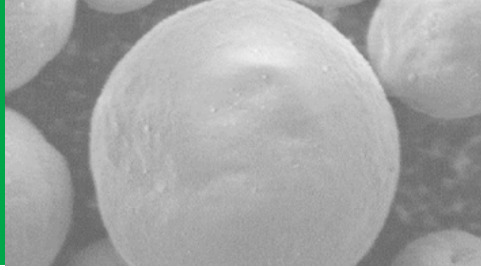
TECHNICAL DATA SHEET

FujiSil™



FujiSil™-The Next Generation of Porous Silica

FujiSil™ is a spray-dried granular amorphous Silica, designed as a superior inert carrier for pharmaceutical applications. FujiSil™ has a unique internal structure and remarkable flow properties giving high internal porosity and superior compressibility properties.

Key Features

- Minimum reactivity with actives
- Very high porosity
  - ✓ High oil adsorption capacity (up to 3.3ml/g)
  - ✓ Solid dispersions
- Superior tabletability
  - ✓ Unique structure and processing improves both the flowability and compressibility

General Properties

Chemical formula		SiO_2
General name		Silicon Dioxide (USP/NF) Silica, colloidal hydrated (EP) Hydrous silicon dioxide (JPE)
Appearance		White powder
Form		Amorphous
Bulk density	Loose (g/ml)	0.17
	Tapped (g/ml)	0.20
Specific surface area (m^2/g)		400
Average particle size (μm)		80
Oil adsorbing capacity (ml/g)		3.3
Pore volume (cm^3/g)		2.1
Angle of repose (°)		30
pH in slurry		4.0 - 8.0
Loss on drying (%)		2.6

Table 1: General properties
*for reference only

Pharmacopoeia & Regulatory

FujiSil™ meets all requirements of the current pharmacopeia;

- JPE: Hydrous silicon dioxide
- USP/NF: Silicon Dioxide
- EP: Silica colloidal hydrated

Handling & Storage

- Packaging: 10 kg Alminum bag in Kraft bag
- Storage: Store at room temperature and avoid high humidity.
- Shelf life: 3 years from the date of manufacture stored in recommended conditions.

Superior Tabletability

The unique internal granular structure of FujiSil™ imparts superior flowability and compressibility during the tableting process. This results in improved tablet strength as illustrated in the following two charts representing key aspects of tablet strength.

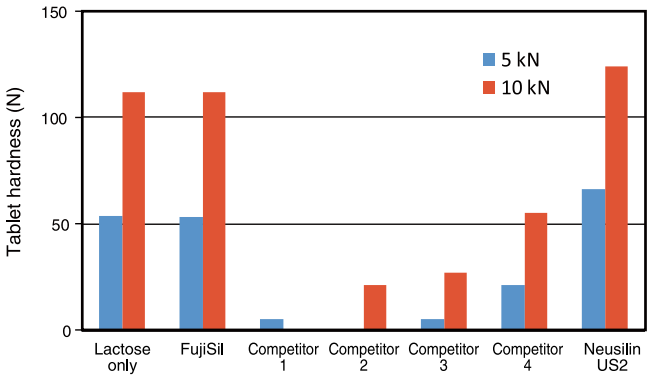


Chart 1: Tablet compressibility Tablets were prepared with a single-punch tableting machine. (90% lactose with 10% silica, Mg stearate applied to punch).

Parameters⌀: 11.3 Flat-Head 500 mg/T; Compression Force: 5 kN, 10 kN

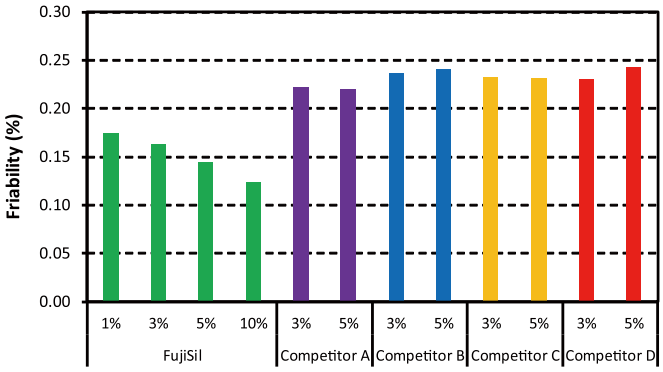


Chart 2: Tablet friability (90% lactose with 10% silica). Composition according to Table 2. Tableting parameters: ⌀8 Flat-Faced, 200 mg/T, Rotary Speed: 30 rpm, Tablet hardness:70 N

