

Syloid[®] FP Silica

Expect More From Your Excipient



Grace Davison
Discovery Sciences

GRACE

Raising Expectations for Excipients

Think Beyond Fillers

Excipients have often been viewed as simply inactive ingredients or processing aids. However, many experienced formulators know that choosing Syloid® FP silica excipients can offer additional formulation value.

Improve Profitability

Choosing the right excipient can substantially impact manufacturing efficiency, dissolution, therapeutic effectiveness and stability of the final dosage form. A functional excipient such as Syloid® FP silica can even be selected for biosimilar and hybrid formulations. Choosing the right excipient early in the process can help reduce time to market and help improve the chance of an NCE or NBE being commercialized.

Minimize Risk

Supply chain optimization and other financial constraints can tempt drug manufacturers to seek out low cost excipients to reduce manufacturing costs. This can inadvertently put security of supply, stability of the formulation, and performance of a new drug at risk.

To minimize risk in excipient selection, explore existing approved excipients and choose a known and trusted manufacturer with accredited product quality and manufacturing certifications. Working with the manufacturer can reduce handling errors and improve transparency.

Expect More

By expecting more from your excipient and developing a collaborative relationship with the manufacturer, you can gain valuable insights on improving your formulations.

Excipients are emerging as strategic drug development tools in today's challenging pharmaceutical landscape.

Partner with Grace to learn more about multi-functional excipients, gain confidence in product quality, and develop future drug delivery solutions.



Syloid® FP Silica

Meeting Higher Expectations

Security and Compliance

Grace is the manufacturer of Syloid® FP silica excipients, facilitating traceability and supply chain custody. Syloid® FP silicas are 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 Colloidal Hydrated Silica.

World-Leading Quality

Syloid® FP silicas are manufactured in Worms, Germany, Baltimore, USA, and Sorocaba, Brazil. Our commitment to quality is demonstrated by REACH, our ISO 9001 plant certifications and LEAN Six Sigma® culture of continuous improvement.

Grace became the first company to receive the IPEA excipient GMP certification. Talk to us to find out how choosing Syloid® FP excipients and working with Grace can help you meet your Quality by Design (QbD) goals.



Baltimore USA Facility

Advanced Silica Manufacturing

Not all silicon dioxides are created equal. Grace pioneered advanced functionality excipients. The Syloid® FP manufacturing process creates micronized particles with highly defined pore structures, resulting in a controlled internal porosity that can be modified to create a range of functionalities. Grace's manufacturing process also includes a unique purifying step to remove metal ions that can cause unexpected interactions in later use. The resulting Syloid® FP silicas have enhanced purity and consistency.



Intelligent Insight: Grace Firsts in Silica and Excipient GMP

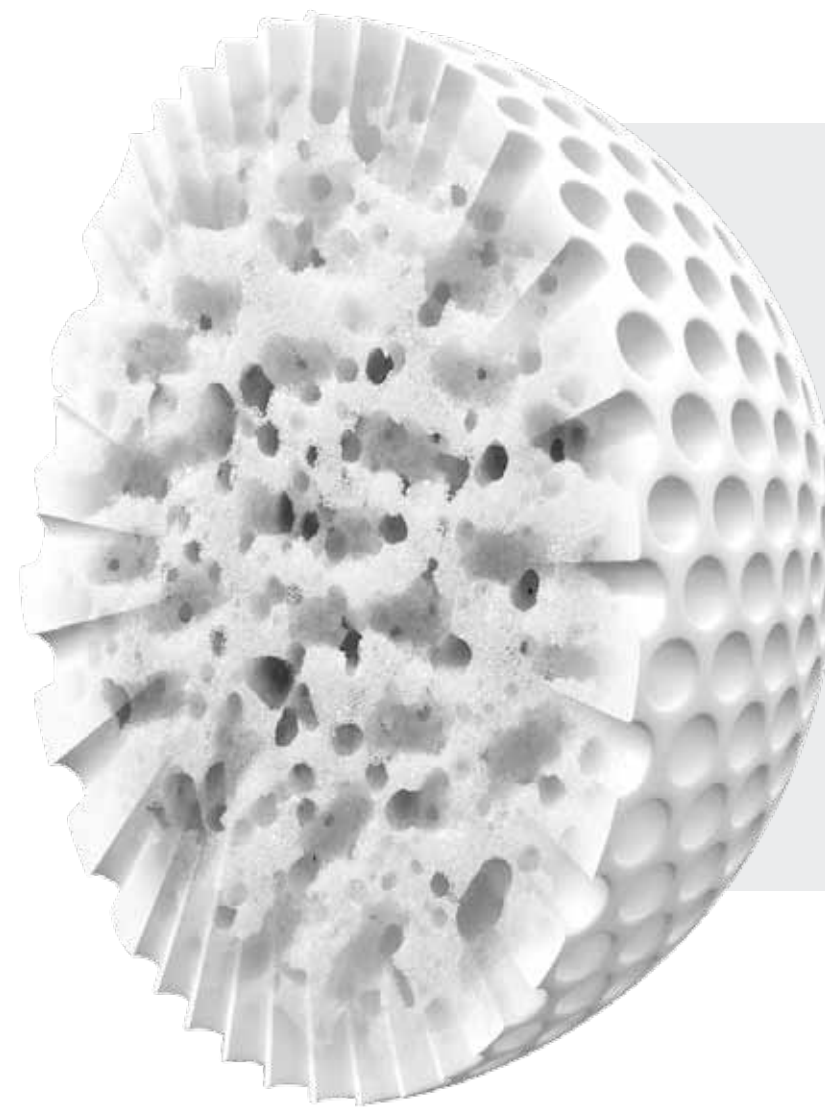
Did you know? Grace was the first company to commercialize silica in 1921. In 2010 Grace was also the first company ever to receive an IPEA GMP certification for quality management of a manufacturing facility pharmaceutical excipients. [1]

