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VALIDATED HPTLC METHOD FOR SIMULTANEOUS ESTIMATION OF DOMPERIDONE IN COMBINATION WITH RABEPRAZOLE SODIUM IN SOLID DOSAGE FORM

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ABSTRACT

The present work describes high performance thin layer chromatographic method for simultaneous estimation of domperidone in combination with rabeprazole sodium in capsule formulation. Chromatography was performed on (10 ×10 cm) silica gel F_{254} TLC plates using mobile phase toluene : methanol (9 : 1 v/v) with 15 min time of saturation with filter paper. Chromatographic conditions were found to effectively separate domperidone (R_f = 0.12 ± 0.0041) and rabeprazole sodium (R_f = 0.17 ± 0.0052). Standard calibration curve was found to be linear in the range 0.06-0.3 µg/spot for domperidone and 0.04-0.2 µg/spot for rabeprazole sodium,, respectively. The proposed method was found to be accurate, precise, reproducible, economic, reliable and specific and can be used for simultaneous analysis of these drugs in capsule formulation.

Key words : Domperidone, Rabeprazole sodium, HPTLC.

INDRODUCTION

Domperidone (DOM) is 5-chloro-1-[1-{3-(2-oxo-2, 3-dihydro-1H-benzimidazol-1-yl) propyl}-piperidin-4-yl]-1, 3-dihydro-2H-benzimidazole-2-one and Rabeprazole sodium (RAB) is 2-[{4-(3-methoxy propoxy) 3-methyl-2-pyridinyl) methyl} sulfinyl] 1H-benzimidazole sodium salt.

Domperidone is an antiemetic drug usually given in combination with either rabeprazole or esomeprazole,, respectively. The combination is useful in treatment of Gastro Esophageal Reflux Disease (GERD). The marketed capsule formulations contain domperidone and rabeprazole sodium in the ratio 3 : 2 (Rablet D, domperidone 30 mg and

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rabeprazole sodium 20 mg, manufactured by Heterolabs limited).

Literature survey revealed Spectrophotometric[3] and RPHPLC [4-7] methods for estimation of domperidone alone and in combination with other drugs in pharmaceutical preparations.

Rabeprazole sodium alone and in combination with other drugs is also reported to be estimated by RPHPLC[8] method.

So far, very few analytical methods are reported for simultaneous determination of domperidone with rabeprazole sodium in pharmaceutical formulation. The present work describes validated HPTLC method for simultaneous determination of these drugs in capsule formulation.

EXPERIMENTAL

Materials and method

Instuments

CAMAG HPTLC system comprising of

(i) CAMAG Linomat V semiautomatic sample applicator,

(ii) Hamilton syringe 100 μL

(iii) CAMAG TLC Scanner 3,

(iv) CAMAG twin trough chamber (10 × 10 cm) and

Sonicator

Pure drug samples of domperidone and rabeprazole sodium were procured from Abbott Pharma, Mumbai, India and Aristo Pharma, Daman, India, respectively. Silica gel 60 F_{254} TLC plates (10 × 10 cm) with thickness 0.25 mm, (E. Merck, Mumbai) were used as stationary phase. All chemicals and reagents used were of analytical grade.

The capsule formulation Rablet D (manufactured by Heterolabs limited), with a labeled claim of 30 mg domperidone and 20 mg rabeprazole sodium, respectively, were obtained from local drug stores.

Standard preparation

Accurately weighed quantity of domperidone (30 mg) and rabeprazole sodium

(20 mg) was weighed and transferred to a standard 100 mL volumetric flask, dissolved and diluted to the mark with methanol. The so prepared stock solution was further diluted with mobile phase to get concentration range of 60-300 ng/spot and 40-200 ng/spot for domperidone and rabeprazole sodium,, respectively. Plotting a graph of peak area vs. concentration allowed the checking of linearity of detector response.

HPTLC Method and chromatographic conditions

TLC plates were prewashed with methanol. The chromatographic conditions maintained were precoated silica gel 60 F_{254} aluminium sheets (10 × 10 cm) as stationary phase, toluene : methanol (9 : 1v/v) as mobile phase. Chamber saturation time was kept 15 minutes and migration distance allowed was 80 mm, wavelength scanning was done at 287 nm keeping slit dimension at 6.0 × 0.3 mm.

Analysis of marketed formulation

About 6 micro liters of sample solutions of marketed formulation were spotted on to TLC plate and developed. The analysis was repeated in triplicate. The content of drug was calculated from peak area recorded.

