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SPIKED FORCE DEGRADATION ASSAY METHOD EVALUATION 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.

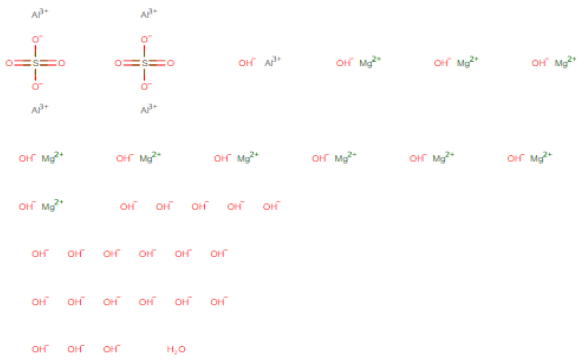
KEYWORDS: Suspension dosage form, Magaldrate and Simethicone.

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

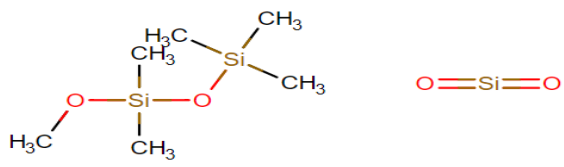
Weight: 1115.3

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.

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.

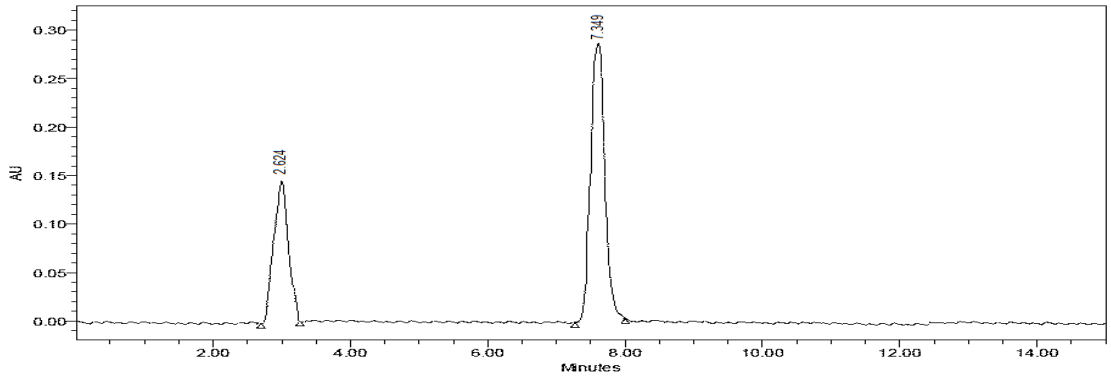
The mixture of two solutions Methanol, Water and Acetonitrile in the ratio of 40:30:30 %v/v/v" with gradient programming was used as mobile phase at 1.6mL/min was found to be an appropriate mobile phase for separation of Magaldrate and Simethicone. The column was maintained at ambient temperature.

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.

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."**

Magaldrate and Simethicone in UPLC System



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)**	**Amountfound (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		***Magaldrate + Simethicone***	
S.No.	**Concentration Taken (µg/ml)**	**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

Magaldrate + Simethicone			
Linearity level	**Concentration in µg/mL**	**Area Magaldrate**	**Area Simethicone**
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

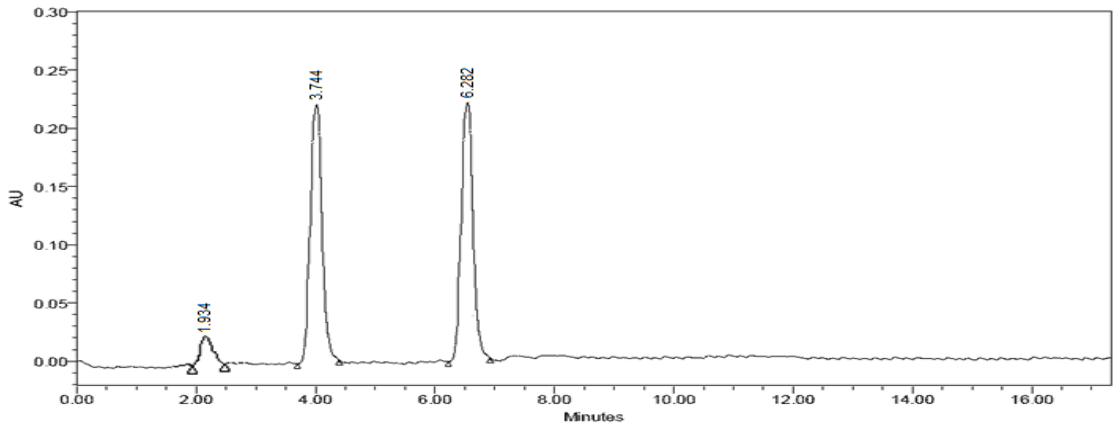
Magaldrate + Simethicone				
Ruggedness				
Parameter	**Peak AreaMagaldrate**	**Peak AreaSimethicone**	**% RSD**	**%LC**
Intraday precision	223698	223876	0.05%	99.96%
	223718	223884		100.03%
	223721	223897		100.04%
Inter day precision	223725	223912	0.02%	99.95%
	223724	223942		99.98%
	223699	223928		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

