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CHARACTERIZATION OF FORCE DEGRADATION ASSAY METHOD EVALUATION FOR SIMULTANEOUS ESTIMATION OF MAGALDRATE AND SIMETHICONE IN SUSPENSION DOSAGE FORM USING UPLC-MS/MS^n

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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

Chemical stability of MAGALDRATE AND SIMETHICONE is a matter of great concern as it affects the safety and efficacy of the finished drug product. Forced degradation studies provide data to support identification of possible degradants; degradation pathways and intrinsic stability of the MAGALDRATE AND SIMETHICONE molecule and validation of stability indicating analytical procedures. (ICH Q2 (R1), 2005).

A detailed literature revealed that several analytical methods have been reported for the determination of MAGALDRATE AND SIMETHICONE in pharmaceutical oral dosage forms. In our present knowledge, there is no method reported for the estimation forced degradation studies of MAGALDRATE AND SIMETHICONE in pharmaceutical oral dosage form by UPLC-MS/MS^n.

As per the stringent regulatory requirements recommended by the ICH and regulatory agencies, it is mandatory and important to identify and structurally characterize any impurity formed during production and stability testing, exceeding the identification threshold. Various analytical instruments and advanced hyphenated techniques are routinely used to carry out the impurity profile study.

The present work aims with the development of method to separate the degradation product by preparative UPLC and subjected to ESI-MS/MS. The study describes the separation of different impurities of MAGALDRATE AND SIMETHICONE, as well as the development and validation of a stability-indicating RP-UPLC method for the estimation of degradation and process-related impurities of MAGALDRATE AND SIMETHICONE. Forced degradation studies were performed on the drug product to show the stability-indicating nature of the method. These studies were performed in accordance with established ICH guidelines.

EXPERIMENTAL METHODOLOGY

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 240 nm showing highest sensitivity.

The mixture of two solutions methanol and acetonitrile in the ratio of 55:45%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

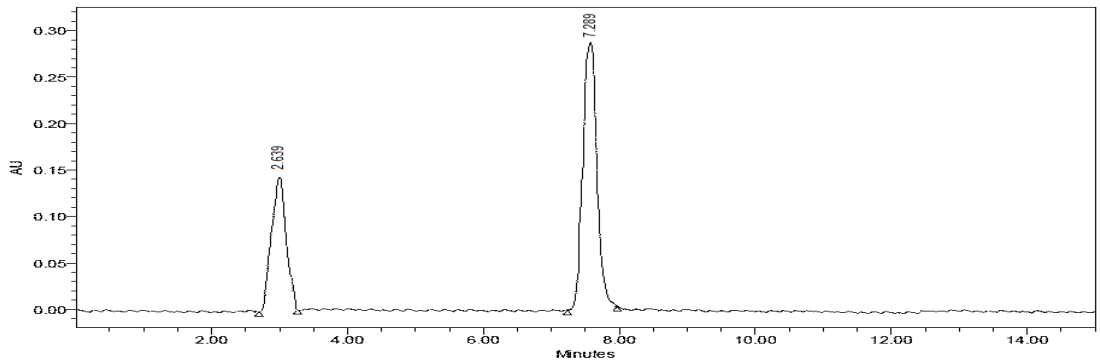
Weighed accurately about 10 mg of Magaldrate and Simethicone working standard and transfer to 100 ml volumetric flask, add 50 ml of mobile phase and sonicate to dissolve it completely and then volume was made up to the mark with mobile phase to get 100 µg/ml of standard stock solution of working standard.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

Preparation of Magaldrate and Simethicone standard solution

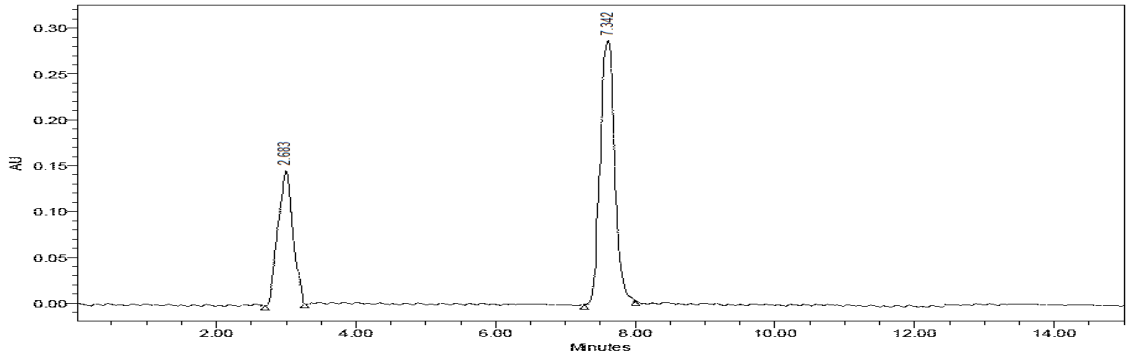
Weighed accurately about 10 mg of Magaldrate and Simethicone and transfer to 100 ml volumetric flask, add 50 ml of mobile phase and sonicate to dissolve it completely and then volume was made up to the mark with mobile phase to get 100 µg/ml of standard stock solution of working standard. Then it was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

