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SIMULTANEOUS ESTIMATION OF LANSOPRAZOLE AND DOMPERIDONE IN TABLET DOSAGE FORM BY RP-HPLC

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ABSTRACT:
A RP-HPLC method has been developed in order to develop a new analytical method for simultaneous estimation of Lansorazole and Domperidone by RP-HPLC. It is a specific blocker of dopamine receptors. It speeds gastrointestinal peristalsis, causes prolactin release, and is used as antiemetic and tool in the study of dopaminergic mechanisms. It acts as a gastrointestinal emptying (delayed) adjunct and peristaltic stimulant. Lansoprazole is a proton pump inhibitor which prevents the stomach from producing acid. It is manufactured by TAP pharmaceutical products.
Column: Xterra C18 (4.6 x 250mm, 5µm, Make: Waters)] was used to analyse LNP and DMP using Phosphate buffer (0.05M) pH 4.6: ACN (55:45%v/v) as mobile phase. The detection was carried out at274with flowrate 1ml/min.The retention times obtained for LNP and DMP were 2.399mins and 3.907mins respectively. Linearity obtained was within the range of 1µg-5µg for Lansoprazole and 100µg-500µg for Domperidone and the Regression Co-efficient obtained was of 0.999 for both drugs. The detection was done using PDA detector at ambient temperature. The proposed method was validated for all the validative parameters and were found to be good accordance with ICH guidelines. Hence the developed method can be successfully applied for simultaneous estimation of Lansoprazole and Domperidone in routine analysis

Keywords: RP-HPLC, Lansoprazole (LNP), Domperidone (DMP)

INTRODUCTION

Domperidone chemically is 5-chloro-1-{1-[3-(2-oxo-2, 3-dihydro-1H-1, 3-benzodiazol-1-yl) propyl] piperidin-4-yl}-2, 3-dihydro-1H-1, 3-benzodiazol-2-one which is used as specific blocker of dopamine receptors. It speeds gastrointestinal peristalsis, causes prolactin release, and is used as antiemetic and tool in the study of dopaminergic mechanisms. Lansoprazole chemically is 2-({[3-methyl-4-(2, 2, 2-trifluoroethoxy) pyridin-2-yl] methane} sulfinyl)-1H-1, 3-benzodiazole and used as a proton pump inhibitor which prevents the stomach from producing acid [1-2].

Literature survey reveals that there are methods to analyse these drugs by spectroscopic methods [3-4], in tablet [5-16], in plasma [17-18].There are no methods reported in tablets using Buffer and Acetonitrile as solvent which is cost effective.

Hence an attempt is made to develop simple, Accurate and Precise and cost effective method [19-20] for simultaneous estimation of Lansoprazole and Domperidone by RP-HPLC in tablet dosage form according to ICH guidelines [21].

EXPERIMENTAL:

Table No1: instruments employed for the present work

S.No.	Instrument	Model No.	Software	Manufacturer's name
1	HPLC Alliance PDA Detector	Waters 2695 Waters 996	Empower	Waters
2	UV double beam spectrophotometer	UV 3000	UV Win 5	Lab India
3	Digital weighing balance	BSA224SCW	-	Satorius
4	pH meter	AD102U	-	Lab India
5	Ultra sonicator	SE60US	-	-
6	Suction pump	VE115N	-	-

Table No 2: The reagents used for the resent study

S.No.	Chemical	Manufacturer	Grade
1	Water	Merck	HPLC Grade
2	Methanol	Merck	HPLC Grade
3	Acetonitrile	Merck	HPLC Grade
4	Potassium dihydrogen fed orthophosphate	Merck	A.R
5	Lansoprazole & Domperidone API	-	-
6	Eurepa mf tablets	Local Pharmacy	-

ANALYTICAL METHOD DEVELOPMENT:

Method development for simultaneous estimation of Lansoprazole and Domperidone in Pharmaceutical dosage forms includes the following steps:

1. Selection of detection wavelength (λ_{max})
2. Selection of column
3. Selection of mobile phase
4. Selection of flow rate
5. Preparations and procedures

1. Selection of Detection wavelength:

10 mg of Lansoprazole and Domperidone was dissolved in mobile phase. The solution was scanned from 200-400 nm the spectrum was obtained. The overlay spectrum was used for selection of wavelength for Lansoprazole and Domperidone. The isobestic point was taken at 255nm as detection wavelength. The overlay spectrum is in the figure-1.

