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Development and Validation of Stability Indicating Method for Simultaneous Estimation of Famotidine and Domperidone in Bulk and Tablet Dosage Forms Using RP-HPLC

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Abstract

A novel, precise, and accurate Reverse Phase-High Performance Liquid Chromatography (RP- HPLC) method was developed and validated for the simultaneous estimation of Famotidine (FAM) and Domperidone (DOM) in bulk and tablet dosage forms. The method was optimized using a Symmetry C18 column (250 mm × 4.6 mm, 5 µm) with a mobile phase consisting of 0.002 M Sodium dihydrogen phosphate buffer (pH 5.8) and acetonitrile (60:40, v/v) at a flow rate of 1 mL/min. Detection was performed at 287 nm using a Photo Diode Array (PDA) detector. The retention times for FAM and DOM were 3.216 min and 5.762 min, respectively, with a resolution of 10.10. The method demonstrated linearity in the range of 5-30 µg/mL for FAM and 2.5-15 µg/mL for DOM, with correlation coefficients r^2 of 0.999 for both drugs. The method was validated as per ICH guidelines, showing excellent accuracy (recovery 99.45%-99.73% for FAM and 99.33%-100% for DOM), precision (RSD < 2%), and robustness. Forced degradation studies under acid, alkali, oxidative, thermal, and photolytic conditions confirmed the stability-indicating nature of the method. FAM was more sensitive to alkali hydrolysis, while DOM showed sensitivity to both acid and alkali hydrolysis. The method was successfully applied to the analysis of commercial tablet formulations, with no interference from excipients. The developed RP-HPLC method is simple, rapid, and reliable, making it suitable for routine quality control and stability studies of FAM and DOM in combined dosage forms.

Keywords: RP-HPLC, Famotidine, Domperidone, validated, stability studies.

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1. Introduction

The combination of famotidine (FAM) {3-[[[2 [diaminomethylene) amino] thiazole-4-yl] methyl] sulphanyl] N'sulphamoyl propanimidamide) can inhibit histamine-gastrin and acetylcholine stimulated acid secretion; pepsin secretion also falls with the reduction in volume of gastric juice and domperidone (DOM){5-chloro-1-[1-[3-(2-oxo-2,3-dihydro-1H-benzimidazole-1 yl)propyl] piperidine- 4-yl]]-1,3-dihydro-2H-benzimidazole-2 one} ,a prokinetic agent is used in gastro oesophageal reflux disorder , peptic acid disorders and protracted vomiting as well in treating hiccups. Patel et al. (2018) developed an RP-HPLC method for Famotidine and Domperidone using a C18 column with methanol: phosphate buffer (pH 3.5). The method was linear (2–20 µg/mL) and validated per ICH guidelines. Forced degradation studies confirmed stability-indicating capability. The method was precise, accurate, and robust for tablet analysis. Sharma & Jain (2019) optimized a gradient RP-HPLC method for

simultaneous estimation using acetonitrile: water (70:30). The method showed good resolution (R > 2) and sensitivity (LOD 0.1 µg/mL). Degradation under acid, base, and oxidative conditions was studied. The method was suitable for stability studies in

Combined tablets. Desai et al. (2020) validated an isocratic RP-HPLC method with UV detection at 265 nm. The method was specific, with no interference from excipients or degradation products. Linearity was observed over 5–50 µg/mL for both drugs. The method was successfully applied to commercial tablets. Gupta & Singh (2017) developed a stability-indicating method using a Phenomenex C18 column. Forced degradation studies included thermal, photolytic, and hydrolytic stress. The method was robust against flow rate and pH variations. Recovery studies showed 98– 102% accuracy for both drugs. By observing existing method their need still optimization in the method development towards green ecofriendly, R.T times and stability indicating study.

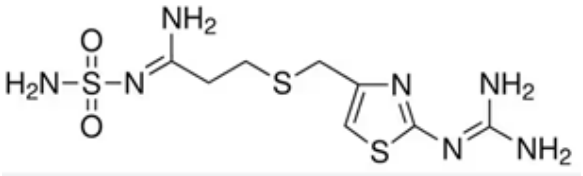

Fig.1 Famotidine

IUPAC Name:
3-[({2-[(diaminomethylidene) amino]- 1,3- thiazol-4-yl} methyl) sulfanyl]-N′ sulfamoylpropanimidamide

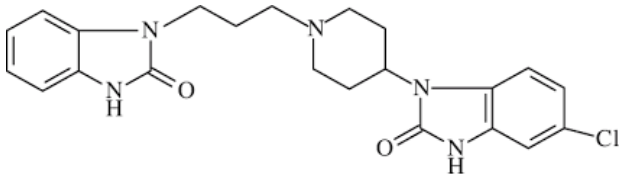

Fig.2 Domperidone

IUPAC Name: 5-Chloro-1-(1-[3-(2-oxo-2,3-dihydro- 1H-benzo[d] imidazol-1-yl)propyl] piperidin-4-yl)-1H-benzo[d] imidazol- 2(3H)-one

