Syloid Silica

Excipients for Pharmaceutical Applications
Think Beyond Fillers

Excipients have often been viewed as simply inactive ingredients or processing aids. However, many experienced formulators know that choosing Syloid® 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® 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 from Your Excipient

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.
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® and Syloid® XDP silica excipients are the intelligent choice for many pharmaceutical applications due to their unique morphology. The combined adsorption, capacity, particle size, density and internal surface area allow Syloid® silicas to provide multifunctional benefits or optimize an application. This helps minimize the number of excipients, reduce the complexity of your formulations and expedite manufacturing which ultimately improves the efficacy of the final dosage form.

Benefits to Manufacturing

For varying relative humidity conditions Syloid® 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
- Easy transformation of liquids into free flowing powders
- Maximizes loading capacity for oily actives or lipid-based drug delivery

Density Advantages

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

Internal Porosity for Greater Adsorptive Capacity

Syloid® AL-1FP/63FP 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 – antitacking 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
Syloid® XDP Silica

Optimized Carrier for Oily Actives and Lipid Based Delivery Systems

Syloid® XDP silicas are engineered with specific particle size and adsorption capacity that creates the ideal carrier for lipids. The combination of density and capacity deliver the highest load of drug or lipid delivery system in a given volume such as a tablet or capsule.

Transform liquid formations into stable solids

- Ease of loading SMEDDS and oily formulations on Syloid® XDP silica for better flowability and content uniformity
- Free flowing powder can easily be converted into capsules and tablets
- Better release of drugs from SMEDDS tablets without compromising other tablets parameters
- Syloid® XDP silica meets test requirements in global monographs

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]
Security and Compliance
Grace is the manufacturer of Syloid® silica excipients, facilitating traceability and supply chain custody. Syloid® 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® 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® silica excipients and working with Grace can help you meet your Quality by Design (QbD) goals.

Advanced Silica Manufacturing
Not all silicon dioxides are created equal. Grace pioneered advanced functionality excipients. The Syloid® silica 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® silicas have enhanced purity and consistency.

Intelligent Insight: Grace First 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]
Explore the Potential of Syloid® Silicas

Are you looking for or investigating novel excipients for your formulations? Consider Syloid® silica excipients to solve your formulation challenges. Syloid® silicas are well known and have been used for decades in pharmaceutical formulations. Discovery the multifunctional benefits and product quality Syloid® silica excipients provide.

Additional Applications

- Liquisolid formulations
- Taste masking
- Improved moisture assisted dry granulation
- Two-step glidant mixing
- Transdermal dosage forms
- Oil absorption in lipid based technologies (SEDDS)

New Developments

- Solvent-free drug loading
- Dermal drug delivery technologies
- Drug layering technologies
- Enteric coatings, controlled or sustained release film coatings
- Co-processed excipients to improve functionality

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]
Syloid Silica Manufacturing and Technical Facilities

www.discoverysciences.com

Syloid Silica
Excipients for Pharmaceutical Applications

References


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