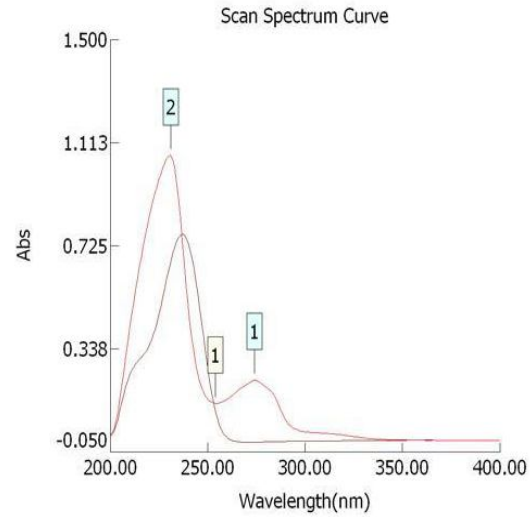

Figure No 1: Overlay spectrum of Lansoprazole and Domperidone

2. Selection of column:

Column is selected based on solubility, polarity and chemical differences among Analytes.Column selected for present study is [Column: Xterra C18 (4.6 x 250mm, 5µm, Make: Waters)]

3. Selection of mobile phase:

Phosphate buffer (0.05M) pH 4.6: ACN (55:45%v/v) has been selected as mobile phase. Buffer pH should be between 2 to 8. If the buffer pH is below 2 siloxane linkages are cleaved. If the buffer pH is above 8 dissolution of silica takes place. pH controls the elution properties by controlling the ionization characteristics. It also decreases the retention and improves separation. Good Response, Area, Tailing factor, Resolution will be achieved.

4. Selection of flow rate:

Flow rate selected was 1ml/min

Flow rate is selected based on

1. Retention time
2. Column back pressure
3. Peak symmetry
4. Separation of impurities.

Assay Calculations for Lansoprazole and Domperidone.

The assay study was performed for the Lansoprazole and Domperidone. Each two injections of sample and standard was inject into chromatographic system and results are in table-3

VALIDATION OF PROPOSED METHOD:

The % purity of Lansoprazole and Domperidone in pharmaceutical dosage form was found to be 100.7% and 101.4% respectively.

Validation results.

1. Accuracy:

The accuracy study was performed for 50%, 100% and 150 % for Lansoprazole and Domperidone. Each level was injected in triplicate into chromatographic system. The area of each level was used for calculation of % recovery and results are listed in table-4

2. PRECISION:

Precision was performed for five injections of Lansoprazole and Domperidone. Each standard was injected into chromatographic system. The area of each Standard injection was used for calculation of % RSD and results are listed in table-5

