAN	OND
1.	60.00	1.60	100.80	99.37
2.	75.00	2.00	99.26	102.50
3.	90.00	2.40	100.11	99.16

RESULT AND DISCUSSION

The extracts of the formulation containing ranitidine hydrochloride and ondansetron hydrochloride showed no significant peaks at the retention times other than the retention times of ranitidine hydrochloride and ondansetron hydrochloride which indicate that the excipients in the tablet are not interfering in estimation by proposed method and therefore the proposed method is specific.

The values of recovery studies are shown in Table-3 indicating that the method is accurate. As the mobile phase is only a mixture of methanol and phosphate buffer, the run time is only 8 min and the flow rate of mobile phase is 1.0 mL/min.