

SYLOID® 244 FP

Pharmaceutical Excipient



Datasheet

Product Description

SYLOID® 244 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 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 2008/84/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	
Chemical			
Sulfate as SO ₄ (wt%)		0.1	GRACE 1260
Silica SiO ₂ (wt%)	99.4		GRACE 1260
Loss on Ignition @ 1832F (wt%)		8.5	GRACE 1701
Loss on Drying @ 145°C (wt%)		5.0	GRACE 1702
Physical			
pH (-)	5.0	8.0	GRACE 1200
Color (L-value) (%)	97		GRACE 1432

Recommended Applications

SYLOID® 244 FP Pharmaceutical Excipient is a fine-sized, high pore volume silica gel with a large internal surface area. Its strong affinity for moisture along with its ease of incorporation can effectively contribute to the processability, stability and shelf life of products in many pharmaceutical and food applications.

Key features are:

- Multifunctional additive, excellent compatibility with active ingredients
- Highly adsorptive as a carrier for liquids and actives, up to 1.6 ml of a liquid per gram
- Can keep powders dry and free flowing for a more consistent and uniform processing / dosing
- Can be highly efficient as an inactive excipient for improving oral formulations, especially of moisture-sensitive pharmaceutical active ingredients

SYLOID® 244 FP Pharmaceutical Excipient

Packaging Information

SYLOID® 244 FP Pharmaceutical Excipient is supplied in bags.

10 kg/bag 14 bags/pallet 140 kg/pallet pallet: 1000 x 1200 mm

Handling & Storage Recommendations

Like other finely powdered products SYLOID® 244 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® 244 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® 244 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,

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

Tested according to US Pharmacopoeia.

GRACE®, GRACE DAVISON® and SYLOID® are trademarks, registered in the United States and/or other countries, of W. R. Grace & Co.-Conn. GRACE DAVISON DISCOVERY SCIENCES™ is a trademark of W. R. Grace & Co.-Conn. This trademark list has been compiled using available published information as of the publication date of this brochure and may not accurately reflect current trademark ownership. Alltech Associates, Inc. is a wholly owned subsidiary of W. R. Grace & Co.-Conn. Grace Davison Discovery Sciences is a product group of W. R. Grace & Co.-Conn. © Copyright 2011 W. R. Grace & Co.-Conn. All rights reserved.

The information presented herein is derived from our testing and experience. It is offered for your consideration and verification. Since operating conditions vary significantly, and are not under our control, we disclaim all warranties on the results that may be obtained from the use of our products. W. R. Grace & Co.-Conn. and its subsidiaries can not be held responsible for any damage or injury occurring as a result of improper installation or use of its products. Grace reserves the right to change prices and/or specifications without prior notification.