RP-HPLC DATA OF DRUGS

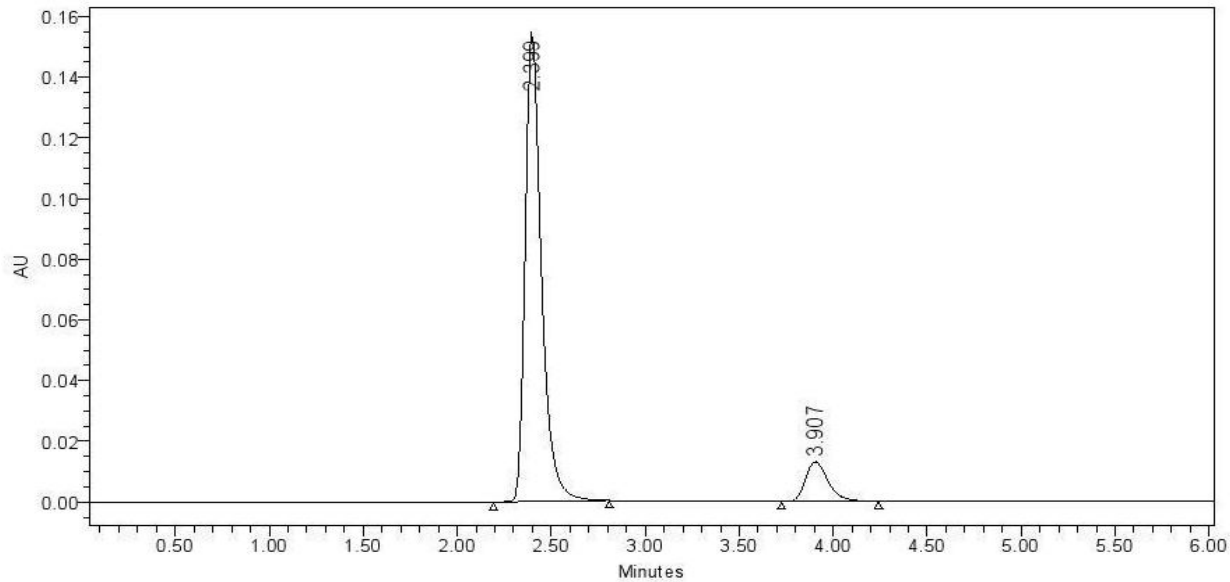

Figure No: 2 RPHPLC Chromatogram of Standard Lansoprazole and Domperidone

Table No 3: Calculations for Lansoprazole and Domperidone

Name : Lansoprazole

	Name	RT	Area	USP Plate Count	USP Tailing	USP Resolution
1	Lansopra	3.525	810802	3527.8	1.0	2.4
2	Lansopra	3.528	808790	3566.2	1.0	2.3
Mean			809796	3547.0	1.0	
Std. Dev.			1422.2			
% RSD			0.18			

Name : Domperidone

	Name	RT	Area	USP Plate Count	USP Tailing
1	Domperi	2.984	681469	3115.4	1.1
2	Domperi	2.989	683696	3209.7	1.1
Mean			682582	3162.5	1.1
Std. Dev.			1575.2		
% RSD			0.23		

Table No 4: Accuracy results of Lansoprazole

% Concentration (at specification level)	Area	Amount Added(mg)	Amount Found(mg)	% Recovery	Mean Recovery
50%	644765	5	5.0	101.3%	
100%	803722	10	9.94	99.4%	100.0%
150%	962917	15	14.8	99.2%	

Table No 5: Calculation of % RSD

Name : Lansoprazole

	Name	RT	Area
1	Lansopra	3.557	819305
2	Lansopra	3.547	807157
3	Lansopra	3.544	804070
4	Lansopra	3.537	808474
5	Lansopra	3.534	804505
Mean			808702
Std. Dev.			6203.7
% RSD			0.77

Name : Domperidone

	Name	RT	Area
1	Domper	3.019	691143
2	Domper	3.011	685431
3	Domper	3.004	683543
4	Domper	2.997	683564
5	Domper	2.994	683532
Mean			685443
Std. Dev.			3289.7
% RSD			0.48

The Method precision study was performed for the %RSD of Lansoprazole and Domperidone was found to be 0.7 and 0.4 (NMT 2).

3. Intermediate precision/Ruggedness

The intermediate precision study was performed for five injections of Lansoprazole and Domperidone. Each standard injection was injected into chromatographic system. The area of each standard injection was used for calculation of %RSD

Table No 6: Intermediate precision/Ruggedness of Lansoprazole and Domperidone

Name: Lansoprazole

	Name	RT	Area
1	Lansopr	3.524	813507
2	Lansopr	3.533	817673
3	Lansopr	3.533	815189
4	Lansopr	3.517	815816
5	Lansopr	3.530	815356
Mean			815508
Std. Dev.			1492.7
% RSD			0.18

Name: Domperidone

	Name	RT	Area
1	Domper	3.001	673725
2	Domper	3.009	672535
3	Domper	3.010	676216
4	Domper	2.997	679037
5	Domperr	3.007	677101
Mean			675723
Std. Dev.			2611.5
% RSD			0.39

The intermediate precision was performed for %RSD of Lansoprazole and Domperidone was found to be 0.18 and 0.39 respectively (NMT 2).

4. Specificity:

The system suitability for specificity was carried out to determine whether there is any interference of any impurities in retention time of analytical peak. The study was performed by injecting blank.

Injection Detection of limit:

LOD's can be calculated based on the standard deviation of the response (SD) and the slope of the calibration curve (S) at levels approximating the LOD according to the formula. The standard deviation of the response can be determined based on the standard deviation of y-intercepts of regression lines

Linearity:

The linearity study was performed for the concentration of 100ppm to 500ppm and1ppm to 5ppm level. Each level was injected into chromatographic system. The area of each level was used for calculation of correlation coefficient

The linearity study was performed for concentration range of 1µg - 5µg and 100µg-500µg of Lansoprazole and Domperidone and the correlation coefficient was found to be 0.999 and 0.999(NLT 0.999).

