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ESTIMATION OF DOMPERIDONE AND PANTOPRAZOLE SODIUM BY AREA UNDER CURVE METHOD

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ABSTRACT

Background: A simple, accurate, rapid and precise spectrophotometric method has been developed for simultaneous estimation of Pantoprazole and Domperidone in pharmaceutical dosage form. **Method:** This method was based on UV spectrophotometric determination of two drugs, using Area under Curve method. It involves measurement of area under curve in the range of 268-278 nm (For Pantoprazole) and 276-290 nm (For Domperidone) for the analysis in methanol. **Result:** The linearity was observed in the concentration range of 2-12 µg/ml for Lafutidine and 3-18 µg/ml for Domperidone. The method showed good reproducibility and recovery with % RSD less than 2. Method was found to be rapid, specific, precise and accurate, can be successfully applied for the routine analysis of Lafutidine and Domperidone in bulk, and combined dosage form without any interference by the excipients. The method was validated according to ICH guidelines.

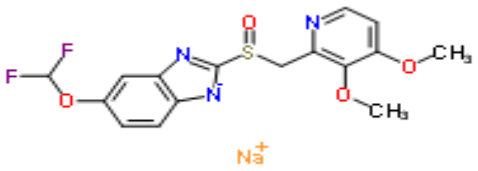
KEYWORDS: Domperidone and Pantoprazole sodium, Ultraviolet spectrophotometry, Area Under Curve method.

INTRODUCTION

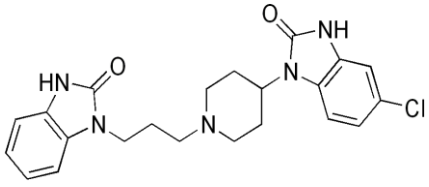
Domperidone acts as a gastrointestinal emptying adjunct and peristaltic stimulant. The gastroprokinetic properties of domperidone are related to its peripheral domperidone receptor blocking properties. Domperidone facilitates gastric emptying and decreases small bowel transit time by increasing esophageal and gastric peristalsis and by lowering esophageal sphincter pressure.The antiemetic properties of domperidone are related to its dopamine receptor blocking activity at both the chemoreceptor trigger zone and at the gastric level. It has strong affinities for both D2 and D3 receptor, which are found in chemoreceptor trigger zone, located just outside the blood brain barrier, which among others- regulaets nausea and vomiting. Chemically it is 5-chloro-1-{1-[3-(2-oxo-2,3-dihydro-1H1,3-benzodiazol-1yl)propyl]piperidin-4-yl}-2,3-dihydro-1H-1,3-enzodiazol-2-one.

Domperidone (Motilium™) is a drug that has, as a side effect, stimulating or increasing milk production, probably by increasing prolactin production by the pituitary gland. Prolactin is the hormone that stimulates the cells in the mother's breast to produce milk. Domperidone increases prolactin secretion indirectly, by interfering with the action of dopamine whose action is to decrease the secretion of prolactin by the pituitary gland. Domperidone is generally used for disorders of the gastrointestinal tract (gut) and has not been released in Canada for use as a stimulant for milk production.

Pantoprazole sodium sesquihydrate is widely used as anti-ulcer drugs (proton pump inhibitors) through inhibition of hydrogen-potassium adenosine triphosphatase (H+/ K+ -ATPase) in gastric parietal cells. Pantoprazole (PNT) reduces the gastric acid secretion regardless of the nature of stimulation. Chemically PNT is Sodium 5-(difluoromethoxy)-2-[(RS)-[3,4,-dimethoxy pyridine-2-yl) methyl]sulphinyl] benzimidazole-idesesquihydrate.



Pantoprazole sodium.



Domperidone HCl.

MATERIALS AND METHODS

Instrument

A Shimadzu UV-1700 UV/VIS Spectrophotometer was used with 1 cm matches quartz cell.

Materials

Gift samples of Pantoprazole sodium and Domperidone were procured from Emcure Pharmaceutical LTD, Pune. Tablets containing both drugs i.e. Pantoprazole sodium and Domperidone were purchased from local pharmacy of commercial brand Domfast DT.

