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SHORT COMMUNICATION

SIMULTANEOUS ESTIMATION OF DOMPERIDONE AND LANSOPRAZOLE IN CAPSULE FORMULATION BY HPTLC METHOD

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ABSTRACT

A simple, fast, accurate and precise high performance thin layer chromatographic method has been developed for the simultaneous estimation of domperidone and lansoprazole in capsule formulation. This method allows the determination of 100-500 ng/spot of domperidone and 100-500 ng/spot of lansoprazole. The mobile phase composition was toluene:isopropyl alcohol:chloroform:acetonitrile (4:3:6:2). Densitometric analysis of domperidone and lansoprazole was carried out in the absorbance mode at 254 nm. The R_f values of domperidone and lansoprazole were found to be 0.22 and 0.76 respectively. The amounts of drugs present in the capsule and recovery studies were also carried out. The method was validated for precision, accuracy and reproducibility.

Key words: Domperidone, Lansoprazole, HPTLC, densitometry.

INTRODUCTION

Domperidone (Dom) is chemically 5-chloro-1-[1-[3-(2-oxo-1,3-dihydrobenzimidazol-1-yl) propyl]-4-piperidyl]-1,3-dihydrobenzimidazol-2-one, widely used as an anti-emetic drug. Lansoprazole (Lan), chemically 2[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl] methyl suphiny]-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 methods¹⁻¹⁰. Besides, UV method for simultaneous estimation of this combination was reported¹¹. The present works depicts simple, precise and accurate HPTLC method for simultaneous estimation of domperidone and lansoprazole in capsule formulation.

EXPERIMENTAL

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 analytical grade. Label claim for domperidone and lansoprazole were 10 mg and 15 mg respectively per capsule. Instrument used for the system was a Camag HPTLC system (with TLC scanner 3 and Lanomat 4 as application device). The samples were spotted in the form of bands of width 6 mm with a Hamilton syringe on a pre-coated silica gel plate 60 F₂₅₄ pre-washed with methanol. The mobile phase consisted of toluene:isopropyl alcohol:chloroform:acetonitrile (4:3:6:2). Linear ascending development of chromatogram was carried out in a Camag twin trough chamber saturated with the mobile phase. The chamber saturation time for mobile phase was optimized at 25 min. The length of chromatogram run was 85 mm. Subsequent to the development the TLC plates were dried in current of dry air. Densitometric scanning was performed using

Camag TLC scanner 3 in the absorbance mode at 254 nm. The source of radiation utilized was deuterium lamp.

An accurately weighed quantity of 100mg of Domperidone (working standard) and 150 mg of Lansoprazole (working standard) were dissolved in diluent [methanol: chloroform (1:1) taken in 10ml volumetric flask. Then the volume is made up to 10 ml with diluent to obtain a stock solution of 10000µg/ml of Domperidone and 15000µg/ml of Lansoprazole.

The linearity of an analytical procedure is its ability (within a given range) to obtain the test results which are directly proportional to the concentration of analyte in the sample. Linearity was assessed by performing single measurement at several analyte concentrations. A minimum of five concentrations recommended for linearity studies.

To evaluate the linearity range of Domperidone varying concentration of standard stock solution is diluted with mobile phase to give minimum of five concentration ranges of 600 to 1400 µg/ml of Domperidone and 900 to 2100 µg/ml of Lansoprazole respectively. A calibration curve was constructed for each sample by plotting the peak areas obtained against the concentration.

Twenty capsules are weighed and triturate the granules to powder. The powder equivalent to 100mg of Domperidone and 150mg of Lansoprazole. Make up to 100ml with methanol: chloroform (1:1), shake for 15 minute. The contents were mixed well using ultra-sonicator and filtered through Whatman filter paper number: 42.

The sample was spotted on the chromplate with help of Linomat IV spotting system. The hotplate was developed in a twin trough chamber containing the mobile phase. The chromatograms were recorded and the peak area for Domperidone and Lansoprazole were noted down (fig 1).

Table-1

SAMPLE	LABEL CLAIM (mg)	AMOUNT ESTIMATED (mg/Tab)	STANDARD DEVIATION	% RSD
DOMPERIDONE	10	9.82	0.1752	1.79
LANSOPRAZOLE	15	14.82	0.202	1.37

Table-2

Parameter	Domperidone	Lansoprazole
Resolution	1.71	
Tailing factor	1.5	0.67
Amt of std.added (mg)	1.0	1.5
Amt of drug recovered*(mg)	0.818	1.441
% Recovery	99.64	98.32

RESULTS AND DISCUSSION

The amount of Dom and Lan present in the formulation was estimated using the calibration curve for Dom and Lan. Results of analysis of formulation are tabulated in Table 1.

The method was found to be specific, since it resolved the peak of Dom (R_f value = 0.22) and Lan (R_f value = 0.76) in the presence of excipients in the formulation. The linear regression data showed good linear relationship over a concentration range of 100-500 ng/spot for Dom (0.9997) and 100-500 ng/spot for Lan (0.999). The stability and recovery studies are given in Table 2.

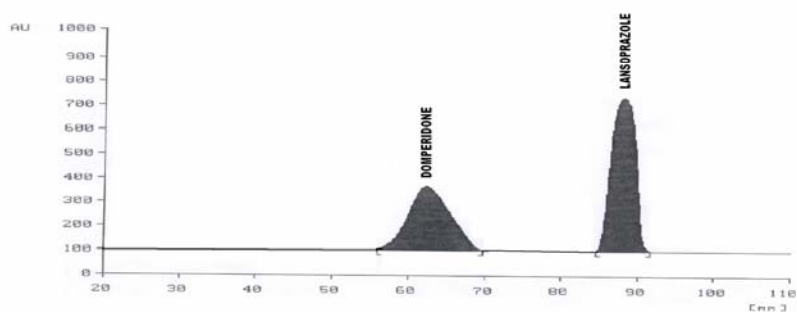
The proposed HPTLC method was found to be simple, reliable, and precise. This method is of high accuracy which depicted good recovery of the drug samples and there was no interference from the excipients used for the formulation and the analysis was less time consuming. The developed HPTLC technique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

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FIGURE 1



DENSITOGAM OF SAMPLE

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