Acidic Degradation

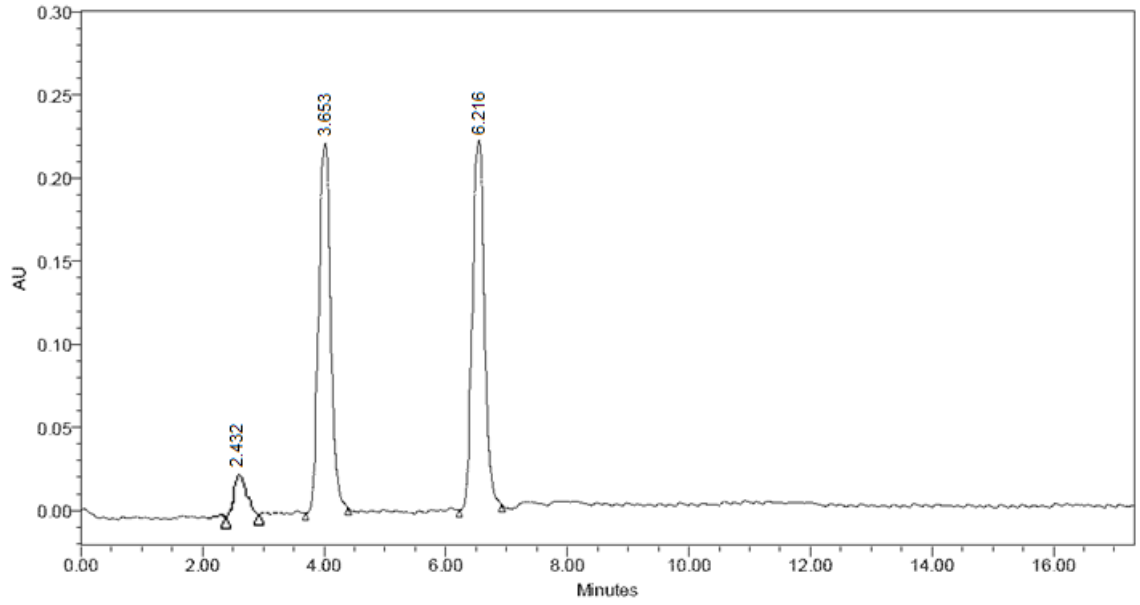
An accurate 10 ml of pure drug sample solution was transferred to a clean and dry round bottom flask (RBF). 30 ml of 0.1 N HCl was added to it. It was refluxed in a water bath at 60°C for 6 hours. Drug became soluble after reflux which was insoluble initially. Allowed to cool at room temperature. The sample was then neutralized using 2N NaOH solution and final volume of the sample was made up to 100ml with water to prepare 100ppm solution. It was injected into the UPLC system against a blank of mobile phase after optimizing the mobile phase composition, chromatogram was recorded."