2. Materials and Methods

2.1 Materials

Famotidine was procured from Kekule Pharma Ltd., Hyderabad, India. Domperidone was obtained from Reddy's laboratories, Hyderabad, India. Acetonitrile of HPLC grade are obtained from Merck chemicals Ltd., Mumbai, India. HPLC grade water was procured from Rankem, India. Sodium dihydrogen phosphate and orthophosphoric acid of AR grade were procured from Finar Reagent, Ahmedabad, India. Dompon-F® tablets were procured from Finecure Pharmaceuticals Limited, India.

2.2 Instruments

Equipment: Waters Alliance e2695 HPLC system with 2998 PDA detector Column: Symmetry C18 column (250 mm×4.6 mm id, 5 µ particle size) Mobile Phase: 0.002 M Sodium dihydrogen phosphate buffer (pH adjusted to 5.8 with orthophosphoric acid) and Acetonitrile (60:40, v/v) Flow rate: 1 mL/min Detection Wavelength: 287 nm Injection volume: 20 µL Column temperature: Ambient Run time : 10 minutes

2.3. Preparation of Solutions:

Preparation of mobile phase

An accurately weighed quantity of 0.312 g of Sodium dihydrogen phosphate was taken into a 1000 mL beaker and diluted to 1000 mL with HPLC grade water and degassed in ultrasonic water bath and filtered through 0.45 µm nylon membrane filter using vacuum filtration gives required buffer concentration of 0.002 M Sodium dihydrogen phosphate and the pH was adjusted to 5.8 with orthophosphoric acid.0.002 M Sodium dihydrogen phosphate buffer with pH adjusted to 5.8 with orthophosphoric acid were mixed with HPLC grade Acetonitrile in the proportion of 60:40, v/v and it was filtered through 0.45µm nylon membrane filter and degassed by ultrasonication.

Preparation of FAM and DOM mixed standard drug stock solutions: The mixed standard drug stock solutions of Famotidine and Domperidone were prepared by dissolving 20 mg of Famotidine and 10 mg of Domperidone in 100 mL of the mobile phase into a 100 mL of volumetric flask and were sonicated to dissolve it completely to get the concentration of 200 µg/mL of Famotidine and 100 µg/mL of Domperidone.

Preparation of sample solution

Sample solution was prepared from Dompon-F® tablets. Twenty tablets of Dompon-F® were taken and weighed individually and the average weight of twenty tablets was calculated. From this calculation the weight of each tablet is determined. Each tablet of Dompon-F® contains 20 mg of Famotidine and 10 mg of Domperidone. After weighing, twenty tablets of Dompon-F® were crushed and mixed in a mortar and pestle to produce powder. An accurately weighed quantity of powder equivalent to 20 mg of Famotidine and 10 mg of Domperidone were transferred into a clean and dry 100 mL volumetric flask and then mobile phase was added and sonicated to dissolve it completely and filtered through 0.45 µm nylon membrane filter and volume was made up to the mark with the same mobile phase to get the concentration of 200 µg/mL of Famotidine and 100 µg/mL of Domperidone. An aliquot of 1ml was pipette out from the above solution and transferred into a 10 mL volumetric flask and diluted up to the mark with mobile phase to get a concentration of 20µg/mL of Famotidine and 10µg/mL of Domperidone.

2.4 Methodology

The study involved developing an RP-HPLC method for the concurrent analysis of Famotidine and Domperidone. After detailed and systematic study of different factors and considerations involved as depicted under results and discussion in this chapter, the following procedure was recommended for the simultaneous estimation of FAM and DOM in bulk and tablet dosage form. The method was validated for system suitability, linearity, intermediate precision, precision, accuracy, robustness, LOQ and LOD per ICH guidelines. The method demonstrated good

resolution, linearity, and reproducibility, making it suitable for pharmaceutical analysis.

Specificity:

Confirm the absence of interference from excipients or degradation products.

Linearity: Determine the correlation between peak area and concentration for FAM and DOM.

Accuracy: Perform recovery studies to evaluate the method's precision and trueness.

Precision:

Assess repeatability, intermediate precision (ruggedness), and reproducibility. Robustness: Evaluate the method's resilience to deliberate variations in chromatographic conditions.

LOD and LOQ: Determine the sensitivity of the method for detecting and quantifying low concentrations.

