

PHARMACEUTICAL SOLUTIONS



Imagine what you could make possible

How much faster would you achieve commercialization if your supplier could actually eliminate costly barriers, delays, and unforeseen complications as they occur?



Imagine what you could do if:

- You could improve efficiency and reproducibility by using the same supplier, from small scale discovery to mass production
- Your supplier could customize their materials to always meet your precise requirements
- Your supplier could help you avoid expensive delays or even failing to launch a life-changing product
- You knew you could rapidly scale up to meet demand upon commercialization

It's all possible with Grace.

We offer unmatched quality and reproducibility of our fine chemicals, chromatography resins, formulation excipients, and active ingredient delivery technologies.

Our unyielding focus on innovation and advanced technical expertise are built upon a 100-year history of exceeding customer expectations at every phase of the drug development process, from discovery to commercialization.

If you find yourself facing a challenge that cannot be met with existing products, we can work with you to customize a solution that meets your needs.

Expertly synthesized fine chemicals



Imagine what you could do with an experienced R&D partner at your side offering you complete support in custom chemical synthesis, including product development, project management, and scale-up expertise.

Our fine chemicals feature:

- Chiral intermediates synthesized on scales up to 80 MT/year per project
- Peptide building blocks and fragments ranging in scale from 1-500 Kg/batch and in lengths from 2-16 amino acids by solution phase chemistry
- Specialty amino acids ranging on scales from grams to low MT levels
- Aryl, aliphatic, and chiral boronic acids and esters
- Specialized fluorine containing building blocks which can be incorporated into a wide range of chiral molecules



Collaborate with us

We have a deep understanding of organic synthesis in a cGMP environment and work collaboratively with our customers, forging strong relationships based upon transparency and communication.





Imagine what you could do with chromatography products that deliver precision, specificity, recovery, reproducibility, and superior efficiency. Now back that up with an experienced technical support team always at your service.

Our chromatography resins provide you with:

- The widest range of pore diameters, particle sizes, and chromatography phases available
- Engineering capabilities that allow particle properties to be fine-tuned to meet your specific needs
- · Batch-to-batch consistency and reproducibility
- Resins that can be used from analytical lab scale through to commercial scale
- ISO 9001 certified and FDA registered products
 - DAVISIL® silica products come in a granular form and are offered in a wide range of particle and pore sizes and in many phases from small to multi-ton quantities.
 - be extremely robust, with narrow particle size distribution resulting in highly reproducible, superior chromatographic performance. Davisil® Sphere also offers capabilities for protein/peptide separation and purification.
- DAVISIL® XWP (Extra Wide Pore) silica offers superior mechanical stability and large pore sizes with narrow pore size distribution, which make it optimal for separations of large biological molecules.
- VYDAC® spheroidal silicas are welldefined, highly pure, and totally porous separation resins with excellent selectivity and reproducibility for biopurification.
- VYDAC® packed columns are available through our exclusive partner HiChrom at hichrom.com.



EXPLORE OUR NEW AND CUSTOMIZABLE PRODUCTS

VYKING™ paramagnetic silica

Features a novel particle design that clads a paramagnetic core with silica to eliminate the need for chromatography, centrifugation, or vacuum filtration steps required in typical biomolecule purifications.

Consult with us

We can develop customized products to suit your specific needs, including custom bonding of Grace's or your chromatography resins.



Imagine what you could do working with a partner who can engineer products to your exact specifications and minimize the number of excipients and complexity of your formulation, while expediting manufacturing and improving the efficacy and stability of your API's final dosage form.

Our SYLOID® mesoporous silica's particles have a unique combination of properties.

We can fine-tune parameters such as pore volume, pore diameter, pore size distribution, and internal surface area to modify the functionality and meet your exact requirements.

- SYLOID® AL-1FP/63FP silicas control trace amounts of moisture and moisture transfer from the surrounding environment which can degrade APIs or cause reactions that negatively impact drugs or decrease shelf life.
- **SYLOID® G silica** for glidant applications is specifically designed as a cost effective glidant in pharmaceutical formulations.
- SYLOID® 244 FP silica is a real multipurpose excipient that can be used in tablet coating. It offers moisture protection, anti-tacking properties, and acts as a glidant and suspension aid.
- SYLOID® XDP silica carrier is an optimized mesoporous material engineered for transforming liquids to free-flowing solids, particularly oily actives and lipid-based systems.



TRUST OUR RENOWNED QUALITY AND EXACTING STANDARDS

Grace's silica excipients are made according to **Good Manufacturing** Practices (cGMP) guidelines and our compendial materials meet the requirements published in the latest edition of the United States Pharmacopoeia-National Formulary (USP-NF) for Silicon Dioxide, European Pharmacopeia, and JPE monographs. SYLOID® silicas are also listed on the FDA inactive ingredient database. Additionally, we are proud to be foremost in Industry Leading **Quality Standards** (Excipact® -GMP).

Exceptionally innovative active ingredient delivery

Imagine what you could do if working with poorly soluble compounds was not an insurmountable issue.

Our SILSOL® silica active ingredient delivery technology combines Grace's extensive expertise in mesoporous silica gel, novel application methods, and patent pending technologies to accelerate the screening and development of solubility enhancing solid dispersions, with the added benefit of doing so with compendial, scalable, and available silicas.



Grace's SILSOL® silica active ingredient delivery technology offers five major benefits:

- Enhanced bioavailability through delivery of the amorphous form of active ingredients
- Sustained stability from amorphous solid dispersions that prevent crystallization/re-crystallization
- Pharmacopoeia acceptance of our cGMP manufactured silica that conforms to global monographs
- Scalable cGMP excipient manufacturing from grams to tons quantities
- FDA compliant materials listed on the FDA inactive ingredient database (IID)

Compared to other bioavailability enhancing techniques such as particle size reduction, complexation, lipid-based systems, and polymer-based solid dispersions, our SILSOL® silica technology introduces techniques that are easier to screen and work in combination with existing technologies to improve usage and stability, thereby reducing the time needed to scale up.



DISCOVER OUR EXPANSIVE, CUSTOMIZABLE PORTFOLIO

Grace's SILSOL® silica active ingredient delivery technology is used with solvent impregnation to create amorphous solid dispersions.

Due to our vast expertise in particle design,
Grace can modify the pore size and surface characteristics of silica to accommodate various API molecules. The net result is enhanced bioavailability with improved stability.

It's all possible

W. R. Grace & Co. is a leading global innovator built on talent, technology and trust. We serve customers in over 60 countries and have over 4,300 highly skilled employees worldwide. Our teams are dedicated to helping you get your product to market through advanced technology, innovative science, and the strictest oversight.

Our extensive experience with the stringent regulatory and quality requirements in the pharmaceutical industry, technical capabilities, customer service, global presence, and culture of continuous innovation round out a partnership you can trust in today's dynamic global pharmaceutical and biotech industry.



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