Acidic Degradation

Basic Degradation

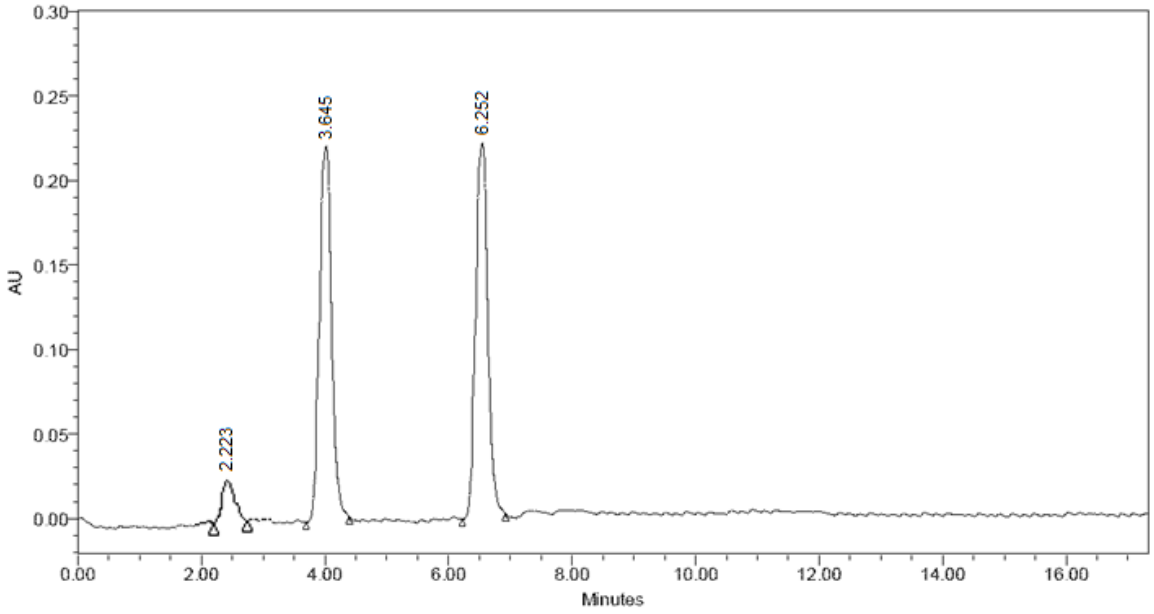
"An accurate 10 ml of pure drug sample solution was transferred to a clean and dry RBF. 30 ml of 0.1N NaOH was added to it. It was refluxed in a water bath at 60°C for 6 hours. Drug became soluble after reflux which was insoluble initially. It was allowed to cool at room temperature. The sample was then neutralized using 2N HCl solution and final volume of the sample was made up to 100ml with water to prepare 100ppm solution. It was injected into the UPLC system against a blank of mobile phase after optimizing the mobile phase composition, chromatogram was recorded."



Basic Degradation

Oxidative Degradation

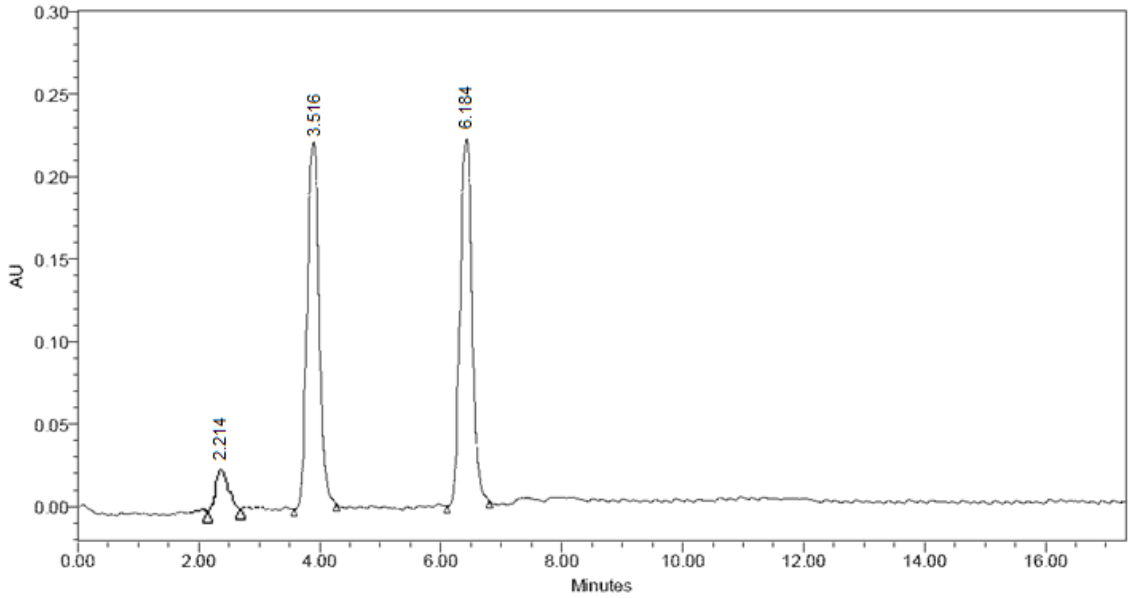
Approximately 10 ml of pure drug sample was transferred in a clean and dry 100 ml volumetric flask. 30 ml of 3% H2O2 and a little methanol was added to it to make it soluble and then kept as such in dark for 6 hours. Final volume was made up to 100 ml using water to prepare 100 ppm solution. The above sample was injected into the UPLC system. The chromatogram was recorded.