3. Results and Discussions

For the optimization of RP-HPLC method several parameters and mobile phase compositions were tried. A satisfactory separation and good peak symmetry for Famotidine and Domperidone were obtained with Symmetry C18 column (250 mm×4.6 mm id, 5particle size) and mobile phase containing a mixture of 0.002 M Sodium dihydrogen phosphate buffer (pH adjusted to 5.8 with orthophosphoric acid) and Acetonitrile (60:40, v/v) was delivered at a flow rate of 1 mL/min to get better reproducibility and repeatability. Both Famotidine and Domperidone were scanned in the wavelength region of 200-400 nm by using photo diode array (PDA) detector. Quantitation was attained with the PDA detector at 287 nm depends on peak area. Therefore 287nm was selected as detection wavelength in the present study. The retention time of Famotidine and Domperidone was found to be 3.216 min and 5.762 min respectively with resolution of 10.10. A typical chromatogram of blank, standard and sample solution of Famotidine and Domperidone is shown in Figure.

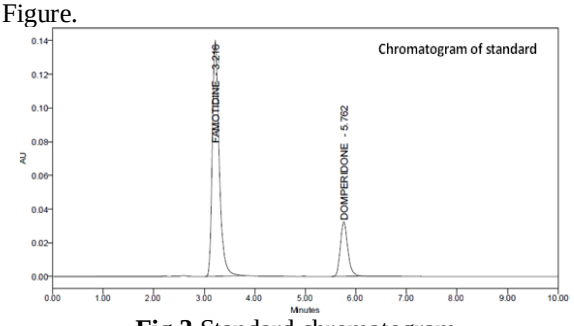

Fig.3 Standard chromatogram

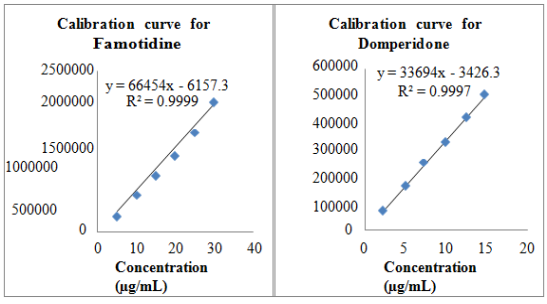

Fig.4 caliberation curve for famotidine and domperidone

Linearity

An aliquots of 0.25, 0.5, 0.75, 1, 1.25 and 1.5 mL from the mixed standard drug stock solutions of 200 µg/mL of FAM and 100 µg/mL of DOM was pippetted out and transferred into the series of a 10 mL of volumetric flask and volume was make up to 10 mL with the mobile phase to get a concentration of 5, 10, 15, 20, 25 and 30 µg/mL of FAM and 2.5,5, 7.5, 10, 12.5 and 15µg/mL of DOM respectively.

Precision

The precision of the proposed method was performed to express the closeness of agreement between a series of measurements obtained from multiple sampling of the same homogeneous sample under the optimized conditions. Precision are of three levels they are repeatability, intermediate precision and reproducibility. Repeatability was carried out by calculating method and system precision. Method precision was performed by injecting six times of a homogenous sample preparation of 20 µg/mL of Famotidine and 10 µg/mL of Domperidone of a single batch sample solution of Dompon-F® tablet powder into the HPLC system to ensure that the analytical method is working properly.

Accuracy

The accuracy of the proposed method was determined by calculating the recoveries of FAM and DOM by standard addition method. Recovery studies were carried out by adding concentration level of 50 %, 100 % and 150 % of standard drug solution of FAM and DOM to the preanalysed sample solution of Dompon-F® tablet powder and the mixtures were re-analyzed by the proposed method. Three replicates were prepared for each concentration level and was injected into the HPLC system and the results were obtained by using following formula and also confirm the accuracy of the proposed method.

Limit of detection and Limit of quantitation

Limit of detection is a smallest concentration of an analyte which gives a measurable response. Limit of quantitation is a smallest concentration of an analyte that gives a measurable response which can be quantified accurately. LOD and LOQ are calculated by using following formula and the results of LOD and LOQ of Famotidine and Domperidone were reported in Table 2.8.

$$\text{Limit of Detection (LOD)} = 3.3\times \frac{\text{Standard deviation of the response}}{\text{Slope of calibration curve}}$$

$$\text{Limit of Quantitation (LOQ)} = 10\times \frac{\text{Standard deviation of the response}}{\text{Slope of the calibration curve}}$$

Robustness

Robustness of the method was carried out by deliberately changing the mobile phase composition by altering the proportion of organic phase by ±10 % and flow rate by ±0.1 mL. There are no marked variations were observed in the system suitability parameters and the results of robustness were reported in Table 2.17 and Table 2.18 ensures that the developed analytical method remain unchanged by a small or deliberate variations in chromatographic method parameters and gives an indication of its consistency during normal usage.

