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Spectrophotometric and HPTLC Method for Simultaneous Estimation of Pantoprazole and Domperidone in Their Pharmaceutical Preparations

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A simple, rapid, spectrophotometric and HPTLC method has been developed for the simultaneous estimation of pantoprazole and domperidone in their pharmaceutical preparations. Developed spectrophotometric method employs simultaneous equations method to estimate both the drugs in the formulation. Pantoprazole and domperidone showed maximum absorbance at 331 and 284 nm, respectively. Pantoprazole and domperidone obeyed Beer Lambert's law in the concentration ranges from 10–50 and 10–50 μg/mL, respectively. In HPTLC method, the mobile phase consists of acetone : toluene : methanol : glacial acetic acid (2 : 8 : 2 : 0.1) using a precoated silica gel 60 F_{254} TLC plate. The plate was scanned by computer controlled HPTLC scanner with Camag Cats software and quantified at 298 nm. Both the methods were found to be precise and accurate and can be adopted in routine analysis of drugs in formulation.

Key Words: Pantoprazole, Domperidone, Spectrophotometry, HPTLC.

INTRODUCTION

Pantoprazole (PAN) is a proton pump inhibitor. It is an anti-ulcerative drug and used in the treatment of peptic ulcer and gastro-oesophageal reflux diseases. It causes irreversible inhibition of proton pump (H^+K^+ ATPase) function. It is rapidly activated under strongly acidic condition. It is official in Martindale Extra Pharmacopoeia. The other reported methods for estimation of pantoprazole were HPLC[1], RP-HPLC[2] for determination of enantiomer, capillary electrophoresis[3] and difference spectroscopy[4].

Domperidone (DOM) comes under the categories of prokinetics agent. It is peripheral dopamine antagonist. It is used as anti-emetic for the short-term treatment of nausea and vomiting of various etiologies including that associated with cancer therapy. It is official in British Pharmacopoeia[5]. Chemically it is 5-chloro-1-[1{3-(2,3-dihydro-2-oxo-1H-benzimidazole-1-yl)propyl}-4-piperidinyl]-1,3-dihydro-2H-benzimidazole-2-one.The other reported methods for estimation of domperidone alone as well as in combination with other drugs were

HPLC[6,7], HPTLC[8,9], first derivative UV spectrophotometry[10] and extractive spectrophotometry[11,12].

In the present communication, the proposed method is suitable for the estimation of drugs in standard laboratory mixture as well as for marketed preparation and found to yield better results.

EXPERIMENTAL

The instrument used in the present study was Shimadzu UV 2401 double beam spectrophotometer with 1.0 cm matched pair quartz cells for spectrophotometric study and Camag HPTLC system comprising Camag Linomat IV automatic sample applicator, Camag TLC Scanner III and CATS 4.0 software for interpretation of the data for HPTLC. The chemicals and reagents used in this work were of AR and HPLC grade.

Spectrophotometric method

Standard stock solutions of PAN and DOM were prepared by dissolving 50 mg of each drug in methanol in 100 mL volumetric flask. Working solutions were prepared by pipetting 2.0 mL of the PAN and DOM stock solution into two separate 100 mL volumetric flasks and diluted up to the mark with 0.1 M HCl. The two solutions were scanned between the wavelengths 200–400 nm, separately. The λ_{max} for PAN and DOM were found to be 331 and 284 nm, respectively (Fig. 1). From standard stock solution, further dilutions were made to get concentration in the range of 10–90 µg/mL for PAN and 10–80 µg/mL for DOM. These solutions were read at two fixed wavelengths to obtain the absorbance. The calibration curves were obtained by plotting concentration *vs.* absorbance of each drug.

