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EVALUATION AND VALIDATION OF A UPLC METHOD FOR SIMULTANEOUS ESTIMATION OF MAGALDRATE AND SIMETHICONE IN BULK SUSPENSION DOSAGE FORM

Meher Afrin*[1], Dr. Osman Ahmed[1], Ashraf Unnisa[1], Mohammed Akthar Sulthana[1] and Dr. Anas Rasheed[2]

[1]Department of Pharmaceutical Analysis, Deccan School of Pharmacy, Hyderabad.
[2]CSO, Gaelib Medications Private Limited, Hyderabad.

***Corresponding Author: Meher Afrin**

Department of Pharmaceutical Analysis, Deccan School of Pharmacy, Hyderabad.

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ABSTRACT

In order to accomplish separation under optimal circumstances following a series of experimental trials, it is necessary to summarise the results. A stationary phase such as the Hypersil BDS C18 (100 mm x 2.1 mm, 1.7 m) column was the most appropriate since it generated symmetrical peaks with high resolution and a very excellent sensitivity, as well as a very good resolution and sensitivity. The flow rate was kept constant at 1.2 mL min-1, indicating acceptable resolution. The reaction of Magaldrate and Simethicone in suspension dose form to the PDA detector was investigated, and it was discovered that the optimal wavelength was 230 nm, which had the maximum sensitivity. Magaldrate and Simethicone were separated using a combination of two solutions, Methanol and chloroform in a 50:50 percent volume ratio, with gradient programming as the mobile phase at 1.2mL/min. This mixture was determined to be an acceptable mobile phase for separation of Magaldrate and Simethicone. The temperature of the column was kept at room temperature.

KEYWORDS: Suspension dosage form, Magaldrate and Simethicone.

INTRODUCTION

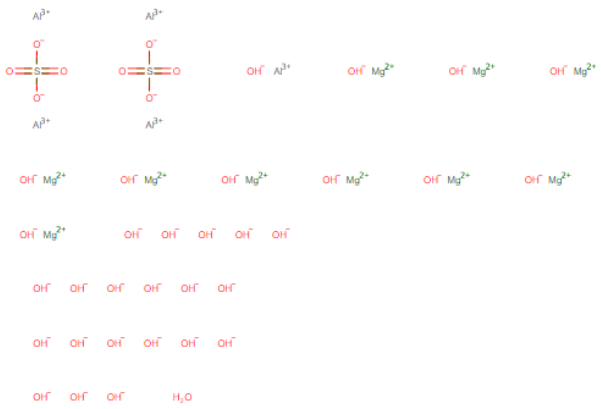
Heart Burn

HB could be a restorative malady characteristic of the substance at the stomach backward and upward into the throat. HB is additionally seen to as HB in certain circles. Heartburn is ordinarily anticipated by stomach, a muscle known as the LES. This muscle, time gotten to be slack, permitting stomach acid to enter the nourishment pipe unprotected. When stomach acid comes into touch with the pipe, it may certain individuals to endure side effects.

Magaldrate Drug Information

Magaldrate may be a well known stomach settling agent medicine that's utilized to treat duodenal and gastric ulcers, esophagitis caused by HB. Magaldrate is an stomach settling agent that's utilized to treat a assortment of illnesses influencing the framework, counting esophagitis, duodenal and gastric ulcers, reflux disease. Gingival reflux illness, duodenal ulcer infection, and gastric ulcer illness are all conditions that will be treated with magaldrate.

CHEMICAL STRUCTURE



CHEMICAL STRUCTURE OF MAGALDRATE

Weight: 1115.3

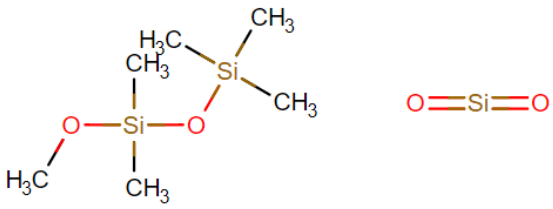
Chemical Formula $Al_5H_{33}Mg_{10}O_{40}S_2$

Simethicone Drug Information

In expansion to being known as simethicone (USAN), Simeticone (Motel) operator that's utilized to reduce bloating, distress, and torment caused by excessive gas. Simeticone pharmaceutical that's utilized to ease the

indications of excessive gas framework, which incorporate bloating, burping, and flatulence. However, that there's no persuading prove that simeticone is accommodating for this reason, thinks about have demonstrated that it may reduce indications of useful dyspepsia and useful bloating.

