CABOT

FUMED METAL OXIDES

CAB-O-SIL® MULTIFUNCTIONAL EXCIPIENT FOR PHARMACEUTICALS

APPLICATION OVERVIEW

CAB-O-SIL FUMED SILICA IN SOLID DOSAGE FORMS

FREE FLOW

Improves flow for tableting and capsule filling, leading to increased production yields and tablet weight uniformity.

MOISTURE ADSORPTION

Due to its hydrophilic chemical structure, can act as a scavenger of moisture and help stabilize drugs that require an acidic pH for optimal stability. In granulation processes, can enable uniform particle size distribution via disintegration of large wet agglomerates and redistribution of the moisture in the mixture.

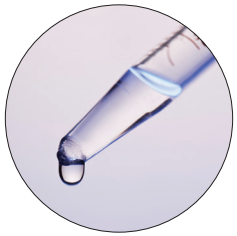
SPRAY DRYING AID

Can increase throughput by reducing clogs in the spray dryer atomizer and decreasing the amount of product sticking to the walls. Can improve the drying profile of tacky materials or act as a nucleation aid.

TYPICAL PROPERTIES

CAB-O-SIL fumed silica	Surface Area	Tapped Density	Features
M-5P	200 m^2/g	〈 60 g/l	Easy to disperse

The data above are typical test values intended as guidance only, and are not product specifications. Product specifications are available from your Cabot representative.



TASTE MASKING AGENT

Can be used as part of a microencapsulation system to mask taste or protect sensitive ingredients from degradation. Can be loaded in the microcapsule wall to help nucleate crystalline domains, or can be loaded at the core/microcapsule wall interface to increase stability or alter the viscosity.

TABLET COATING

Can stabilize highly concentrated pigment suspensions, preventing them from settling in liquid tablet coatings. Can be added to build-up powders to improve flow and promote fast drying.

CAPSULE ANTI-BLOCKING

Can be added to the capsule shell wall to form a smooth film. Can promote high-speed filling of gelcaps by reducing adhesion of the liquid filling to the machinery.

CONTROLLED DRUG RELEASE

Adjusting the concentration of fumed silica can facilitate the control of drug release rates. For poorly soluble drugs, it can increase the dissolution rate. This is achieved by dissolving the drug in an organic solvent with the fumed silica and evaporating the mixture to dryness. Fumed silica can also decrease dissolution rates in controlled-release liquid dosage forms by increasing viscosity.

LIQUID AND SEMI-SOLID DOSAGE FORMS

STABILIZATION, ANTI-SETTLING

Can enable the stabilization of dispersions of solids in liquids and prevent the formation of sediments in liquid suspensions.

THICKENING

Can convert non-polar liquids into spreadable gels. Promotes gel stability at body temperature, enabling applications where precise area-dosing is required.

TRANSPARENCY

Clear gels can be formulated if the refractive index of the product matches that of CAB-O-SIL fumed silica (1.46).

STABILITY AND UNIFORM DISTRIBUTION

Can improve the consistency and stability of a suppository. Can increase the softening point without affecting the melting point.

SPRAYING AID

In topical aerosol products can help reduce clogs in the atomizer and prevent the formation of sediments.

PERFORMANCE AS A GLIDANT

Glidants are designed to improve the flow properties of powders and reduce friction and static charge in high speed tablet and capsule machines. Glidants also prevent bridging in the hopper, and enable increased tablet hardness, uniformity in tablet weight and content. These features are key to ensure product regulatory compliance, maintain high productivity, reduce waste from tablet breakage and minimize content variability.

CAB-O-SIL FUMED SILICA

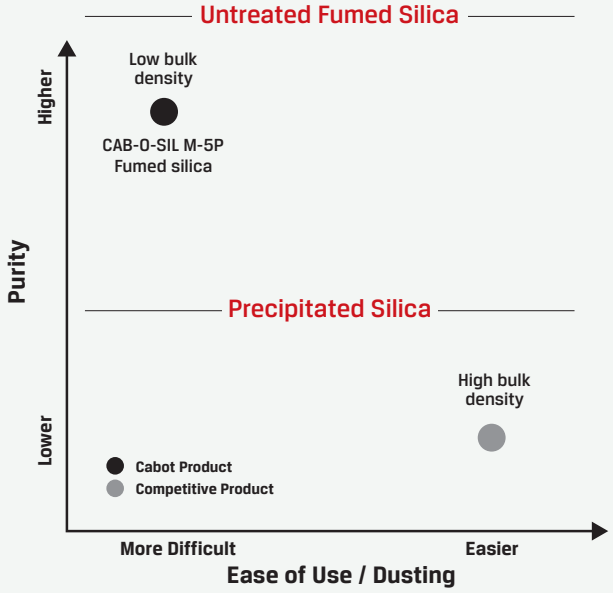
Product	Product Characteristics
M-5P	◆ Cabot's easiest to process glidant. Due its lower density, this product is easier to disperse in both solid and liquid formulations. ◆ Due to its higher purity, M-5P fumed silica is recommended over lower purity precipitated silicas.

Regulatory Compliance:

CAB-O-SIL M-5P fumed silica is in compliance with:

- ◆ USP 37/NF 32 colloidal silicon dioxide monograph.
- ◆ EP 8th Ed. (2014) silica colloidal anhydrous monograph.
- ◆ JP 16th Ed (2011) light anhydrous silicic acid monograph.

PERFORMANCE REQUIREMENTS



Purity:

All CAB-O-SIL fumed silicas are produced through a pyrogenic process that results in one of the purest commercially available forms of colloidal silicon dioxide as defined by the US Pharmacopeia. In contrast, the production of precipitated silica requires the addition of a mineral acid to an alkaline silicate solution, resulting in a lower purity product that contains higher moisture, sulfates and chloride impurities. These impurities can have the following impact:

- ◆ High sulfates and chloride content can affect the stability of some active ingredients. Fumed silica has a lower level of ionic sulfates and chloride than precipitated silica.
- ◆ High levels of moisture can affect moisture-sensitive compounds. Fumed silica has a lower level of moisture than precipitated silica.

Ease of Handling:

A powder's "ease of use" is assessed according to its fluffiness, ease of handling, and storage. At higher bulk densities and particle sizes the product is less fluffy and easier to handle and store.

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www.cabotcorp.com

Technical Support
North America: 1 800 462 2313
South America: +55 11 2144 6400
Europe: +31 71 888 4132
Asia Pacific: +86 21 5175 8800