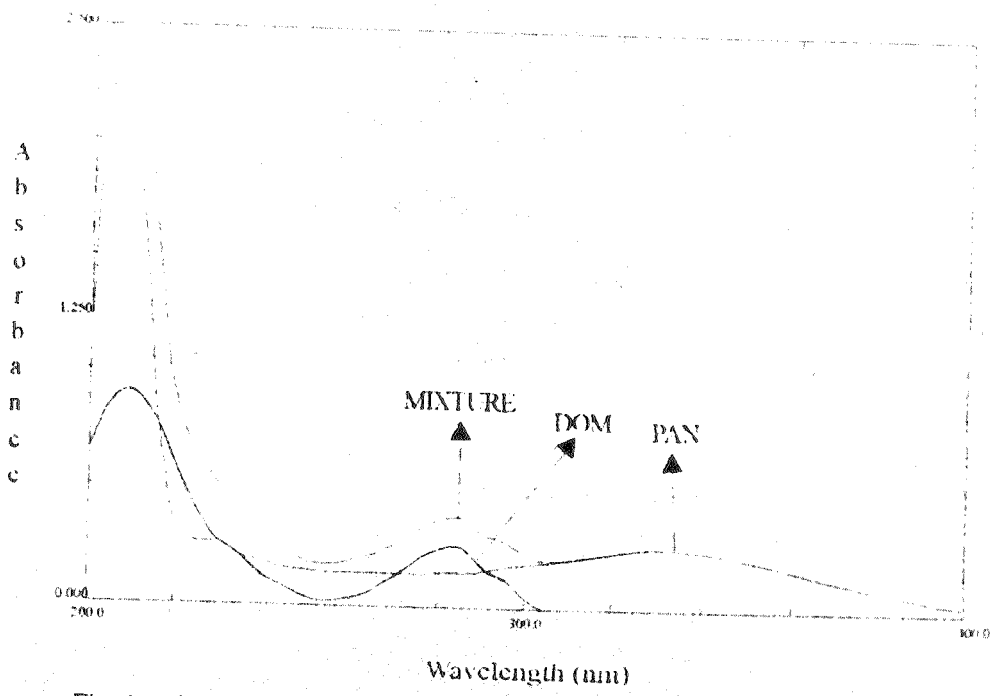

Fig. 1. Overlain spectra of pantoprazole, domperidone and its mixture

HPTLC determination

Standard solutions of PAN and DOM were prepared by dissolving 20 mg of PAN and 10 mg of DOM in 25 mL of methanol and volume was made up to 50 mL with the same solvent. From this stock solution 5 µL were applied on precoated TLC

silica gel 60 F_{254} plate using a Camag Linomat IV automatic sample applicator. The plate was developed using acetone : toluene : methanol : glacial acetic acid (2 : 8 : 2 : 0.1) as a mobile phase in a twin trough chamber. The proposed mobile phase shows good resolution of both the components in their mixture (Fig. 2). The saturation time was 15 min., temperature controlled at 20 ± 5°C with 50–60% relative humidity, migration distance of 70 mm, scanning mode of absorbance with detection wavelength at 298 nm. The selection of wavelength was based on nearly equal absorbance by both the components. After removal of the plate from the chamber, it was dried and scanned and peak height/area were recorded.

The mixed standard solutions ranging from 1–10 µL were applied on TLC plate by microlitre syringe with the help of automatic sample applicator. The plates were developed in twin trough glass chambers. After development, they were immediately dried and densitometrically scanned at 298 nm. Peak height and area were recorded for each concentration of drugs and curves of concentration against peak height/area were plotted. The standard curve was found to be linear between concentration range 2.0–3.6 µg/µL for PAN and 1.0–1.8 µg/µL for DOM.

