

SYLOID® FP and XDP Silica Pharmaceutical Excipients Multifunctional Excipients for the Pharmaceutical Industry

SYLOID® FP and XDP silicas excipients are micronized synthetic amorphous silica gels of high purity which are widely formulated into many pharmaceutical products. In therapeutic categories such as anti-infectives, central nervous system and cardiovascular formulations, they effectively contribute to the processability, stability, and release of active pharmaceutical ingredients (API) as well as the shelf life of their finished dosage forms.

Applications

- Glidant
- Tableting Aid
- Carrier for Active Ingredients
- Carrier for Liquisolds/SEDSS
- Thickening, Gelation, and Suspension
- Moisture Scavenger
- Disintegrant Aid

Higher Effectiveness, Lower Costs

SYLOID® FP silicas are efficient in many pharmaceutical applications due to a unique morphology. A unique combination of adsorption capacity, meso-porosity, particle size, and surface morphology allows it to promote consistent release of the drug and protect it from degeneration.

Pharmaceutical and nutraceutical formulations often rely on a combination of many ingredients with widely different properties. SYLOID® FP silica's structure allows both oily and aqueous ingredients to be effectively dried and uniformly dispersed on the ingredient surface, resulting in a free flowing powder.

Multiple Uses

- Pharmaceutical and OTC Drugs
- Multi-vitamins/Minerals
- Preparations
- Dietary and Herbal Supplements

SYLOID® FP and SYLOID® XDP Silicas – Product Specifications*

Property	SYLOID® 63FP/AL-1	SYLOID® 72FP	SYLOID® 244FP	SYLOID® XDP 3050	SYLOID® XDP 3150
SiO ₂ (dried basis) (%)	99.6	99.6	99.6	99.6	99.6
Average particle size (via Malvern) (µm)	7.5	6.0	3.5	50	150
Oil adsorption (lbs/100lbs)	80	220	300	300	300
Bulk density (g/l)	566	112	70	275	275
Average Pore Volume (cc/gm)	0.4	1.2	1.6	1.7	1.7

* 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 and SYLOID® XDP silica shipment.

The Advantages of Syloid FP® Silicas

- Increased the stability of moisture-sensitive APIs
- Efficiency as a conditioner for powder formulations used in suspensions
- Better release and disintegration as it functions as a capillary wetting agent
- Low dusting and ease of handling

Glidant

SYLOID® 244FP silica should be incorporated in your formulation at levels from 0.25-1.0% to achieve a free flowing powder that will not stick 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 oral dosage form of pharmaceutical. The adsorptive properties of SYLOID® 244FP silica, along with its ease of incorporation, make it a highly effective glidant for pharmaceuticals.

Tabletting

SYLOID® 244FP silica incorporated into your powder during the granulation process ensures uniform flow through your equipment. Good powder flow is required for the successful manufacturing of solid dosage forms.

This results in higher consistency during the tabletting process and improvement in:

- Content uniformity
- Structural stability
- Reduced friability and improved hardness
- Resistance to capping, lamination and sticking
- Quicker tabletting because of unique moisture adsorption
- Controlled drug release rate

During the compression cycle of the tabletting process, liquid ingredients can be forced to the surface or even caused to exude from the tablet. The large internal porosity of SYLOID® 244 FP silica provides greater capacity for any liquid ingredients in a formulation to help prevent this.

Carrier for Liquids, Oils and Active Ingredients

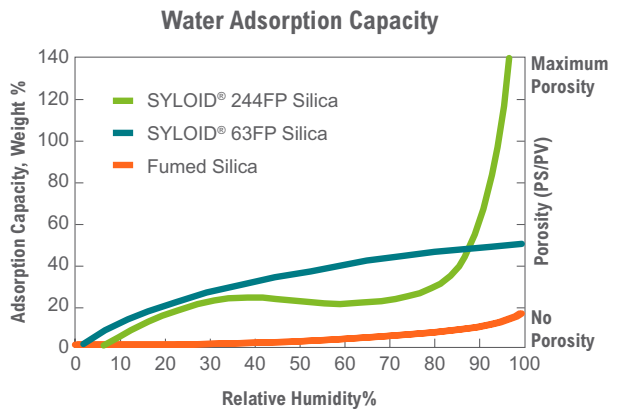
The high porosity of SYLOID® XDP silicas enables them to absorb up to 300g of liquid per 100g of silica. Liquid ingredients can be easily turned into free flowing powders with optimum density. This is an advantage for lissolids, solid SEDDS, oily API and powders used in oral suspension dosage forms and tablets to be developed for higher API potency.

Carrier for Active Ingredients

The high porosity of SYLOID® FP silicas enables them to absorb up to 300g of liquid per 100g of silica. Hence 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.

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 maximize product shelf life. Trace quantities of moisture can degrade your API, it can cause reactions between your ingredients and can decrease shelf life. SYLOID® FP silica acts as an extremely efficient dehydrating agent even at a very low moisture content. It removes moisture for maximum shelf life protection.



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.

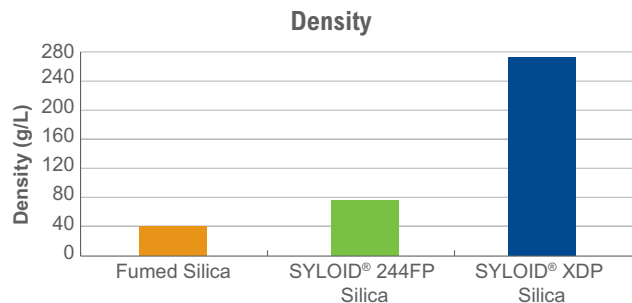
Coating

SYLOID® FP silica helps improve suspension stability as well as protecting pharmaceuticals from light and moisture by reducing hydrophobicity. It plays a role in taste making, modified drug release and is used as a matting agent.

Ease of Handling and Dispersion

The higher density of SYLOID® FP silicas, when compared to most fumed (colloidal) silicas*, makes it easier to handle and results in less dust and a cleaner production environment as well as eliminating the need for sieving prior to usage. SYLOID® 244FP silica provides significantly higher moisture adsorption than fumed silica.

*Fumed silica is identified as colloidal silica in the USP/NF monograph.



Property	Benefit
High internal MESO porosity and surface area	High efficiency for lower costs Controlled release of active pharmaceutical ingredients.
High adsorptive capacity	Carry higher level of liquids/actives
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

SYLOID® 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.

Grace has decades of experience supplying the pharmaceutical industry with its approved silica excipients and its reliable customer support. Quality assurance is given by full regulatory and analytical expertise including application of the HACCP concept during processing and final product release of our SYLOID® FP silicas. SYLOID® 244FP silica is packed in bags and palletized.

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For more information about SYLOID® FP silica, visit: SYLOIDFP.com

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