

SYLOID® AL-1 FP

Pharmaceutical Excipient



Datasheet

Product Description

SYLOID® AL-1 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	Unit	Specification	Test Method
Moisture (145°C, 4h)	%	1.5 max.	GRACE Q 047
Loss on ignition	%	8.5 max.	GRACE Q 048
Average Particle Size (Malvern Mastersizer)	µm	6.5 – 8.1	GRACE Q 013
Wet Screen Residue	%	0.01 max.	GRACE Q 004 (DIN EN ISO 787-18)
pH (5% aqueous suspension)		4.0 – 6.0	GRACE Q 011
Assay (SiO ₂ , dry basis)	%	99.0 min.	GRACE Q 046

Typical Properties

The following Typical Properties data are given for informational purposes only and are not to be interpreted as product or in-process specifications.

Property	Unit	Typical Value	Test Method
Pore Volume (H ₂ O)	ml/g	0.4	GRACE Q 053
Oil Adsorption	g/100g	80	GRACE Q 015 (DIN EN ISO 787-5)

Recommended Applications

SYLOID® AL-1 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® AL-1 FP Pharmaceutical Excipient

Packaging Information

SYLOID® AL-1 FP Pharmaceutical Excipient is supplied in bags.

25 kg/bag 18 bags/pallet 450 kg/pallet pallet: 800 x 1200 mm

Handling & Storage Recommendations

Like other finely powdered products SYLOID® AL-1 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® AL-1 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® AL-1 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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Tested according to US Pharmacopoeia.

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