Apparatus

Jasco model V-530 UV-Visible double beam spectrophotometer with single monochromator with spectra manager software, and Perkin Elmer UV-Visible double beam spectrophotometer with UV Winlab Software were used. Sartorius ADD-BL-02 balance was used. Calibrated glasswares were used for the study. Trans-o-sonic ultrasonicator, 0.45 µ filter papers (PVDF/Nylon filters) also used.

Selection of solvent

Methanol was selected as the solvent for dissolving Pantoprazole sodium and Domperidone.

Preparations of drug stock solutions

Stock solution of Pantoprazole sodium and Domperidone were prepared separately by dissolving 10 mg of Pantoprazole sodium and 10 mg of Domperidone in 50 ml of Methanol. Then the volume was made up to the mark with methanol to give the drug stock solution of concentration 100 µg/mL.

Preparations of working standard solutions

From the stock solution of Pantoprazole sodium and Domperidone, appropriate volumes were pipetted out and transferred to 10 ml volumetric flasks. The volume was made up to the mark with methanol to give the samples of desired concentrations like 2, 4, 6, 8, 10, 12 µg/mL.

Determination of λmax

Both the standard solutions were scanned separately between 400 nm to 200nm. The overlain spectrum of both drugs was recorded, Fig. 3; from the overlain spectrum, two wavelengths 290 nm (λmax of Pantoprazole sodium) and 286 nm (λmax of Domperidone) were selected for estimation of drugs.

Selection of analytical wavelength range (Area under the curve) for analysis

Suitable concentrations of solutions were prepared accurately to determine the range of Domperidone for analysis. The standard solutions were scanned in the spectrum mode of the instrument from 400 nm to 200 nm. The absorbance maxima of these solutions were obtained at wavelength 286 nm. The area under the curve between 276 nm to 290 nm was selected (Fig3.) for domperidone and 292 nm -310 nm was selected for Pantoprazole sodium because the linearity was obtained within these areas with good reproducibility of results.

Application of proposed method for estimation of Domperidone and Pantoprazole sodium in tablet dosage forms

20 tablets were weighed and powdered, quantity of sample powder containing equivalent to 10 mg of DOM and 40 mg of PANTO were transferred to 100 ml volumetric flask. Sufficient quantity of Methanol was added, and sonicated for 15 minutes and diluted upto mark with methanol. The solution was filtered through 0.45µ membrane filter paper. A 1 ml of filtrate was further diluted to 10 ml with Distilled water to get final concentration of about 10 µg/ml DOM and 10µg/ml ESO. The absorbance of resulting solutions was calculated by measuring area under curve in the range of 276.0-290.0 nm (for DOM) and 292.0-310.0 nm (for PANTO). (Table no. 5 & 6).

Method validation

Accuracy

It was done by recovery study. Sample solutions were prepared by spiking at about 80%, 100% and 120% of specification limit to Placebo and analyzed by the proposed method. % Recovery was determined using the formula. Results are shown in Table 1 & 2.

Precision

Precision study was carried out for the repetability of sample measurement and the result was expressed as % RSD. Variability of the method was studied by analyzing aliquots of standard solutions of (20, 40, 60, 80, 100, 120 µg /ml) each of Domperidone and Pantoprazole sodium, on the same day (intra-day precision) and on different days (inter-day precision), and the results were expressed as % RSD. (Table 3 & 4).

Linearity and Range

The six-point calibration curves that were constructed were linear over the selected concentration range for both DOM and ESOMG ranging between 20-120 µg/mL. Each concentration was repeated 3 times. The assay was performed according to the experimental conditions previously described.

RESULT AND DISCUSSION

Table no. 1: Standard addition technique for determination of Domperidone and Pantoprazole sodium using Area under curve method

Tablet Sample	Level of Recovery (%)	Amount Present (mg/tab)	Amount of Std. added (mg)	Total amount recovered (mg)	%Recovery
PAN-D	80	10	8	17.94	99.75
		10	8	17.98	99.91
		10	8	17.97	99.87
	100	10	10	19.99	99.95
		10	10	19.84	99.21
		10	10	19.89	99.45
	120	10	12	21.82	99.22
		10	12	22.00	100
		10	12	21.94	99.75

Table no. 2: Statistical data for recovery studies (Domperidone).