Innovative Particle Design for Better Formulations

The ever-increasing demands to improve formulations, the need to bring new drugs to market faster, and ongoing technological advances in pharmaceutical manufacturing equipment all raise the need for a more in depth understanding of excipients' properties.

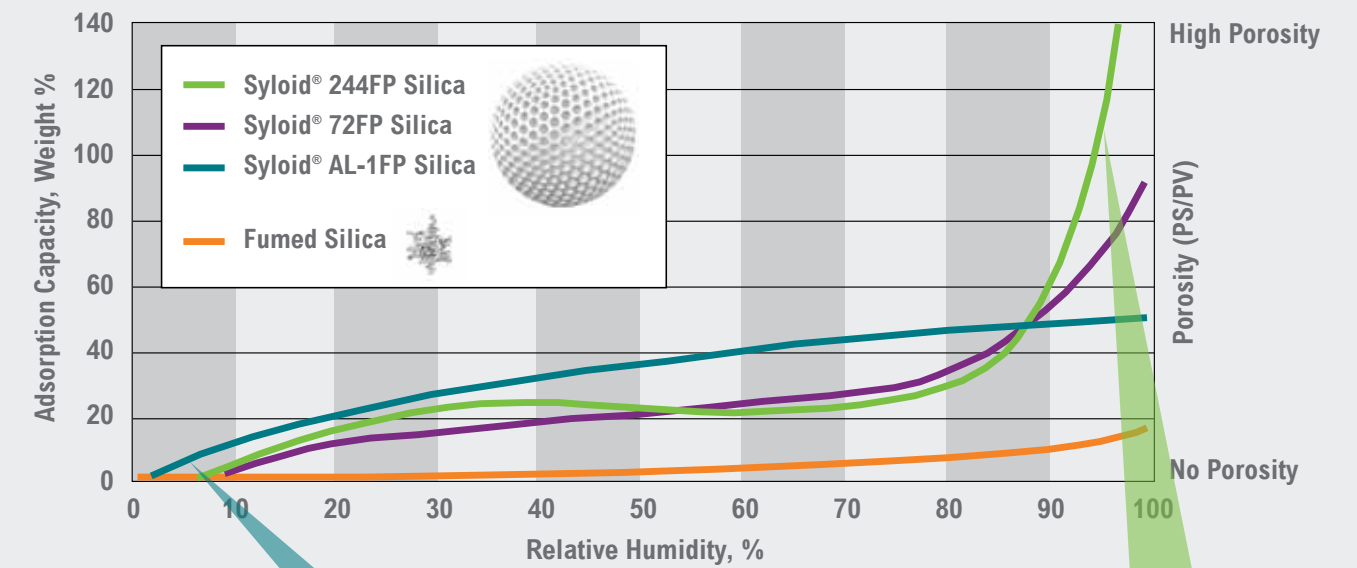
Syloid® FP silicas are the intelligent choice for many pharmaceutical applications due to their unique morphology. The combined adsorption capacity, porosity, particle size, and greater internal surface area allow it to provide several benefits simultaneously that can help minimize the number of excipients required, expedite manufacturing, and improve efficacy of the final dosage form.

Syloid® FP silicas are specifically cited in numerous drug patents due to their unique properties that improve the handling, adsorption, dissolution of many pharmaceuticals. Learn how Syloid® FP silicas can benefit your formulation.



Syloid® FP silicas have a highly developed network of meso-pores that define their performance

Internal Porosity for Greater Adsorptive Capacity



Syloid® AL-1FP Silica

For Moisture Control

Trace amounts of moisture can affect a formulation in many ways. Moisture transfer from the surrounding environment can degrade APIs or cause reactions that negatively impact drugs or decrease shelf life.

Stabilizer / Protectant

- Protects moisture-sensitive APIs
- Prevents moisture uptake with hygroscopic materials
- Helps ensure long-term product storage stability

Dessicant / Drying Agent

- Adsorbs liquids that exude during compression
- Prevents condensation by adsorbing moisture from capsule walls
- Reduces moisture uptake in the formulation of effervescent tablets

Syloid® 244FP Silica

For Advanced Adsorptive Capacity

Syloid® FP silicas have a high porosity and large available internal surface area that enable them to adsorb up to 3x their weight in liquid.