Oxidative Degradation

Wet Heat Degradation

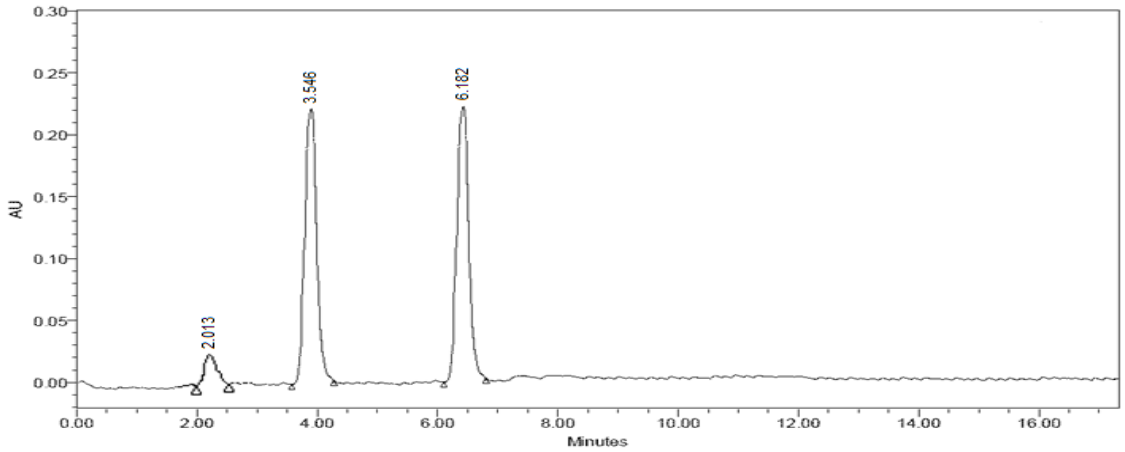
"Accurate 10 ml of pure drug sample was transferred to a clean and dry RBF. 30ml of UPLC grade water was added to it. Then, it was refluxed in a water bath at 60°C for 6 hours uninterruptedly. After the completion of reflux, the drug became soluble and the mixture of drug and water was allowed to cool at room temperature. Final volume was made up to 100 ml with UPLC grade water to prepare 100 ppm solution. It was injected into the UPLC system against a blank of mobile phase after optimizing the mobile phase composition, chromatogram was recorded."



Wet Heat Degradation

Photolytic Degradation

The photochemical stability of the drug was also studied by exposing the drug solution (4ml) to sunlight for 6 h. Twenty microlitres of the resultant solutions were injected onto column and the chromatograms were run as described.



Photolytic Degradation

Nature of Stress	Degradation condition	Time(h)	Number of degradation products
Acidic	60°C	6	1
Basic	60°C	6	1
Oxidative	RT	6	1
Wet Heat	105°C	6	1
Photolytic	AT	6	1

Forced Degradation

Acidic Degradation

$$\% \ Assay = \frac{1333584}{1368742} \times \frac{12.5}{100} \times \frac{1}{25} \times \frac{100}{12.5} \times \frac{25}{1} \times \frac{625.65}{625} \times 99.98 = 97.50\%$$

Alkaline Degradation

$$\% \ Assay = \frac{1334826}{1362541} \times \frac{12.5}{100} \times \frac{1}{25} \times \frac{100}{12.5} \times \frac{25}{1} \times \frac{625.65}{625} \times 99.98 = 98.04\%$$

Oxidative Degradation

$$\% \ Assay = \frac{1334629}{1368855} \times \frac{12.5}{100} \times \frac{1}{25} \times \frac{100}{12.5} \times \frac{25}{1} \times \frac{625.65}{625} \times 99.98 = 97.57\%$$

Wet Heat Degradation

$$\% \ Assay = \frac{1332145}{1345133} \times \frac{12.5}{100} \times \frac{1}{25} \times \frac{100}{12.5} \times \frac{25}{1} \times \frac{625.65}{625} \times 99.98 = 99.11\%$$

Photolytic Degradation

$$\% \ Assay = \frac{1334794}{1358233} \times \frac{12.5}{100} \times \frac{1}{25} \times \frac{100}{12.5} \times \frac{25}{1} \times \frac{625.65}{625} \times 99.98 = 98.35\%$$

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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