Added Silica	0%	1%	3%	5%	10%
Lactose	55.3	54.6	53.2	51.8	48.3
Corn Starch	23.7	23.4	22.8	22.2	20.7
MCC	20.0	20.0	20.0	20.0	20.0
Silica	-	1.0	3.0	5.0	10.0
Mg-St	1.0	1.0	1.0	1.0	1.0

Table 2: Compositions of Chart 2

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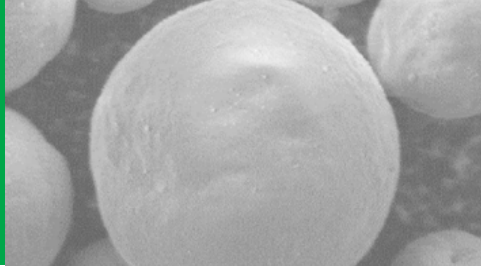

Typical Applications

- Transform liquids to solid dosage forms
- Solid dispersions
  - ✓ Improved processability and stability
  - ✓ Solubility enhancement for BCS class II & IV drugs
- Granules suitable for coating
  - ✓ Taste masking
  - ✓ Controlled / Delayed release
- Moisture protection properties

Application in oil adsorption

With a high internal porosity, FujiSil™ can be used as a carrier for liquids, both aqueous and oil based. Up to 3.3ml/g of oil can be adsorbed onto FujiSil™ while it remains as a free-flowing powder. As an example, a typical loading of 1:1 is recommended for tableting, in which case the loaded FujiSil™ retains an angle of repose of 34° and can easily proceed thru a tableting process without leakage of oil.

Figure 1: (i)Via capillary forces, an oily API is readily adsorbed onto the Fujisil in order to create (ii) the free-flowing oil-loaded powder, prior to the tableting process to create (iii) Hard tablets without oil leakage.

Application in solid dispersion

FujiSil™ is an excellent adsorbent carrier for solid dispersions that may be utilized, for example, to improve dissolution profile of poorly water-soluble drugs (BCS Class II & IV API's) and stability of amorphous solid dispersion state. Multiple preparation methods are available including:

- •Spray-drying
- •High energy milling
- •Processing above the APIU melting point
- •Hot Melt Extrusion (HME)
- •Adding via a solvent step to transport the API into the pores (prior to evaporating out the solvent).

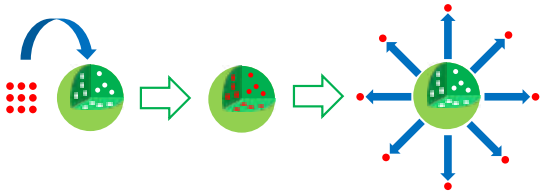

Figure 2: Solid dispersions for improved API solubility

(i) Crystalline API is added into the pores using a relevant method (discussed in text), resulting in

(ii) A free-flowing solid dispersion (where the API is in a stable amorphous phase), that is incorporated into the relevant solid dosage form.

(iii)After application, the drug is released in the body via diffusion with increased solubility (due to the amorphous form and high surface area).

Granules suitable for coating

FujiSil™ can be loaded prior to a coating step in order to encapsulate specific chemistries for:

- Separation of chemistries
- Taste Masking
- Controlled release
- Delayed release

Application in taste masking granules

FujiSil™ can be used as an inert core to create smaller taste masking granules than conventional carriers. In addition, it can shorten the granulation time compared to other inert cores.

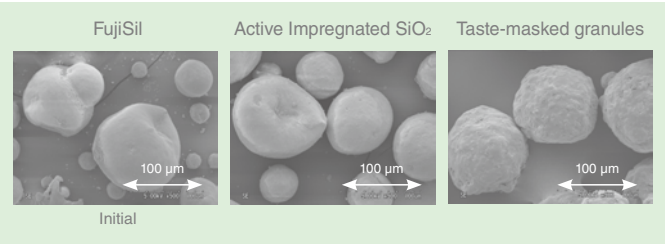

Figure 3: Example of loading and coating of FujiSil™ for taste-masking application.

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