



Multifunctional Excipients for the Pharmaceutical Industry

Syloid® FP silica is efficient in many pharmaceutical applications due to its unique morphology. It has a highly developed network of meso-pores that provide access to the large surface area that defines its performance.

The result is a product that is :

- Easy to incorporate, providing more uniform dispersion of actives and improved content uniformity
- High in adsorptive capacity - both for hydrophilic and hydrophobic compounds



Applications:

- **Glidant**
- **Tabletting Aid**
- **Carrier for Active Ingredients**
- **Thickening, Gelation and Suspension**
- **Moisture Scavenger**
- **Disintegrant**

Syloid® FP Silicas - Product Specifications*

| Property | 63FP | 72FP | 244FP |
|------------------------------------------|-------|-------|-------|
| SiO ₂ (dried basis) (%) | 99.6 | 99.6 | 99.6 |
| Average particle size (via Malvern) (µm) | 6.0 | 6.0 | 5.5 |
| Oil adsorption (lbs/100lbs) | 90 | 220 | 300 |
| Bulk density (lbs/ft ³) | 29 | 10 | 6 |
| pH (of 5% H ₂ O slurry) | 4.7 | 6.7 | 7.0 |
| Loss on Drying (%) | < 5.0 | < 5.0 | < 5.0 |
| Loss on Ignition (%) | < 8.5 | < 8.5 | < 8.5 |
| Average Pore Volume (cc/gm) | 0.4 | 1.2 | 1.5 |

* These specifications are provided for informational purposes only. Not to be used as sales, product, or in-process specifications.

Note: Certificate of Analysis is supplied with each SYLOID® FP silica shipment.

Excipients

Syloid® excipients are micronized synthetic amorphous silica gels of high purity that are widely formulated into many pharmaceutical products. In therapeutic categories, i.e. Anti-infectives, Central Nervous System and Cardiovascular, they can effectively contribute to the processability, stability and release of active pharmaceutical ingredients (API) and the shelf life of their finished dosage forms.

Multifunctional

Syloid® FP silica's unique combination of adsorptive capacity, meso-porosity, particle size and surface morphology allows it to promote the consistent release of the drug and protect it from degradation.

Syloid® FP Excipients Advantages

- Effective desiccant to increase the stability of moisture-sensitive APIs
- Efficient conditioner for powder formulations used in suspensions
- Capillary wetting agent for better release and disintegration
- Contribution to the controlled release of active pharmaceutical ingredients (API)
- Low dusting and easy to handle

Applications

Glidant

Syloid® FP silica as a glidant should be incorporated in your formulation at levels from 0.25 - 2.0% to achieve a free flowing powder that will resist sticking to the walls of your transfer system, tableting and other equipment. Uniform powder flow is critical to achieving a consistent product dosage, whether the product is a capsule, tablet or other solid dosage form. The adsorptive properties of Syloid® FP silica, along with its ease of incorporation, make it a highly effective glidant for pharmaceutical use.

Carrier for Active Ingredients

The high porosity of Syloid® FP silicas enables them to absorb up to 300g of liquid per 100g of silica. Therefore, liquid ingredients can be easily turned into free flowing powders. This is an advantage for powders used in oral suspension dosage forms and tablets to be developed for higher API potency.

Tabletting

Good powder flow is required for the successful manufacturing of solid dosage forms.

Syloid® FP silica incorporated in your powder during the granulation process or direct compression means uniform flow through your equipment. This can boost consistency during the tableting process and provide improvement in the following parameters:

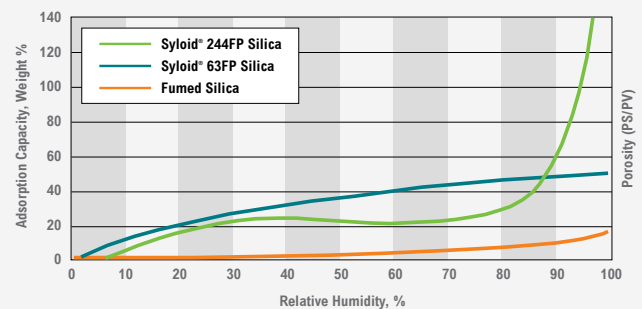
- Reduced friability and improved hardness
- Content uniformity
- Structural stability
- Quicker tableting because of unique moisture adsorption
- High resistance to capping, lamination and sticking
- Controlled release

During the compression cycle of the tableting process, liquid ingredients can be forced to the surface or even caused to exude from the tablet. The large internal porosity of Syloid® FP silica provides greater capacity for any liquid ingredients that may be included in your formulation, which can prevent the occurrence of the above problems.

Moisture Scavenger / Protector

Syloid® FP silica can act as an extremely efficient dehydrating agent, even at a very low moisture content. This can help to maximise product shelf life. Trace quantities of moisture can affect a formulation in many ways. It can degrade your API, it can cause reactions between your ingredients and can decrease shelf life. By adsorbing moisture from the atmosphere, Syloid® FP silica can help protect the bulk powder from these effects.

