

EVALUATION AND VALIDATION OF A UPLC METHOD FOR ESTIMATION OF MAGALDRATE AND SIMETHICONE IN MARKETED (NUCOOL) SUSPENSION DOSAGE FORM

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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 1.6 mL min⁻¹, indicating acceptable resolution. The response of Magaldrate and Simethicone PDA detectors was investigated, and it was discovered that the optimal wavelength for achieving the maximum sensitivity was 250 nm. Mobile phase was found to be an acceptable mobile phase for separation of Magaldrate and Simethicone when a combination of two solutions Methanol, Water, and Acetonitrile in the ratio of 40:30:30 percent v/v/v" with gradient programming was utilised at 1.6mL/min. The temperature of the column was kept at room temperature.

KEYWORDS: Suspension dosage form, Magaldrate and Simethicone

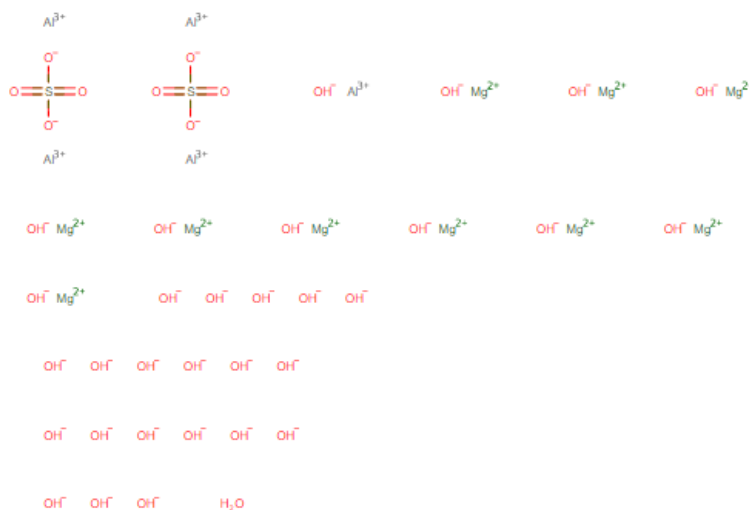
INTRODUCTION

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

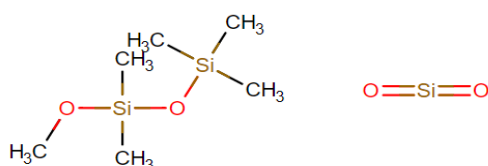


CHEMICAL STRUCTURE OF MAGALDRATE

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.

Magaldrate and Simethicone in UPLC System

Magaldrate and Simethicone	
System	UPLC
Stationary Phase	C18 column
"Mobile Phase"	"Methanol, Water and Acetonitrile in the ratio of 40:30:30 %v/v/v"
Diluents	Acetonitrile
Injection volume	20µl
Temperature	Ambient
Flow rate	1.6 ml/min
UV detection	250nm
Retention Time	Magaldrate– 7.349 mins; Simethicone – 2.624 mins
Inference	"Satisfactory separation of the drugs was achieved with good resolution and minimal tailing."

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 1.6 mL min⁻¹ shows good resolution. The PDA detector response of Magaldrate and Simethicone was studied and the best wavelength was found to be 250 nm showing highest sensitivity.

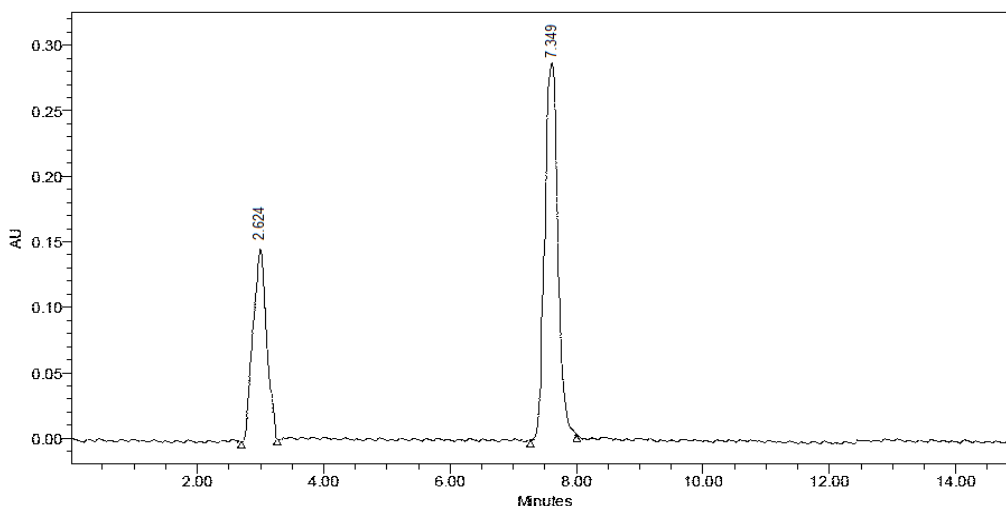
The mixture of two solutions Methanol, Water and Acetonitrile in the ratio of 40:30:30 %v/v/v" with gradient programming was used as mobile phase at 1.6mL/min was found to be an appropriate mobile phase for separation of Magaldrate and Simethicone. The column was maintained at ambient temperature.