Table No 6: Linearity results of Domperidone

S.No	Linearity Level	Concentration	Area
1	I	100ppm	226418
2	II	200ppm	432920
3	III	300ppm	677256
4	IV	400ppm	869825
5	V	500ppm	1095759
Correlation Coefficient			0.999

Acceptance Criteria:
Correlation coefficient should be not less than 0.999

Linearity Results (for Lansoprazole):

Table No 7: Linearity results of Lansoprazole

S.No	Linearity Level	Concentration	Area
1	I	1ppm	277182
2	II	2ppm	521695
3	III	3ppm	808274
4	IV	4ppm	1033875
5	V	5ppm	1285804
Correlation Coefficient			0.999

Acceptance Criteria:
Correlation coefficient should be not less than 0.999.

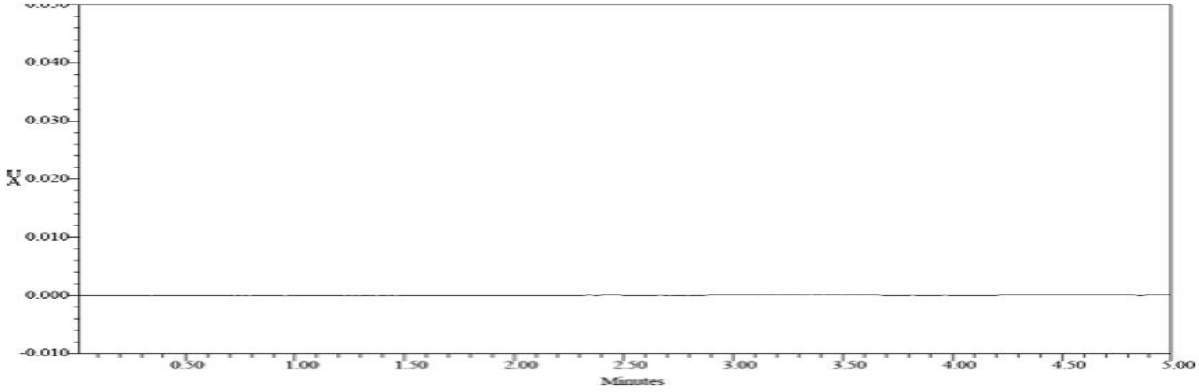

Figure No 3: Chromatogram of Blank

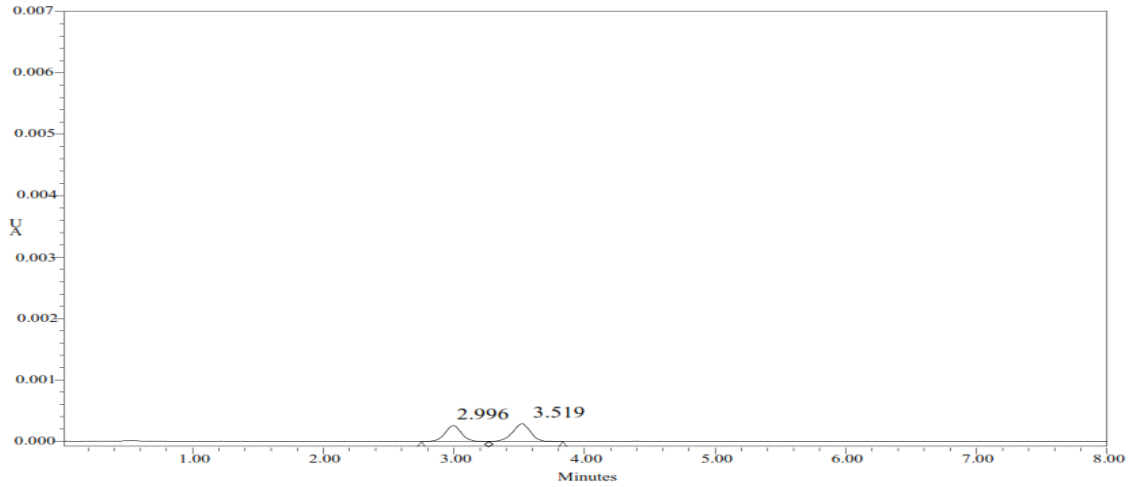

Figure No 4: Chromatogram of LOD Quantitation Limit

The LOD was performed for Lansoprazole and Domperidone was found to be 2.95and 3.04 respectively.