Chemical Structure



CHEMICAL STRUCTURE OF SIMETHICONE
Weight: 238.461
Chemical Formula $C_6H_{18}O_4Si_3$

EXPERIMENTAL METHODOLOGY
Method Validation
The analytical procedure refers to the way of performing the analysis. It should describe in detail the steps necessary to perform each analytical test. This may include but is not limited to: the sample, the reference standard and the reagents preparations, use of the apparatus, generation of the calibration curve, use of the formulae for the calculation, etc. The described method extensively validated in terms of specificity, system suitability, linearity, accuracy, precision, limit of detection, limit of quantification and robustness.

RESULTS
Preparation of Standard Stock Solution
Preparation of Diluent
In order to achieve the separation under the optimized conditions after experimental trials that can be summarized. Stationary phase like Hypersil BDS C18 (100 mm x 2.1 mm, 1.7 µm) column was most suitable one, since it produced symmetrical peaks with high resolution and a very good sensitivity and with good resolution. The flow rate was maintained 1.2 mL min-1 shows good resolution. The PDA detector response of Magaldrate and Simethicone was studied and the best wavelength was found to be 230 nm showing highest sensitivity.

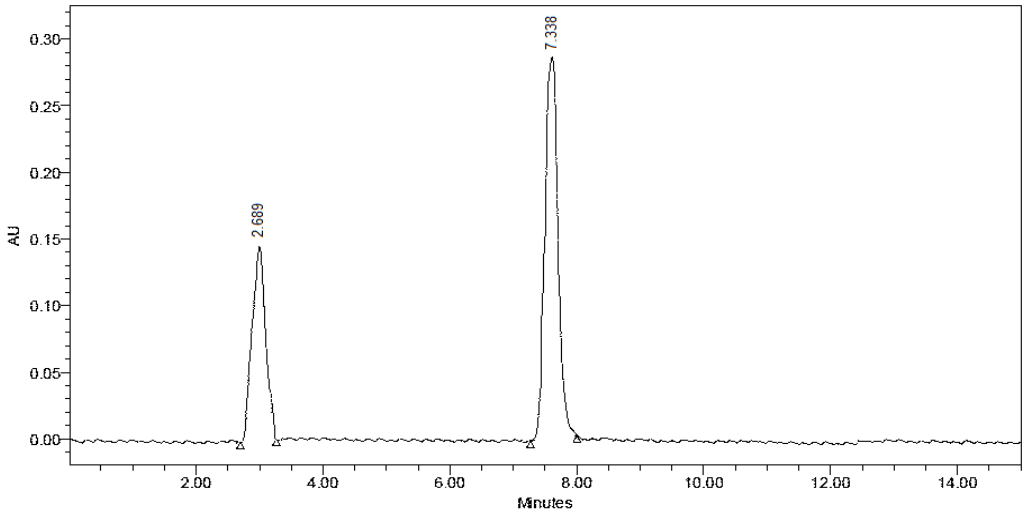
The mixture of two solutions Methanol and chloroform in the ratio of 50:50 %v/v" with gradient programming was used as mobile phase at 1.2mL/min was found to be an appropriate mobile phase for separation of Magaldrate and Simethicone. The column was maintained at ambient temperature.

Preparation of internal standard solution
Weighed accurately about 10 mg of Magaldrate and Simethicone working standard and transfer to 100 ml volumetric flask, add 50 ml of mobile phase and sonicate to dissolve it completely and then volume was made up to the mark with mobile phase to get 100 µg/ml of standard stock solution of working standard. Then it was ultrasonicated for 10 minutes and filtered through 0.20 µ membrane filter.

Preparation of Magaldrate and Simethicone standard solution
Weighed accurately about 10 mg of Magaldrate and Simethicone and transfer to 100 ml volumetric flask, add 50 ml of mobile phase and sonicate to dissolve it completely and then volume was made up to the mark with mobile phase to get 100 µg/ml of standard stock solution of working standard. Then it was ultrasonicated for 10 minutes and filtered through 0.20 µ membrane filter.

Magaldrate and Simethicone in UPLC System

Magaldrate and Simethicone	
System	UPLC
Stationary Phase	C18 column
"Mobile Phase"	"Methanol and chloroform in the ratio of 50:50 %v/v"
Diluents	Methanol
Injection volume	20µl
Temperature	Ambient
Flow rate	1.2 ml/min
UV detection	230nm
Retention Time	Magaldrate– 7.338 mins; Simethicone – 2.689 mins
Inference	"High column pressure were observed"



Chromatogram of standard preparation of Magaldrate and Simethicone (Methanol and chloroform in the ratio of 50:50 %v/v)