Table.1 Caliberation Results for famotidine and domperidone

Concentration of Famotidine (µg/mL)	Peak Area	Concentration of Domperidone (µg/mL)	Peak Area
5	337138	2.5	84256
10	651929	5	163706
15	983591	7.5	246929
20	1318503	10	331588
25	1655865	12.5	416755
30	1993676	15	505138

Table.2 Precision for Famotidine

Injection No.	Name of the drug	Concentration (µg/mL)	Retention time (min)	Peak Area	Assay %
1	FAM	20	3.212	1331754	99.10
2	FAM	20	3.214	1340245	99.74
3	FAM	20	3.211	1330654	99.02
4	FAM	20	3.211	1341548	99.83
5	FAM	20	3.211	1348552	100.35
6	FAM	20	3.214	1334578	99.31
Average			3.212	1337889	99.6
SD			0.00147	6834.98	0.464315
RSD %			0.05	0.51	0.51

Table.3 Precision for Domperidone

Injection No.	Name of the drug	Concentration (µg/mL)	Retention time (min)	Peak Area	Assay %
1	DOM	10	5.755	335558	99.72
2	DOM	10	5.751	334414	99.38
3	DOM	10	5.754	335607	99.74
4	DOM	10	5.752	338900	100.72
5	DOM	10	5.756	338940	100.73
6	DOM	10	5.751	339250	100.82
Average			5.753	337112	100.19
SD			0.00214	2147.963	0.6383
RSD %			0.04	0.64	0.64

Table.4 Accuracy for Famotidine

Concentration Level in %	Amount added (µg/mL)	Amount recovered (µg/mL)	% Recovery	% Mean Recovery	RSD %
S_1:50%	10	9.93	99.3	99.73	0.59
S_2:50%	10	10.04	100.4		
S_3:50%	10	9.95	99.5		
S_4:100%	20	19.93	99.65	99.45	0.23
S_5:100%	20	19.9	99.5		
S_6:100%	20	19.84	99.2		
S_7:150%	30	29.75	99.17	99.72	0.88
S_8:150%	30	30.22	100.73		
S_9 :150%	30	29.78	99.27		

Table.5 Accuracy for Domperidone

Concentration Level in %	Amount added (µg/mL)	Amount recovered (µg/mL)	% Recovery	% Mean Recovery	RSD %
S_1:50%	5	4.95	99.01	99.33	0.31
S_2:50%	5	4.97	99.4		
S_3:50%	5	4.98	99.6		

S4:100%	10	9.98	99.8	100	0.53
S5:100%	10	10.06	100.6		
S6:100%	10	9.96	99.6		
S7:150%	15	14.98	99.87	99.64	0.23
S8:150%	15	14.91	99.4		
S9 :150%	15	14.95	99.67		

Table.6 Robustness for Famotidine

Variations in method parameters	Retention Time (mins)	Average peak area*	RSD %	System suitability parameters	
				Theoretical Plates	Asymmetry
Buffer : ACN (64:36,v/v)	3.200	1227791	0.01	2994	1.37
Buffer : ACN (56:44,v/v)	3.188	1235656	0.02	3003	1.15
0.9 mL/min Flow rate	4.470	1887335	0.03	3057	1.12
1.1 mL/min Flow rate	2.521	1056073	0.06	2555	1.15

Table.7 Robustness for Domperidone

Variations in method parameters	Retention Time (mins)	Average peak area*	RSD%	System suitability parameters	
				Theoretical Plates	Asymmetry
Buffer : ACN (64:36,v/v)	5.435	310876	0.01	7632	1.17
Buffer : ACN (56:44,v/v)	5.158	314721	0.04	4179	1.05
0.9 mL/min Flow rate	8.054	480464	0.05	7647	1.19
1.1 mL/min Flow rate	4.507	267993	0.19	6975	1.19

Table.8 Results of stability indicating assay of FAM and DOM

Degradation condition	Drug Recovered %		Drug Decomposed %		Retention time of degrades (min)
	FAM	DOM	FAM	DOM	
Acid hydrolysis	99.60	96.95	0.40	3.05	2.653, 4.404
Alkali hydrolysis	97.30	96.36	2.70	3.64	2.574, 4.386
Oxidative degradation	99.61	99.73	0.39	0.27	-----
Thermal degradation	99.47	98.44	0.53	1.56	2.589
Photolytic degradation	99.79	97.65	0.21	2.35	2.598, 4.379

4. Conclusion

The RP-HPLC method developed thorugh this Resarch for the simultaneous estimation of Domperidone and Famotidine found to be precise, accurate, and reliable, making it applicable for routine analytical assurance in both bulk and pharmaceutical dosage forms. The developed method complied with all validation parameters as per ICH guidelines, with excellent linearity, recovery, and precision. Furthermore, the stability studies confirmed that the analyzed drugs exhibited satisfactory resistance to various degradative environments. Thus, the proposed method proved to be efficient and robust for routine quality control analysis of Domperidone and Famotidine.

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Conflict of Interest

We affirm that there are no conflicts of interest.

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