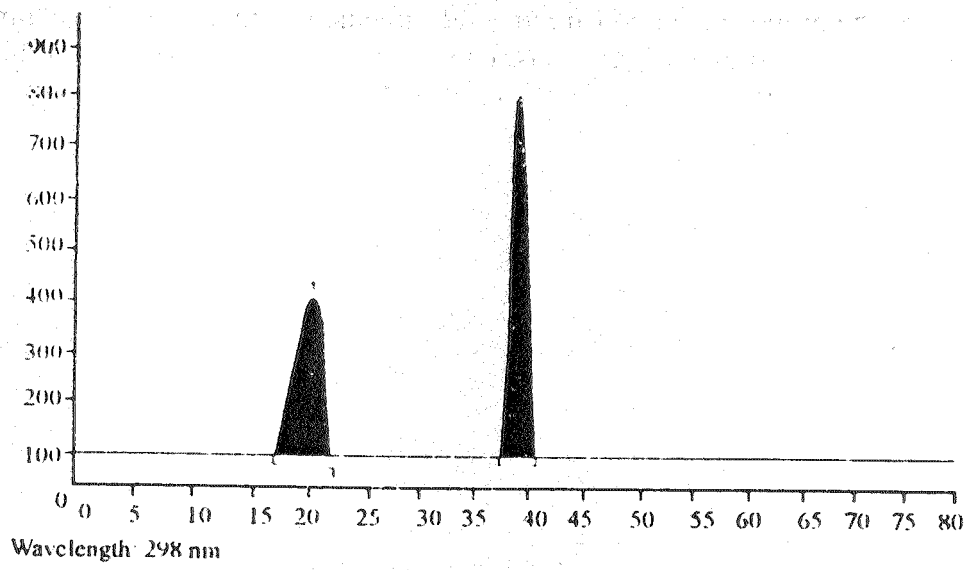

Fig. 2. Densitogram of pantoprazole and domperidone

Estimation of PAN and DOM in Capsules

Twenty capsules were weighed and powdered .The powder equivalent to 50 mg of PAN was taken in a 100 mL volumetric flask and 50–60 mL of methanol was added. The flask was shaken for 15 min and volume was made up to the mark with the same solvent. The solution was then filtered through Whatman No. 1 filter paper and filtrate was used as sample solution. 10 mL of this solution was pipetted out in 100 mL volumetric flask and volume was made up to the mark with 0.1 M HCl. Standard solutions were prepared from stock solutions by diluting 10 mL of PAN and 5 mL of DOM stock solution in 100 mL volumetric flask and volume was made up to the mark with 0.1 M HCl. The absorbance of standard and sample solutions was read at 331 and 284 nm.

In method II, a powder equivalent to 20 mg of PAN was transferred to a 50 mL volumetric flask and 25 mL methanol was added. The flask was shaken for 15 min

and volume was made up to the mark with the same solvent. The solution was then filtered through Whatman No.1 filter paper and filtrate was used as sample solution. The same volume (7 μL) of standard and sample solution was applied on precoated silica gel 60 F_{254} TLC plate. The plate was developed and scanned as mentioned above. The peak areas and heights were recorded. The amount of PAN and DOM present in formulations was estimated. The results of analysis of two different brands of formulation are tabulated in Table-1.

The validation of the proposed method was carried out for precision, accuracy, specificity and ruggedness. The recovery studies were performed using the "standard addition" method. A known concentration of the standard PAN and DOM were added to preanalyzed capsules solution and quantified as mentioned above. The results of recovery study are given in Table-1.

RESULTS AND DISCUSSION

Both the methods were found to be simple, rapid, accurate and precise for routine simultaneous analysis of PAN and DOM in their pharmaceutical preparations. From Table-1, it is evident that in each formulation, PAN and DOM amounts obtained by the proposed method are in good agreement with the labelled claimed. Further, recovery studies also gave satisfactory results, which proved the validity of the method. Hence, the proposed method can be used for the routine analysis of the two drugs in their pharmaceutical preparations.

TABLE-1
RESULT OF MARKETED FORMULATIONS AND RECOVERY STUDIES BY PROPOSED METHOD

Method	Maketed preparation	Ingredient & label claim (mg/caps)	Label claim estimated* (%) ± SD	RSD (%)	Recovery† (%)	RSD (%)
I	A	PAN-20	99.66 ± 0.573	0.577	99.83 ± 1.459	1.461
		DOM-10	98.69 ± 0.604	0.613	99.90 ± 1.089	1.090
	B	PAN-20	98.41 ± 0.540	0.549	99.20 ± 0.850	0.857
		DOM-10	99.25 ± 1.410	1.421	100.14 ± 1.033	1.031
II	A	PAN-20				
		Height	99.14 ± 0.841	0.849	99.67 ± 0.628	0.630
		Area	99.22 ± 1.113	1.122	99.62 ± 0.731	0.741
		DOM-10				
		Height	100.52 ± 0.372	0.370	100.58 ± 1.167	1.161
		Area	99.45 ± 1.086	1.092	99.49 ± 1.820	1.829
	B	PAN-20				
		Height	99.31 ± 0.690	0.695	99.32 ± 0.515	0.518
		Area	99.63 ± 0.941	0.914	99.01 ± 0.526	0.531
		DOM-10				
		Height	99.51 ± 1.404	1.411	101.02 ± 1.322	1.308
		Area	100.58 ± 1.335	1.327	100.06 ± 0.880	0.880

*Mean of five readings. †Mean of six readings.

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