

Syloid® 244 FP silica: Formulation of viscous Simethicone in to chewable tablets

Introduction

Simethicone is viscous, greyish-white, opalescent preparation used as anti foaming agent to prevent formation of gas in gastro intestinal tract. As per USP, it is a mixture of fully methylated linear siloxane polymers containing repeating units of the formula [–(CH3)2SiO–]n, stabilized with trimethylsiloxy end-blocking units of the formula [(CH3)3 SiO–], and silicon dioxide. It contains not less than 90.5 percent and not more than 99.0 percent of polydimethylsiloxane ([–(CH3)2SiO–]n), and not less than 4.0 percent and not more than 7.0 percent of silicon dioxide.

Chewable tablets are preferred by most of the formulators for addressing the ailments related to GIT specially digestion. For Simethicone being viscous in nature, formulators find it challenge to make tablets of liquid Simethicone. Syloid® 244FP silica being highly porous can convert viscous Simethicone into compressible free flowing powder. The detailed formulation and role of Syloid® 244FP silica in Simethicone chewable tablet preparation is discussed in detail below

Materials and Methods

Simethicone was received from Riocare India Pvt Ltd. Syloid[®] 244FP is mesoporous silica gel used from W. R. Grace & Co. All the remaining excipients were of Pharma grade from leading manufacturers.

Chewable tablets of Simethicone were prepared using procedure mentioned as below:

- 1. Simethicone liquid was added to Syloid[®] 244FP silica in the ratio of 2:1 and mixed properly to get free flowing powder.
- 2. Powdered Simethicone was mixed with other tablet ingredients uniformly. The obtained powder was lubricated with Syloid[®] 244FP silica and Talc.

S No	Ingredients	mg/tab	%				
1	Simethicone	40	8				
2	Syloid [®] 244FP silica-adsorbent	20	4				
3	Ludiflash(D-Mannitol+Crosspovidone)	75	15				
4	Crospovidone	50	10				
5	Microcrystalline cellulose 102	200	40				
6	Dicalcium Phosphate	78	15.6				
7	Poly vinyl Pyrrolidone	25	5				
8	Menthol	1	0.2				
9	Sodium Saccharine	1	0.2				
10	Syloid [®] 244FP silica-glidant	5	1				
11	Talc	5	1				
	Total Tablet weight	500	100				

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Table 1	Formulation	of chowable	Simothicono tablote	using Sylaid	244ED silica
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3. Lubricated powder was subjected to compression by using Tablet press.

4. In process quality control parameters were evaluated for the manufactured tablets.



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Results

The prepared tablets were evaluated for various parameters and observations are comprised in table below:

Simethicone tablets				
Tablet weight	500 mg			
Hardness	110 N			
Compression force	10 KN			
Thickness	4.7 mm			
Disintegration time	40 Sec			
Friability	< 1%			

Table 2: Observations of Simethicone tablets



Viscous Liquid Simethicone

Table 3: Simethicone from liquid to tablet



Free flowing powder-Simethicone + Syloid[®] 244FP silica



Simethicone tablets using Syloid[®] 244FP silica

Conclusions

Syloid[®] 244FP silica can convert viscous liquid Simethicone in to free flowing compressible powder. Compressed Simethicone tablets meets all desired specifications and found physically stable at accelerated conditions of humidity and temperature. This confirms the dual role of Syloid[®] 244FP silica i.e. as adsorbent for converting liquid Simethicone into powder and as glidant in tablet dosage form.

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