

SYLOID® FP Silica

Multifunctional Excipients for the
Nutraceutical and Pharmaceutical Industry





Formulation Challenges

Nutraceutical and vitamin formulations can be very challenging due to a variety of factors. They generally contain numerous active ingredients, which create formulating challenges due to the differences in particle size, flow, compressibility, moisture sensitivity, and ingredient interaction. For example, some active ingredients may be available in granular form, while others may be available only in fine powder form. Thus, the ingredient blend will have many different particle sizes leading to non-homogeneous distribution of actives and tablet-to-tablet variability. Another factor contributing to formulation challenges is lot-to-lot variation of physical characteristics of botanically derived ingredients. Additionally, oily or sticky raw materials are difficult to formulate into solid dosage forms, especially in the presence of fine powdered ingredients.

Hygroscopicity

Plant extracts tend to be hygroscopic, and they can absorb moisture from the environment, resulting in the formation of sticky masses adhering to other powdered ingredients and the equipment. The severity of the problem depends on the Relative Humidity (RH) of the environment and the specific RH over which the ingredient loses its free-flowing properties.

SYLOID® FP silicas are a highly porous, micronized silica powder. When added to a formulation, SYLOID® FP silicas are capable of adsorbing a considerable amount of moisture, keeping the active ingredient dry and free-flowing.

Stability

In addition to flow improvements, SYLOID® FP porous silica gel can also help improve the stability of moisture sensitive ingredients such as natural products and vitamins by adsorbing moisture during manufacturing and storage of the final product. This helps prevent degradation and extends the shelf life.

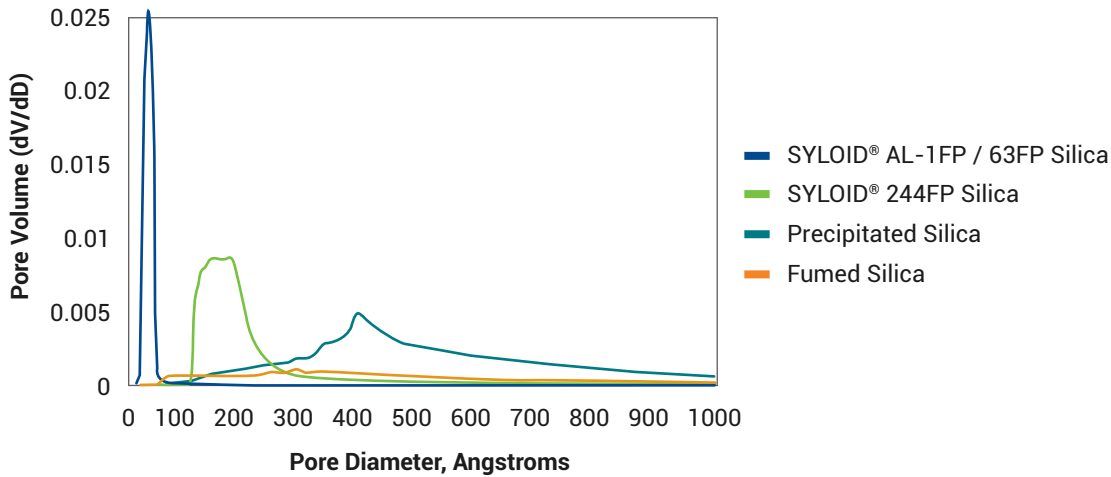
Dosage Size

The high number of active ingredients combined with the constraints of dose size often result in limited available volume for excipients. The typical nutraceutical formulation has 70-90% actives leaving only 10-30% for excipients. The lower level of excipients and variety of actives in the same formulation can make it difficult to achieve certain desired formulation outcomes such as good flow, optimal disintegration time, tablet hardness and reduced friability. SYLOID® FP silicas are highly efficient, multi-functional excipients that can achieve several formulation requirements simultaneously. At the same time, their high bulk density results in a relatively small contribution to the final dosage size. Grace's SYLOID® FP silicas can help in mitigating or resolving these key formulation challenges.