Magaldrate and Simethicone	
Method development by UPLC OPTIMISED TRIAL	
System	**UPLC**
Stationary Phase	**C18**
"Mobile Phase"	**"Methanol and Acetonitrile in the ratio of 55:45 %v/v"**
Injection volume	**20µl**
Temperature	**Ambient**
Flow rate	**1.2 mL/min**
UV detection	**240 nm**
Retention Time	**Magaldrate – 7.289mins; Simethicone – 2.639 mins**
Inference	**"Better resolution of the peaks with clear base line separation was found."**

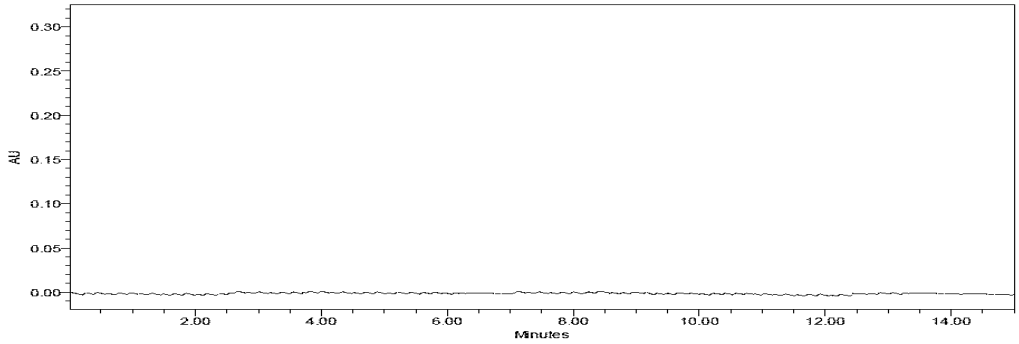
Method development of Magaldrate and Simethicone in UPLC System



Chromatogram of standard preparation of Magaldrate and Simethicone (Methanol and Acetonitrile in the ratio of 55:45 %v/v)



Chromatogram of test preparation of Magaldrate and Simethicone (Methanol and Acetonitrile in the ratio of 55:45 %v/v)