VALIDATION

ACCURACY

***Accuracy Result of* Magaldrate**

Magaldrate						
Level %	**Amount added (µg/ml)**	**Amount found (µg/ml)**	**% Recovery**	**Mean recovery (%)**	**Std.Dev**	**% RSD**
50	07.54	07.52	99.73	99.79	0.1011	0.98%
100	15.39	15.35	99.74			
150	23.34	22.32	99.91			

Accuracy Result of Simethicone

Simethicone						
Level %	**Amount added (µg/ml)**	**Amount found (µg/ml)**	**% Recovery**	**Mean recovery (%)**	**Std.Dev**	**% RSD**
50	07.63	07.61	99.73	98.40	2.405	0.99%
100	15.24	15.22	99.86			
150	23.35	22.33	95.63			

Method Precision

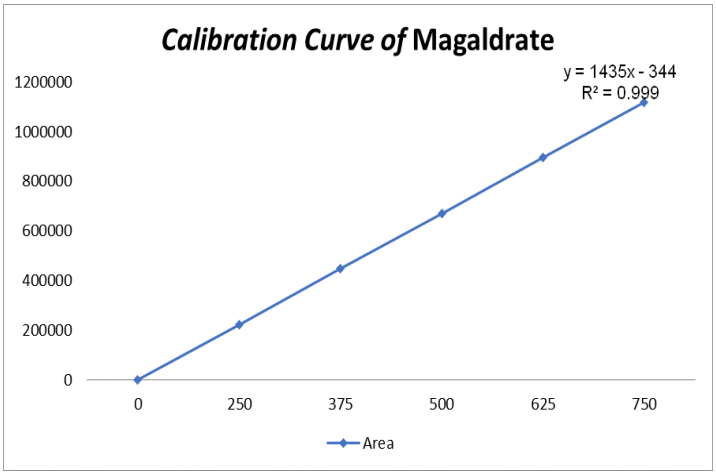
Replicate		***Magaldrate + Simethicone***	
S.No.	**Concentration Taken (µg/ml)**	**Area *Magaldrate***	**Area *Simethicone***
1	20	223775	223809
2		223693	223824
3		223659	223812
4		223753	223818
5		223833	223813
6		223744	223816
Average		223742	223815
Std.Dev		61.287	5.278
% RSD		0.03%	0.01%
Standard weight		20 mcg	20 mcg
Standard potency		99.50 %	99.50 %

PRECISION

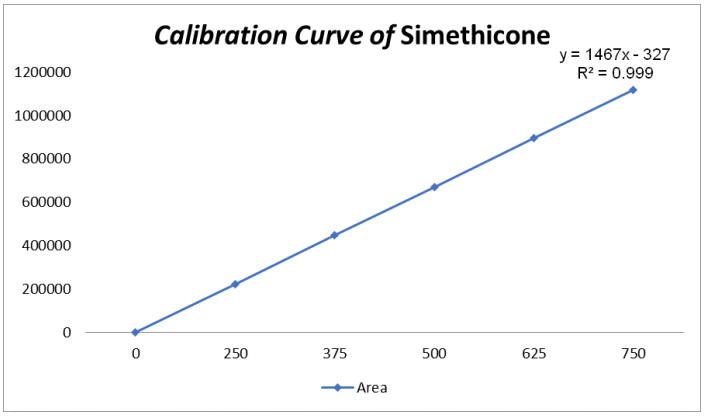
Linearity

Magaldrate + Simethicone			
Linearity level	**Concentration in µg/mL**	**Area Magaldrate**	**Area Simethicone**
1	20 µg/mL	223659	223809
2	40 µg/mL	447318	447618
3	60 µg/mL	670977	671427
4	80 µg/mL	894636	895236
5	100 µg/mL	1118295	1119045
Correlation co-efficient		0.9991	0.9995
Slope		344.01	327.01
Intercept		1435.085	1467.034

LINEARITY



Calibration Curve of Magaldrate



Calibration Curve of Simethicone

Robustness

ROBUSTNESS

Robustness Studies				
Parameter	**Value**	**Peak Area Magaldrate**	**Peak Area Simethicone**	**% RSD**
Flow Rate	**Low**	223659	223809	0.05%
	Actual	223750	223849	
	Plus	223705	223843	
Temperature	**Low**	223663	223817	0.04%
	Actual	223698	223876	
	Plus	223680	223831	
Wavelength	**Low**	223727	223818	0.02%
	Actual	223714	223840	
	Plus	223728	223874	