Key Properties of Silica

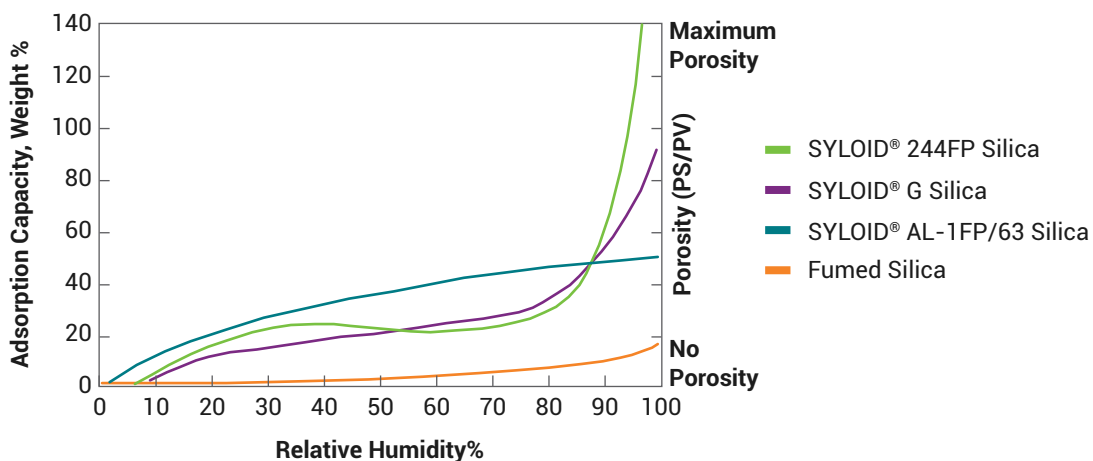
Pore Size Distribution

The carefully controlled, tight pore size distribution of the SYLOID® silicas offer formulators additional benefits such as superior moisture control and uniform interaction between silica and adsorbates.



Adsorptive Capacity

Pore size can greatly impact the moisture adsorption behavior of the silica. Small pore size silica has the ability to adsorb moisture at low relative humidity, acting as a desiccant. The wider pore size silicas adsorb a significant amount of water at higher relative humidity.



Case Study

Description

SYLOID® 244FP silica was compared to precipitated and pyrogenic (fumed) silica at the optimized amount (1%) in the multivitamin formula. Powder flow was characterized by an angle of repose, and later the powder was compressed into tablets.

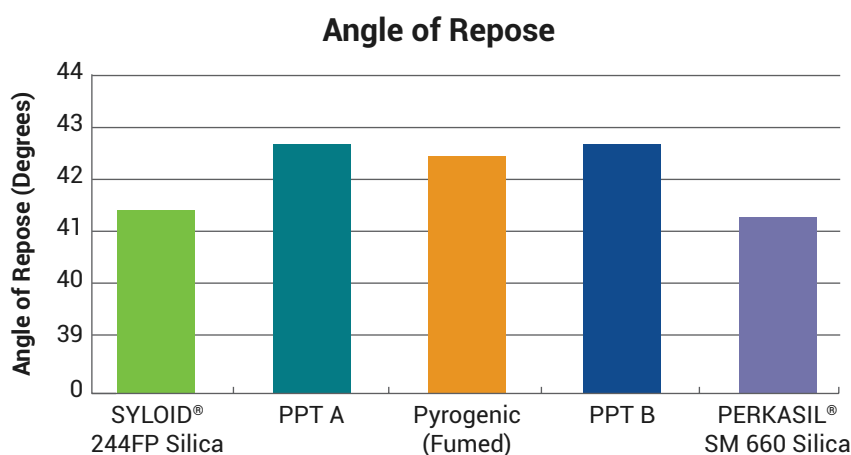


Frame Formulation

Ingredients	% Composition
Vitamin A	2
Vitamin B1	2
Vitamin B2	2
Vitamin B3	4
Vitamin B6	0.4
Vitamin B12	0.001
Biotin	0.01
Folic acid	0.2
Vitamin C	15
Vitamin D3	0.003
MCC	61.8
AcDiSol	6
PVP K30	5
SYLOID® FP Silica - Glidant	1
Mg Stearate	0.5
Total	100

Results: Silica Effect on Flow and Hardness

Flowability of the powder is the most important factor, and unfavorable flow affects the table weight uniformity and processability. Glidants are added to the formulation to improve the flow properties of the mixture.

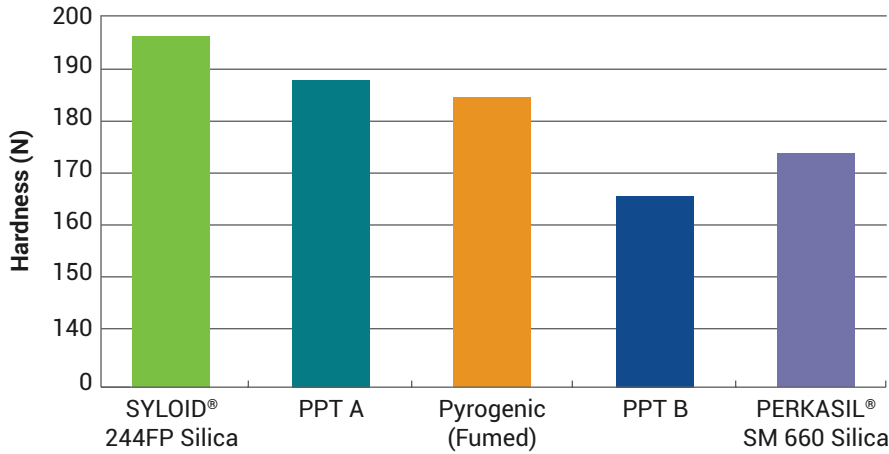


The flow of the tablet blend is superior with SYLOID® 244FP and PERKASIL® SM 660 silicas (the lowest angle is best) resulting in:

- Uniform distribution of actives
- Better tablet weight consistency
- Reduced production time

Tablets with SYLOID® 244FP silica are superior in hardness, as compared to the pyrogenic (fumed) and precipitated silica, preventing breakage during processing, packaging, and transport.