Recovery studies

To study the accuracy of proposed method, recovery experiments were carried out. About 6 µL of sample solution was applied as 6 mm bands. These were then spiked with 5, 6 and 7 µL of standard solution of each drug. Peak areas were recorded.

Validation of method

The developed method was validated in terms of linearity, accuracy, limit of detection, limit of quantitation, interday and intraday precision.

RESULTS AND DISCUSSION

A solvent system that would give dense and compact spots with significant R_f values was desired for quantification of domperidone and rabeprazole sodium.

The mobile phase consisting of toluene : methanol (9 : 1 v/v) gave R_f values of 0.12 ± 0.0041 for domperidone and 0.17 ± 0.0052 for rabeprazole sodium, respectively. The linear regression data (n = 5) showed good linear relationship over a concentration range of 60-300 ng/spot for domperidone and 40-200 ng/spot for rabeprazole sodium, respectively.

To confirm specificity of proposed method, the solution of formulation was spotted on the TLC plate, developed and scanned. It was observed that the excipients present in the formulation did not interfere with the peaks of domperidone and rabeprazole sodium. Validation of the developed method was carried out by using validation parameters.

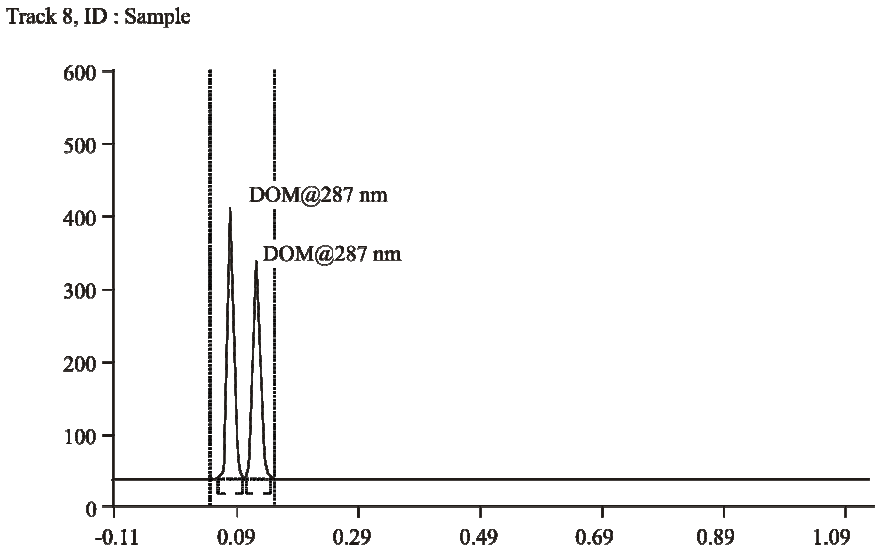

Fig. 1 : Chromatogram of domperidone [R_f 0.09] and rabeprazole sodium [R_f 0.18] in marketed formulation

CONCLUSION

The proposed HPTLC method is simple, precise, accurate, reliable, economic and validated and can be used for routine analysis of these drugs in quality control laboratory.

Table 1 : Results of analysis of capsule formulation

Capsule formulation	Label claim (mg/capsule)		Amount of drug estimated(mg)		% of label claim* ± SD	
	DOM	RAB	DOM	RAB	DOM	RAB
Rablet D	30	20	30.054	19.98	100.18 ± 0.59	99.89 ± 0.76

*Mean of six determinations

Table 2 : Results of recovery studies

Solution of pure drug spiked each (µL)		% of drug found on preanalysed basis		% recovery	
DOM	RAB	DOM	RAB	DOM	RAB
5	5	100.81	100.15	99.26	99.48
6	6	101.01	100.68	99.37	99.15
7	7	100.25	99.86	99.66	100.11

Table 3 : Method validation parameters

Parameter	DOM	RAB
Accuracy : Recovery studies	99.43 % ± 0.52	99.58 % ± 0.48
Precision (RSD, n = 6)	0.0059	0.0076
Linearity and range	60-300 ng/spot	40-200 ng/spot
Regression equation	y = 17863x + 9.908	y =26232x - 12.714
Slope (m)	17863	26232
Intercept (c)	9.908	12.714
Correlation coefficient (r^2)	0.9996	0.9998
Limit of detection (ng)	0.3115	0.2102 ng
Limit of quantitation (ng)	0.9345	0.6306
Intraday precision (RSD, n =3)	0.0091	0.0023
Interday precision (RSD, n=3)	0.0082	0.0051
Different analysts (RSD, n=3)	0.0049	0.0077

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