

# SYLOID® 63 FP

## Pharmaceutical Excipient



Datasheet

## Product Description

SYLOID® 63 FP Pharmaceutical Excipient is a synthetic amorphous silica appearing as white free flowing powder. It has a very high purity and is taste and odor free. It meets the test requirements as published to date by the U.S. Pharmacopoeia-National Formulary for Silicon Dioxide, and the Japanese Pharmaceutical Excipients for Hydrated Silicon Dioxide. It also meets the following food additive standards as published to date: the Food Chemical Codex (FCC); the requirements for E 551, specified in the European Commission Directive 96/77/EC; and D326 of the Japanese Specification and Standards for Food Additives.

## Product Specifications

The following specification parameters will be stated on our Certificate of Analysis.

Property	Specification		Test Method
	Min	Max	
<b>Chemical</b>			
Sulfate as SO <sub>4</sub> (wt%)		0.1	GRACE 1260
Silica SiO <sub>2</sub> (wt%)	99.4		GRACE 1260
Loss on Ignition @ 1832F (wt%)		8.5	GRACE 1701
Loss on Drying @ 145°C (wt%)		4.0	GRACE 1702
<b>Physical</b>			
pH (None)	4	6	GRACE 1200

## Recommended Applications

SYLOID® 63 FP Pharmaceutical Excipient is a fine-sized, low pore volume gel with a huge internal surface area. Its very strong affinity for moisture along with its ease of incorporation can effectively contribute to the processability, stability and shelf life of moisture-sensitive products in many pharmaceutical and food applications. Due to its very low moisture content, however, it is critical to carefully follow storage and sampling instructions.

Key features are:

- Multifunctional additive, excellent compatibility with active ingredients
- Can keep powders dry and free flowing, which contributes to uniform flow through equipment and a more consistent product dosing
- Can be highly efficient in comparison to other inactive excipients for improving oral formulations, especially of moisture-sensitive pharmaceutical active ingredients

# SYLOID® 63 FP Pharmaceutical Excipient

## Packaging Information

SYLOID® 63 FP Pharmaceutical Excipient is supplied in bags.  
22.7 kg/bag    30 bags/pallet    681 kg/pallet    pallet: 1118 x 1448 mm

## Handling & Storage Recommendations

Like other finely powdered products SYLOID® 63 FP Pharmaceutical Excipient has a tendency to develop dust. During handling, precautions should be taken against electrostatic discharges. Additional information can be found in our Material Safety Data Sheet (MSDS). SYLOID® 63 FP Pharmaceutical Excipient should be stored in a clean, dry warehouse to protect against contamination. Its high adsorptive capacity necessitates keeping it separately from odors such as organic solvents and odorant materials during transportation, storage and handling. Open packages, including shrink-wrapped pallets, should be immediately resealed to prevent uptake of moisture and contamination of the product. Once a single bag is opened, it is best to place it in a PE bag shortly thereafter. The material should be used within 12 months from the date of production. Provided the storage recommendations are followed, silica gels stored beyond the recommended shelf life are typically fit for use. However, it is advised that a quality control test be performed on the properties relevant to the application.

## Health & Safety Information

SYLOID® 63 FP Pharmaceutical Excipient is a synthetic amorphous silica. Additional information can be found in our Material Safety Data Sheet (MSDS). Please refer also to national laws and regulations.

## ISO Certification

ISO 9001: 2000 Registered. Pharmaceutical Quality Group (IPEC-PQG) GMP Certification for Pharmaceutical Excipients (depending on manufacturing location).

## Other Information

The information contained herein is based on our testing and experience and is offered for the user's consideration, investigation and verification. Since operating and use conditions vary and since we do not control such conditions, we **DISCLAIM ALL WARRANTIES, EXPRESSED OR IMPLIED**, with regard to results that may be obtained from the use of this product. Test methods are available on request.

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### W. R. Grace & Co.-Conn. 7500 Grace Drive, Columbia, MD 21044

**Americas**  
Deerfield, Illinois  
Tel: 1 847 948 8600  
discoverysciences@grace.com

**Europe**  
Lokeren, Belgium  
Tel: +32 (0)9 340 65 65  
discoverysciences.EU@grace.com

**India**  
Pune  
Tel: +91 20 6644 9900  
pune@grace.com

**China**  
Shanghai  
Tel: 86 21 5467 4678  
dsbiz.asia@grace.com

**Australia**  
Rowville  
Tel: +61 3 9237 6100  
Email: discoverysciences.AU@grace.com

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### Tested according to US Pharmacopoeia.

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