Sr.No.	Tablet Sample	Type of Recovery (%)	%Mean*	S.D.	C.O.V.	S.E.
1	PAN-D	80	99.76	0.135	0.136	0.07839
2		100	99.67	0.315	0.316	0.1819
3		120	99.65	0.3983	0.399	0.2300

Table no. 3: Statistical data for recovery studies (Pantoprazole Sodium).

Sr.No.	Tablet Sample	Type of Recovery (%)	%Mean	S.D.	C.O.V.	S.E.
1	PAN-D	80	99.84	0.083	0.083	0.048
2		100	99.45	0.377	0.379	0.218
3		120	99.65	0.398	0.399	0.230

Precision

The results of repeatability and intermediate precision are shown. The developed method was found to be precise for repeatability and intermediate precision studies.

Table no. 4: Precision studies of Domperidone and Pantoprazole Sodium by Area under curve method.

Drug	Conc µg/ml	Intraday found Conc.± SD	RSD%	Interday found Conc.±SD	RSD%
Domperidone	40	39.83±0.08083	0.20293	39.82±0.01000	0.02511
	60	59.81±0.06028	0.10078	59.83±0.05568	0.0930
	80	79.80±0.05132	0.06431	79.86±0.07767	0.09725
Pantoprazole Sodium	40	39.82±0.01000	0.02511	39.83±0.08083	0.20293
	60	59.83±0.05568	0.09306	59.81±0.06028	0.10078
	80	79.86±0.07767	0.09725	79.81±0.05132	0.06430

Table no. 5: Statistical data for precision studies (Domperidone).

Sr.No.	Component	Mean*	S.D.*	C.O.V.*	S.E.
1	Intra-Day	99.83	0.02683	0.02687	0.01095
2	Inter-Day	99.45	0.00894	0.00898	0.00365

Where*n=6.

Table no. 6: Statistical data for precision studies (Pantoprazole Sodium).

Sr.No.	Component	Mean*	S.D*	C.O.V.*	S.E.
1	Intra-Day	99.75	0.02675	0.02587	0.01069
2	Inter-Day	99.55	0.00894	0.00897	0.00324

Where*n=6.

Table no. 7: Analysis of Marketed formulation (Domperidone).

Sr.No.	Tablet Sample	Label claim (mg/tab)	Label claim found (mg/tab)	% drug found
1	PAN-D	30	29.99	99.6
2		30	29.91	99.5
3		30	29.98	99.7
4		30	29.88	99.6
5		30	29.85	99.4
6		30	29.96	99.8

Table no. 8: Analysis of Marketed formulation (Pantoprazole Sodium).

Sr.No.	Tablet Sample	Label claim (mg/tab)	Label claim found (mg/tab)	% drug found
1	PAN-D	40	39.99	99.9
2		40	39.91	99.7
3		40	39.98	99.9
4		40	39.88	99.6
5		40	39.85	99.5
6		40	39.96	99.8

Table no. 9: Statistical data for analysis of marketed formulation (Domperidone).

Sr.No.	Tablet	%mean*	S.D.*	C.O.V.*	S.E.*
1	**PAN-D**	99.64	0.0200	0.200	0.01155

Table no. 10: Statistical data for analysis of marketed formulation (Pantoprazole Sodium).

Sr.No.	Tablet	%mean*	S.D.*	C.O.V.*	S.E.*
1	**PAN-D**	99.73	0.1633	0.1636	0.0667

CONCLUSION

Area under curve method was developed and validated as per ICH guidelines for estimation of Domperidone and Pantoprazole sodium. This method was applied for estimation of these compounds in the marketed formulation. the method has been evaluated for the linearity, accuracy, precision and robustness in order to ascertain the suitability of the method. It has been proved that the developed method was linear in the concentration range of 20-120µg/ml.

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