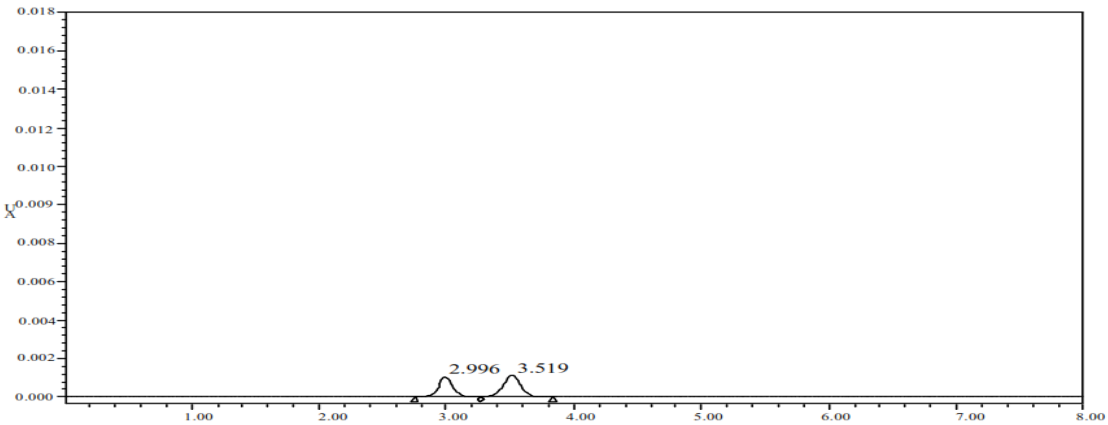

Figure No 5: Chromatogram of LOQ

The LOQ was performed for Lansoprazole and Domperidone was found to be 9.87 and 10 respectively**.**

Plotting of calibration graphs:
The resultant areas of linearity peaks are plotted against Concentration

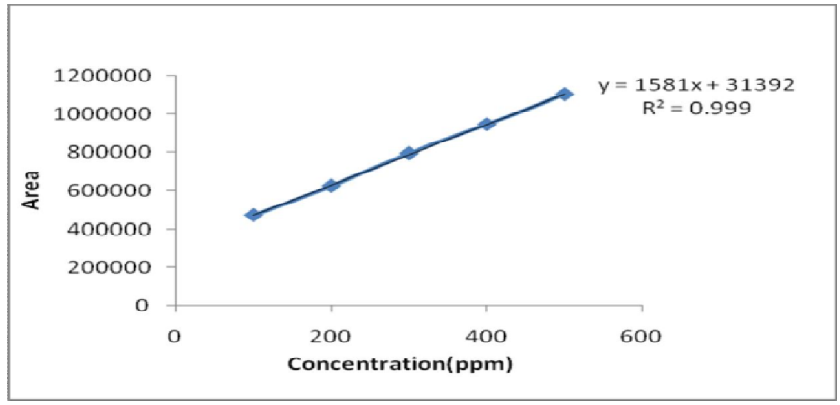

Figure No 6: Calibration curve of Domperidone

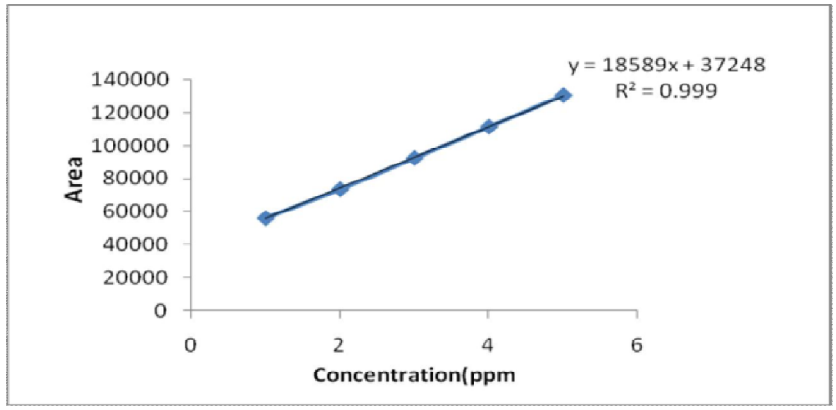

Figure No 7: Calibration curve of Lansoprazole

Conclusion:

An attempt was made in order to develop a simple, accurate and cost effective analytical method to simultaneously estimate Domperidone and Lansoprazole in tablet dosage form by RP-HPLC using Phosphate buffer and Acetonitrile in 45:55 ratios. The method was found to be accurate, precise and robust. Linearity studies were done in which Regression co-efficient was 0.999 for both drugs. The method was validated according to ICH guidelines and RSD, %RSD were less than one which states that the proposed method was in fair agreement. Hence the proposed method can be used for routine analysis of Domperidone and Lansoprazole in Pharmaceutical preparations.

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