Multivitamin Tablet Hardness Comparison



Tablet Weight Variation

In the process of compressing a tablet, issues often arise. One of them is weight variation. Tablet weight variation in a compressing process is an important issue that can affect the amount of actives per dose.

Silica	Dusting	Tablet Weight Standard Deviation
SYLOID® 244FP Silica	No dusting	1.32
Precipitated Silica A	No dusting	5.27
Pyrogenic (Fumed) Silica	Nuisance dust	2.98
Precipitated Silica B	No dusting	4.51
PERKASIL® SM 660 Silica	No dusting	2.82

Using SYLOID® 244FP silica as a glidant results in the lowest tablet weight variation.



Attributes in Powder Nutritional Supplements

Grace's SYLOID® and PERKASIL® silicas are particularly suited for formulating powder-based nutritional supplements. In bulk powder applications, maintaining a free-flow behavior during processing is critical to minimize downtime and ensure product quality and homogeneity. Free-flow describes the ability to maintain the powder velocity once it is in motion. In this respect, Grace's SYLOID® and PERKASIL® silicas act as free-flow agents and serve the following functions:

- Prevent packing of particles and act as a physical barrier upon compaction
- Coat and smooth the edges of bulk powders reducing
- inter-particle friction
- Adsorb excess moisture from the atmosphere before it can be absorbed by the bulk powder
- Adsorb moisture and oil diffusing out of the bulk powder

Grace's silicas are of high purity, chemically inert, and are very efficient in helping to ensure free-flow, even for the most troublesome powdered supplement products.

Benefits of SYLOID® FP Silica Excipients for Moisture Control and Adsorption


- Improved product uniformity during blending
- Increased efficiency
 - Low usage levels, lower cost
 - High carrying level
- Protection against moisture pick up
- Reduced dusting during production
- Decreased tablet weight variation
- Lower friability and improved tablet hardness
- Increased production rates
- Allows direct compression instead of granulation processes

Benefits of SYLOID® 72FP Silica and SYLOID® G 156F* Silica for Glidant Applications

SYLOID® 72FP and SYLOID® G 156F* silica for glidant applications silica is specifically designed as a cost effective glidant in pharmaceutical formulations.

- Improves flow for standard and challenging formulations
- Less dust, reduced potential for cross contamination
- Less bulky, easier to handle and store

* only available in Americas



Summary

Choosing your excipient wisely is very important and can improve processing time, product quality and formulation development validation time and helps overcome many of the challenges that are common in nutraceutical and vitamin formulations.

Adding SYLOID® silica excipient to the formulation can address many of the common nutraceutical and vitamin challenges. It can greatly improve flow properties of the blend and allow the formulator to achieve the consistent flow that will result in better product uniformity and greater tablet strength while minimizing tablet weight variation.

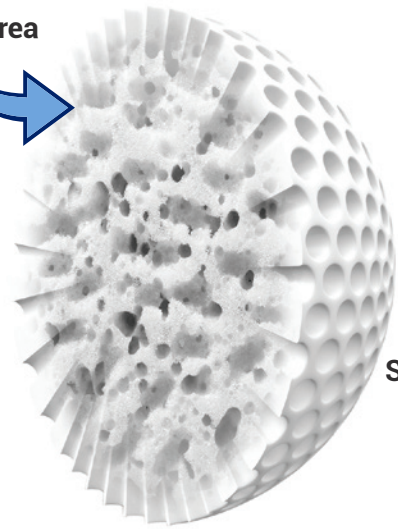
Regulatory Compliance

SYLOID® FP silica products are manufactured and certified to meet the test requirements as published in the latest USP-NF edition for silicon dioxide; JPE for hydrated silicon dioxide; EP for silica, colloidal hydrated as well as silica, dental-type, and the Chinese National standard GB25576-2010 Class III.

All FP products also meet food additive standards such as the Food Chemical Codex (FCC); the requirements for E551 as specified by the EU Directive No. 231/2012; D326 of the Japanese Specification and Standards for Food Additives and JECFA requirements for Silicon Dioxide, Amorphous.




**Internal
Surface Area**



**External
Surface Area**





For more information about SYLOID® FP silica,
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