Ruggedness

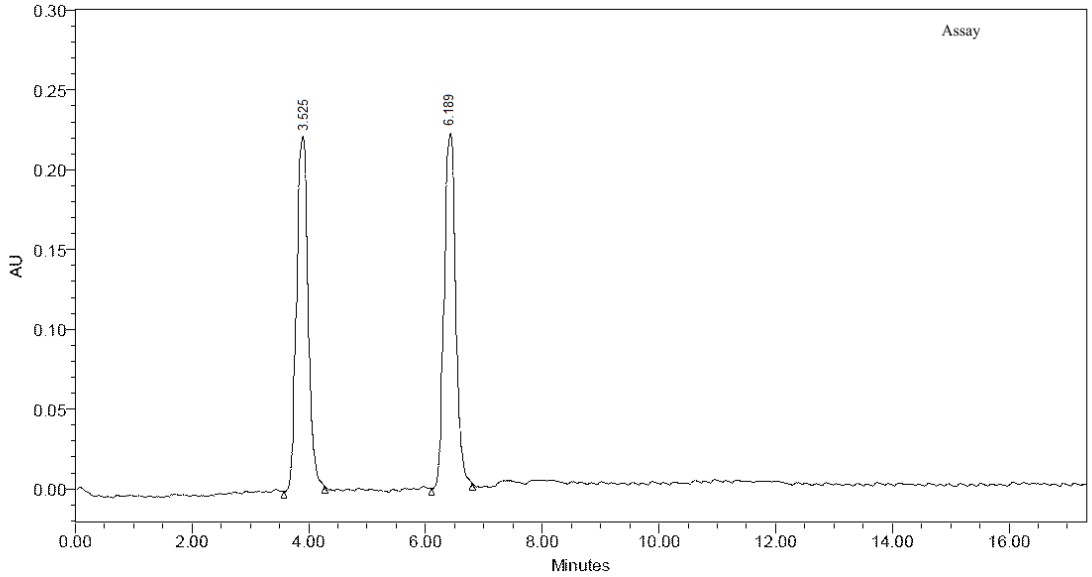
Magaldrate + Simethicone				
Ruggedness				
Parameter	**Peak AreaMagaldrate**	**Peak AreaSimethicone**	**% RSD**	**%LC**
Intraday precision	223698	223876	0.05%	99.96%
	223718	223884		100.03%
	223721	223897		100.04%
Inter day precision	223725	223912	0.02%	99.95%
	223724	223942		99.98%
	223699	223928		100.01%
Instrument:1 Acquity UPLC Waters,2695H	223736	223949	0.05%	99.99%
	223702	223908		100.05%
	223735	223981		100.06%
Instrument:2 Agilent Technologies,1290	223701	223982	0.04%	99.98%
	223749	223969		100.09%
	223742	223887		100.06%
Average				**100.01**
Std.Dev				**0.0447**
%RSD				**0.04%**

EVALUATION OF METHOD

Assay Studies

- Then, an exact 10 ml of the naturally arranged working standard arrangement of clear working arrangement was exchanged to a dry and well cleaned RBF for investigation. The test volume was raised to 100 milliliters (mL). Altering the UPLC columns' fixings and working parameters, as well as recording chromatograms to upgrade chromatographic characteristics, were at that point connected to a pre-mixed column arrangement of acetonitrile 65 percent/water/35 percent v against an octane sulfonic acid buffer (or HCL) slope to get the specified chromatographic characteristics.

- **Analysis of Magaldrate + Simethicone**



ASSAY OF *(API)*

Calculation formula for Magaldrate +Simethicone

$$\%\ Assay = \frac{AT}{AS} \times \frac{W1}{100} \times \frac{1}{25} \times \frac{100}{W2} \times \frac{25}{1} \times \frac{AW}{LC} \times P$$

Magaldrate +Simethicone

$$\%\ Assay\ of\ API = \frac{2119.484}{2120.638} \times \frac{20.62}{100} \times \frac{1}{25} \times \frac{100}{20.44} \times \frac{25}{1} \times \frac{20.40}{20.42} \times 99.50$$

= 100.21%

Simethicone

$$\%\ Assay\ of\ API = \frac{2144.345}{2147.932} \times \frac{20.62}{100} \times \frac{1}{25} \times \frac{100}{20.44} \times \frac{25}{1} \times \frac{20.40}{20.42} \times 99.50$$

= 100.11%

CONCLUSION

For the ultrafast and gushed item, a unique, accurate, and special ultra chromatographic approach was developed for analysing the dose distribution pattern in bulk pharmaceutical and applications, and in specifically for this medication, in particular. Because it is associated with care, a clean assessment technique that is not in contradiction with the execution of the strategy may be used to accomplish this goal without causing confusion. It is both effective and fast to implement this strategy because of its high impact and repetition while also maintaining accuracy. All of the data indicated that the approach looked to be acceptable in terms of approval parameters being authorised using the technique.

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