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Validated method for the simultaneous estimation of domperidone and lansoprazole in pure and pharmaceutical dosage form by RP-HPLC

M.VijeyAanandhi*[1], N.Thiyagarajan[1], S.Sesha Panindra[1], P.Shanmugasundaram[1], R.Sujatha[2]

[1]Vel's College of Pharmacy, Chennai,Tamilnadu, (INDIA)

[2]Government College of Arts and Science for Women, Bargur,Tamilnadu, (INDIA)

Tel : 91-9840959519

E-mail : mvaanandhi@yahoo.co.in

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ABSTRACT

A novel simple, fast, accurate and precise reverse phase high performance liquid chromatographic method has been developed for the simultaneous estimation of domperidone and lansoprazole in capsule formulation. In this method, the chromatographic resolution was carried out on a Hypersil ODS C_{18} (250×4.6 mm) column by using a mobile phase containing phosphate buffer and acetonitrile (pH 7.4) in the ratio of 60:40, in an isocratic elution at a flow rate of 1.5 ml/ min. The detection of eluents was done at 302 nm. The retention time for domperidone and lansoprazole were 5.49 min and 2.10 min respectively. Linearity for domperidone was found to be in the range 40-100µg/ml and 60-140µg/ ml for lansoprazole respectively.

KEYWORDS

Domperidone;
Lansoprazole;
RP-HPLC.

INTRODUCTION

Domperidone (Dom) is chemically 5-chloro-1-[1-[3-(2-oxo-1,3-dihydrobenzoimidazol-1-yl) propyl]-4-piperidyl]-1,3-dihydrobenzoimidazol-2-one, widely used as an anti-emetic drug. Lansoprazole (Lan), chemically 2[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl] methyl suphinyl]-1H-benzimidazole is an anti-ulcer drug. Dom (10 mg) and Lan (15 mg) is available commercially as Lancer-D. On detailed literature survey, it was found that these drugs have been estimated individually and in combinations by various methods[1-10]. Besides, UV method for simultaneous estimation of this combination was reported[11]. The present works depicts simple, precise and accurate reverse phase HPLC method for simultaneous estimation of domperidone and lansoprazole in capsule formulation.

EXPERIMENTAL

Chemicals and reagents

The pure drugs were obtained as gift sample from ATOZ labs, Chennai. The capsules were procured from the local market. All other chemicals used were of HPLC grade. Label claim for domperidone and lansoprazole were 10 mg and 15 mg respectively per capsule.

Instrumentation

A Shimadzu LC system comprising pump (model: LC-20AT) with 20 ml loop, a PDA detector, (model: SPD-M20A) with class VP software (version 6.12)

TABLE 1: Accuracy

Lansoprazole and domperidone capsules				
Theortical amount (%)	Obtained (in mg)		% Recovery	
	For domperidone	For lansoprazole	For domperidone	For lansoprazole
100	100.33	100.02	100.33	100.02
110	110.08	110.24	100.07	100.21
120	120.14	120.31	100.11	100.25
	Mean % recovery		100.17	100.16
	Standard deviation		0.1400	0.12288
	% RSD		0.1397	0.12268

*RSD: Relative standard deviation

TABLE 2 : System suitability parameters

Parameter	Domperidone	Lansoprazole
Retention time	5.49	2.10
Tailing factor	2.08	1.12
Theoretical plates	6659	13312
Resolution	6.78	
% RSD	0.29	0.26

*RSD: Relative standard deviation

was used for the analysis. The column used was hypersil ODS_{18} (250×4.6 mm), the mobile phase was pumped at a flow rate of 1.5 ml/ min and the detection was performed at 302 nm. The separation was carried at an ambient temperature.

Preparation of mobile phase

Dipotassium hydrogen phosphate buffer was mixed with acetonitrile in the ratio of 60:40 v/v, which was then filtered through 0.45µ millipore membrane filter and was degassed in an ultrasonic bath before use.

Preparation of standard stock solution

An accurately weighed quantity of domperidone (50 mg) and lansoprazole (50 mg) were transferred to 100 ml volumetric flask, which was then dissolved and made up to volume with methanol and dimethylformamide (95:5) (stock solution). From this a final concentration of 100µg/ ml was made.

Preparation of working standard solution

From this stock solution varying amounts (6 ml, 8 ml, 10 ml, 12 ml, and 14 ml) of lansoprazole and domperidone (4 ml, 5 ml, 6 ml, 8 ml and 10 ml) were transferred to 10 ml volumetric flasks which was then made up to volume with methanol to give final concentrations of 60, 80, 100, 120 and 140µg/ml of lansoprazole and 40, 50, 60, 80 and 100 µg/ml of domperidone and the linearity of these drugs were recorded.

Preparation of sample

Twenty capsules were weighed accurately and the contents were removed from the capsules. The contents were crushed in to fine powder. An accurately weighed quantity of powder equivalent to 10 mg of domperidone and 15 mg lansoprazole were transferred in to a 100 ml volumetric flask and dissolved and made up to volume with methanol and dimethylformamide (95:5) to get a final concentration of 100µg/ml of domperidone and 150µg/ml of lansoprazole and the chromatogram were recorded at 302 nm.

RESULTS AND DISCUSSION

Accuracy

The accuracy of the method was determined by recovery experiments. The recovery studies were carried out three times and the percentage recovery and standard deviation of the percentage recovery were calculated and represented in Table 1. The recovery was found to be between 100% to 101% for domperidone and 100% to 101% for lansoprazole respectively. The values are given in TABLE 1.

Parameters of system suitability

The mobile phase consisting of phosphate buffer and acetonitrile in varying proportions was tried and finally ratio of 60:40 was selected because it was found to give a base line separation for the peaks of Domperidone (Rt = 5.49) and Lansoprazole (Rt =3.2). The resolution factor obtained was 6.78 for domperidone and lansoprazole. The tailing factor obtained was 2.08 for domperidone and 1.12 for lansoprazole. The precision of the method was demonstrated by interday and intraday variation studies. In the intraday and interday, five repeated injections of sample solutions were made and the percentage RSD was calculated. The data obtained for % relative standard deviation (RSD) is less than 2% for all the parameters are given in TABLE 2.

Wavelength was selected by scanning standard solution of both drugs over 200 nm to 400 nm wavelengths. Both components show reasonably good re

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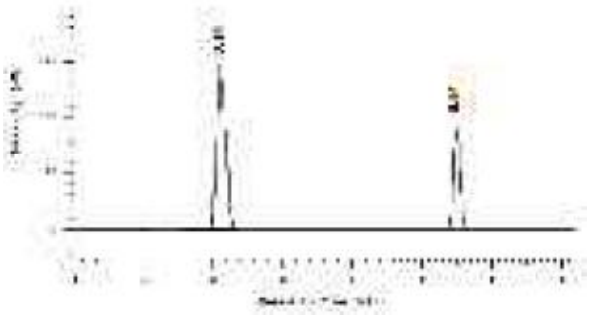

Figure 1 : Identification chromatogram of domperidone and lansoprazole sample by hplc method

sponse at 302 nm. The method was also applicable to the capsule formulation and the peaks obtained were well resolved as shown in figure 1.

The proposed RP-HPLC method was found to be simple, reliable, and precise because of the commonly used buffer, and solvents and shorter runtime. This method is of high accuracy which depicted good recovery of the drug samples and there was no interference from the excipients used for the formulation and the analysis was less time consuming. The developed RP-HPLC technique can be applied for routine quality control of combined capsule dosage form containing domperidone and lansoprazole.

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