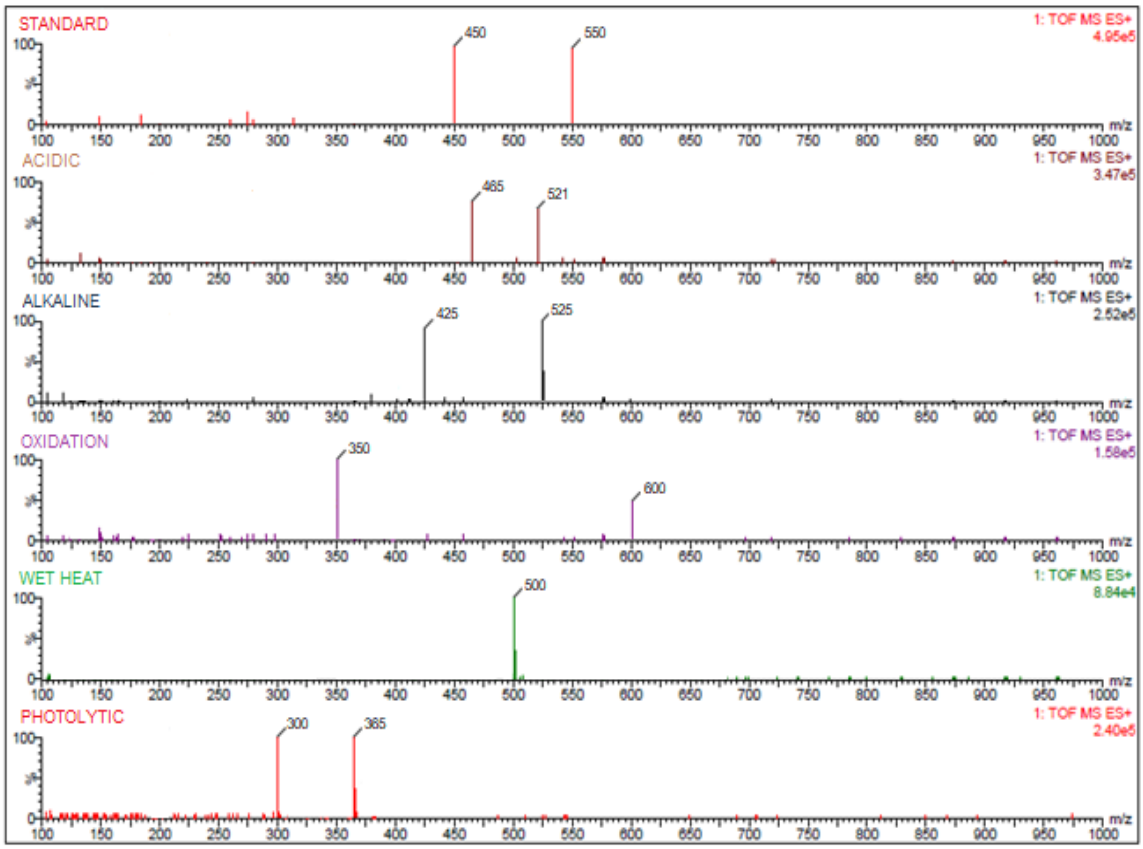


Blank Chromatogram of Magaldrate and Simethicone (Methanol and Acetonitrile in the ratio of 55:45 %v/v)

Gradient Composition of Magaldrate and Simethicone

Time Interval (Mins.)	Solvent – A% (Sodium phosphate buffer)	Solvent – B% (Mobile Phase)
0-2	0	100
2-4	0	100
4-6	15	85
6-8	20	80
8-10	20	80
10-12	0	100
12-14	0	100

Gradient Composition of Magaldrate and Simethicone in UPLC System



LCMS

Analyte	Observed ion mass (Da)	Proposed formula	Calculated mass (Da)
Unknown	300.42	C13H23N3O3S	301.40
Unknown	350.46	C16H19N3O4S	349.40
Unknown	365.36	C16H19N3O5S	365.40
Unknown	425.45	C15H27N3O7S2	425.52
Unknown	450.35	C16H24N3O6S3	450.57
Unknown	465.32	C16H24N4O6S3	464.58
Unknown	500.25	C16H28N4O6S4	500.68
Unknown	521.47	C15H28N4O6S5	520.73
Unknown	525.13	C15H32N4O6S5	524.76
Unknown	550.87	C15H26N4O6S6	550.78
Unknown	600.23	C15H28N4O7S7	600.86

Lcms interpretation

Summary of Results

Parameters	Acceptance Criteria	Value Found	Inference
Linearity Range (µg/ml)	Linear Regression	*MAG* - 20-1000 (µg/ml) *SIM* - 20-100 (µg/ml)	The concentration of linearity range was found to be Linear.
Correlation Coefficient	Correlation Coefficient of $r^2 \geq 0.995$	*MAG* - 0.999 *SIM* - 0.999	It is found to be under the acceptance criteria.
Method Precision (%RSD)	%RSD nmt 2%	*MAG* - 0.01%, *SIM* - 0.02%	The Method Precision is found to be precised.
Accuracy (%Recovery)	The % recoveries should be in between 98-102% w/w	*MAG* - 98.69% *SIM* - 98.98%	The good recoveries shows the method is Accurate.
LOD (µg/ml)	Signal to noise ratio (S/N) ≥ 3.3	*MAG* - 0.0029 µg/mL *SIM* - 0.0052 µg/mL	It is found to be under the acceptance criteria.
LOQ (µg/ml)	Signal to noise ratio (S/N) ≥ 10.1	*MAG* - 0.0091 µg/mL *SIM* - 0.0160 µg/mL	It is found to be under the acceptance criteria.
Robustness (Low, Actual, High) (%RSD)	%RSD nmt 2%	*MAG – (0.03%,* 0.02%, 0.02%) *SIM – (0.04%,* 0.02%, 0.03%)	With small deliberate variations in the method parameters has proven that the method is robust.
Intra Day (%RSD)	%RSD nmt 2%	*MAG* - 0.02% *SIM* - 0.04%	The repeatability is excellent, indicating the ruggedness of the method.
Inter Day (%RSD)	%RSD nmt 2%	*MAG* - 0.01% *SIM* - 0.03%	The reproducibility is excellent, indicating the ruggedness of the method.
Analysis of Formulation (% Assay)	The % Assay should be in between 98-102% w/w	*MAG -99.28* % *SIM -99.41* %	Satisfactory quantitative detection of the analytes

SUMMARY OF RESULTS

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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