Tablet Wetting Properties

- Improves dissolution profile
- Facilitates gastric and aqueous wetting
- Aids in disintegration for ODT's
- Improves dispersion of tablets in water

Film Coatings

- Use in enteric or sustained release coatings
- Prevents sticking – antitackling agent

Carrier

- Converts liquid ingredients into powders
- Acts as carrier and improves API potency
- Stabilizes oil suspensions

Viscosity and Suspension (72FP)

- Turns liquids into clear gels, creams, or pastes
- Prevents segregation
- Improves aroma storage

Benefits to Manufacturing

For varying relative humidity conditions Syloid® FP silicas can improve flow properties for direct compression and prevent valve blockage during manufacturing.

- Improves glidant properties and homogeneity
- Increases tablet hardness at lower compression force
- Decreases friability, capping, and lamination
- Acts as an anti-static agent and reduces API loss
- Eliminates or reduces need for sieving prior to use

Density Advantages

Greater density gives several manufacturing benefits. It creates less dust for easier GMP compliance and is more compact to store.



Intelligence Insight: Excipient Selection in a QbD World

Did you know? Considerations related to excipients and QbD include the following:

1. Effective Communication between Suppliers and Users
2. Development of Dosage Form
3. Excipient Critical Quality Attributes (CQAs)
4. Equipment and Production
5. Supply of Samples for Development [2]

Excipients to Technologies

Expect More From Your Excipient

Explore the Potential of Syloid® FP Silica

Are you looking for or investigating novel excipients for your formulations? Consider Syloid® FP silicas with existing accredited product quality and discover their unique functionalities.

Additional Applications

- Liquisolid formulations
- Higher loading
- Two-step glidant mixing
- Taste masking
- Chewable dosage forms
- Transdermal dosage forms
- Oil adsorption in lipid based technologies (SEDDS)

New Developments

- Tuning silicas
- Agent to increase permeability
- Coprocessed excipients to improve functionalities
- Hybrid formulations
- Enteric coatings, controlled or sustained release film coatings

Partner with Grace for Drug Delivery Solutions

Grace has a strong commitment to innovation. Our team of research scientists continually strives to improve the quality of our products and respond to customer needs. We believe in open innovation and seeking synergistic partnerships to advance drug delivery technologies.

Grace has formed a strategic partnership with Formac Pharmaceuticals. Formac specializes in the development of silica-based drug delivery technologies and uses its high-throughput screening platforms to identify optimal silica-drug combinations that increase the bioavailability of poorly water-soluble drugs. Bringing together Formac's proprietary drug delivery platforms with Grace's silica R&D and manufacturing expertise will provide a unique opportunity to discover and develop innovative technologies to address solubility challenges.

Evolving developments in the pharmaceutical and biotech industries, combined with novel drug delivery platforms hold the promise of making new medical treatments and cures a reality.

GRACE

Enriching Lives, *Everywhere.*®



Intelligent Insight: The Solubility Challenge

Did you know? 40% of drugs on the market are poorly soluble and more than 70% of APIs in development are poorly soluble. Improving the solubility and bioavailability of NCEs and NBEs can enable commercialization or improve efficacy. Research has shown that the unique properties of Grace silicas can increase the dissolution rate of drugs that are sparingly soluble. [3,4]

Grace Davison Discovery Sciences Delivers More Pharmaceutical Solutions

From Discovery to Delivery

Discovery

The Reveleris® flash chromatography system combined with Reveleris® cartridges packed with Grace® silica, helps medicinal chemists to detect more, purify more, recover more and submit NCEs faster.

Synthesis

Synthetech customized peptide building blocks and specialty amino acids support clinical development, including regulatory starting materials, advanced intermediates, and early stage APIs.

Purification

Grace offers a broad range of products for pilot and process scale purification, including Davisil® and Vydac® media, Spring® columns, and the Multipacker® column packing station.

Delivery

Syloid® FP silica excipients have unique properties that improve the handling, adsorption, and dissolution of many pharmaceutical compounds. Partner with Grace to develop new drug delivery solutions.



Syloid® FP Silica Manufacturing and Technical Facilities



www.discoverysciences.com

Syloid® FP Silica

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References

- [1] IPEA, Inc. Web Site: <http://www.ipeainc.com/Certification%20Documents/IPEAAccreditationPressRelease%204-23-10.pdf>
- [2] GMP Compliance Organization Web Site: http://www.gmp-compliance.org/eca_news_1692_6006,6021,6033,6034,5898.html
- [3] AshLesh Sheth and Charles I. Jarowski, *Use of Powdered Solutions to Improve the Dissolution*, Drug Development and Industrial Pharmacy, 16(5) 769-777 (1990)
- [4] Pushpa Sindhu Aremanda, *Improving Solubility of Poorly Water Soluble Drug Indomethacin by Incorporating Porous Material in Solid Dispersion*, Dissertation: Long Island University (2010)

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