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.



*Chromatogram of standard preparation of Magaldrate and Simethicone
("Methanol, Water and Acetonitrile in the ratio of 40:30:30 %v/v/v")*

VALIDATION ACCURACY

Magaldrate						
Level %	Amount added (µg/ml)	Amount found (µg/ml)	% Recovery	Mean recovery (%)	Std.Dev	% RSD
50	07.55	07.53	99.74	99.83	0.1013	0.98%
100	15.37	15.36	99.75			
150	23.33	22.34	99.96			

Accuracy Result of Magaldrate

Simethicone						
Level %	Amount added (µg/ml)	Amount found (µg/ml)	% Recovery	Mean recovery (%)	Std.Dev	% RSD
50	07.65	07.63	99.74	98.42	2.406	0.99%
100	15.27	15.25	99.87			
150	23.34	22.34	95.68			

Accuracy Result of Simethicone Method Precision

Replicate	Concentration Taken (µg/ml)	Magaldrate + Simethicone	
S.No.		Area Magaldrate	Area Simethicone
1	20	223776	223803
2		223695	223827
3		223656	223816
4		223757	223815
5		223834	223814
6		223746	223813
% RSD		0.03%	0.01%
Standard potency		99.50 %	99.50 %

PRECISION**Linearity**

<i>Magaldrate + Simethicone</i>			
<i>Linearity level</i>	<i>Concentration in µg/mL</i>	<i>Area Magaldrate</i>	<i>Area Simethicone</i>
1	20 µg/mL	223658	223804
2	40 µg/mL	447319	447614
3	60 µg/mL	670978	671425
4	80 µg/mL	894637	895237
5	100 µg/mL	1118296	1119046
Correlation co-efficient		0.9991	0.9995
Slope		344.01	327.01
Intercept		1435.085	1467.034

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

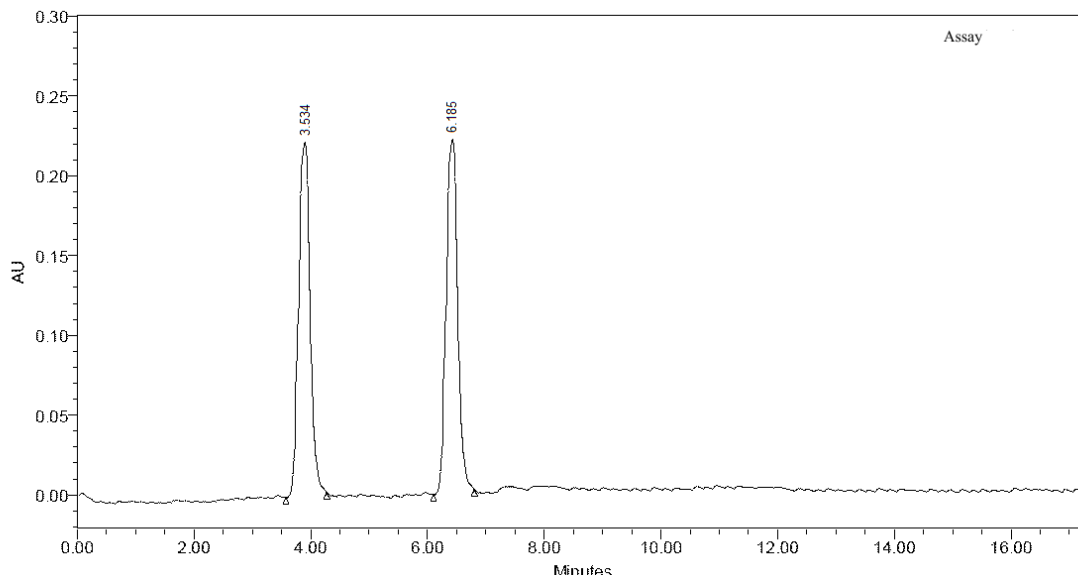
Magaldrate + Simethicone				
Ruggedness				
Parameter	Peak Area Magaldrate	Peak Area Simethicone	% RSD	%LC
Intraday precision	223698	223876	0.05%	99.96%
	223718	223884		100.03%
	223721	223897		100.04%
Inter day precision	223725	223912	0.02%	99.95%
	223724	223942		99.98%
	223699	223928		100.01%
Instrument:1 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 MARKET****Calculation formula for Magaldrate +Simethicone**

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

% Assay ofMarket sample

$$= \frac{2118.682}{2120.638} \times \frac{20.62}{100} \times \frac{1}{25} \times \frac{100}{20.44} \times \frac{25}{1} \times \frac{20.40}{20.42} \times 99.50$$

$$= 100.18\%$$

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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