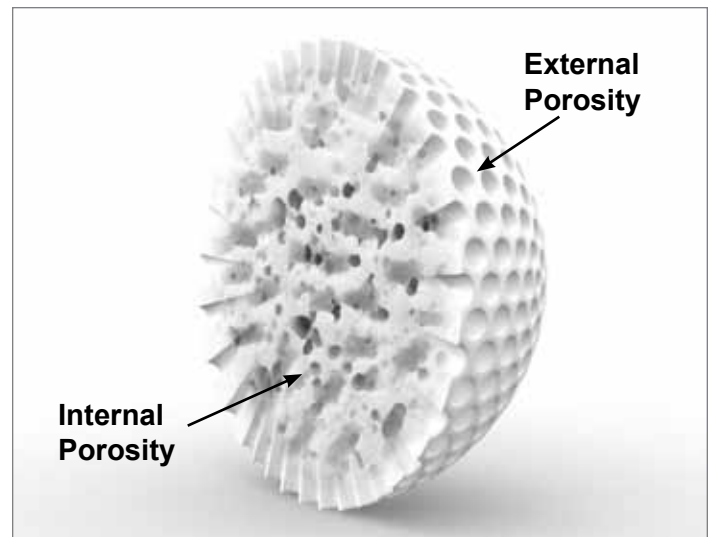
Water Adsorption Capacity



The moisture adsorption capacities of the different grades of Syloid® FP silicas are compared to fumed silica. It can be seen that for any relative humidity, a Syloid® FP silica can be chosen which will give the highest moisture adsorption.

Coating

- Protection from light and moisture
- Taste masking
- Wetting of tablets by reducing hydrophobicity
- Matting agent
- Modified drug release



The combined internal and external porosity of Syloid® FP silica gives it greater available surface area.

Syloid® FP Silica Can Bring

- Superior, strong absorptive capacity for both oil and water
- High capability for improving flow and reducing caking of many APIs during their processing and in their final dosage forms
- Enhanced compactibility for direct compression in combination with other excipients
- Reduced risk of cross-contamination by minimizing "dusting problems"

Ease of Handling and Dispersion

The higher density of Syloid® FP silicas, when compared to many fumed (colloidal) silicas, makes it easier to handle, results in less dust for a cleaner production environment and eliminates the need for sieving prior to usage.

Compliance

Syloid® FP silica grades are manufactured and certified to meet the specific test requirements as published in the latest editions of the United States Pharmacopoeia-National Formulary (USP-NF) for Silicon Dioxide, Japanese Pharmaceutical Excipients (JPE) for Hydrated Silicon Dioxide and the European Pharmacopoeia (EP) for Silica, Colloidal Hydrated.

Your Partner from Discovery to Delivery

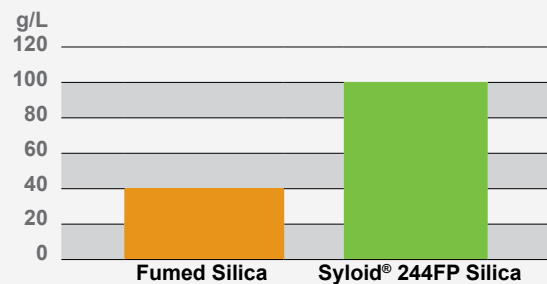
Grace Davison has a strong commitment to innovation.

The R&D group is staffed by a team of research scientists who continually strive to improve the quality of our products and respond to customers needs.

New compounds in development by the pharmaceutical and biotech industries hold the promise for future medical treatments and cures.

We pride ourselves in the contribution we make to the process using our silica as a vehicle in the development of new drug delivery platforms that facilitate these discoveries, and ultimately lead to the creation of better drugs.

Density Comparison



| Property | Benefit |
|----------------------------------------------|---------------------------------------------------------------------------------------------|
| High internal nano porosity and surface area | High efficiency for lower costs Controlled release of active pharmaceutical ingredients. |
| High adsorptive capacity | Carry higher level of actives/ reduced level of inactives |
| High bulk density for lower dust | Cleaner work areas and less chance of cross contamination |
| Controlled particle size distribution | More uniform blending resulting in improved content uniformity |

Today's and Future Applications of Syloid® FP Silicas in Pharmaceuticals

| Pharmaceutical Applications | Grace Silicas |
|---------------------------------------------------------------------------------------------|----------------------------|
| As free flow regulator | Syloid® 244FP silica |
| As active agent carrier | Syloid® 244FP silica |
| As tableting aid and for direct tableting | Syloid® 244FP, 63FP silica |
| As suspension aid (water, oily, alcohol) | Syloid® 244FP silica |
| For increasing the disintegration speed and improvement in the capillary wetting of tablets | Syloid® 63FP, 244FP silica |
| For the shortening of Dragee processing times for sugar dragees | Syloid® 244FP silica |
| For gel formation | Syloid® 72FP, 244FP silica |
| Adsorption of wound secretions | Syloid® 244FP silica |
| Limitation of electrostatic charges during sieving | Syloid® 244FP silica |
| Orodispers tablets | Syloid® 244FP silica |
| Taste masking | Syloid® 244FP silica |
| Moisture scavenger / protector | Syloid® 63FP silica |

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

| | | | | | | |
|------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| Americas Illinois Tel: 1 847 948 8600 discoverysciences@grace.com | Australia Victoria Tel: +61 3 9237 6100 Email: discoverysciences.AU@grace.com | Belgium Lokeren Tel: +32 (0)9 340 65 65 discoverysciences.BE@grace.com | China Shanghai Tel: 86 21 5467 4678 dsbiz.asia@grace.com | France Eperron Tel: +33 (0)2 37 18 86 70 discoverysciences.FR@grace.com | Germany Worms Tel: +49 (0)6241 403 2037 discoverysciences.DE@grace.com | India Chennai Tel: +91 44 4393 7400 chennai@grace.com |
| India Pune Tel: +91 20 6644 9900 pune@grace.com | Italy Passirana Tel: +39 02 935 371 discoverysciences.IT@grace.com | Japan Tokyo Tel: 81 3 3537 6096 dsbiz.japan@grace.com | The Netherlands Breda Tel: +31 (0)76 571 7576 discoverysciences.NL@grace.com | Russian Federation Moscow Tel: + 7 495 9374839 discoverysciences.RU@grace.com | United Kingdom Cannforth Tel: +44 (0)1524 734451 discoverysciences.UK@grace.com | |

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 or status. 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.