# CAB-O-SIL® M-5F AND EH-5F FUMED SILICA

## FOR FOOD APPLICATIONS

### Application Guide

<table>
<thead>
<tr>
<th>System</th>
<th>CAB-O-SIL Food-Grade Fumed Silica Benefits</th>
<th>Application Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>LIQUIDS &amp; SEMI SOLIDS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CARRIER, FLAVOR MASKING AGENT: CAB-O-SIL food-grade fumed silica adsorbs liquids to produce dry powders that can be easily mixed with other solids. At higher concentrations, CAB-O-SIL fumed silica can act as a flavor masking agent to facilitate the formulation of fortified/nutritious foods.</td>
<td>Yes</td>
<td>Vitamin E and Omega 3 adsorption Masking of bitter/metallic flavors</td>
</tr>
<tr>
<td>MICROENCAPSULATION: CAB-O-SIL food-grade fumed silica encapsulates volatile compounds, reducing evaporation rates. This increases flavors' shelf life and reduces costly losses due to flavor change in the final product.</td>
<td>Yes</td>
<td>Flavor microencapsulation</td>
</tr>
<tr>
<td>DRYING AID, PROCESS EFFICIENCY: CAB-O-SIL food-grade fumed silica reduces clogs in the spray dryer atomizer and decreases the amount of product sticking to the walls; it delivers higher powder recovery, improves drying efficiency, and increases throughput by facilitating lower spray dryer atomizer temperatures.</td>
<td>Yes</td>
<td>Non-dairy coffee creamer Spray dried tomato powder Canned vegetable oil spray</td>
</tr>
<tr>
<td>THICKENING, ANTI-SETTLING, EMULSIFICATION: CAB-O-SIL food-grade fumed silica is an effective thickening, emulsification, and anti-settling agent, due to its ability to form a network and hold heavier ingredients in place. Its low sensitivity to temperature and pH makes it an attractive replacement for other stabilizers and viscosity control agents.</td>
<td>Yes</td>
<td>Salad dressing Frozen desserts Gelling oils Pickering emulsions</td>
</tr>
<tr>
<td>POWDERS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FREE FLOW, TRANSPARENCY, STORAGE STABILITY: CAB-O-SIL food-grade fumed silica acts as a spacer and moisture absorbent, reducing lump formation and crystallization, and facilitating free flow, exact dosing, and storage stability.</td>
<td>Yes</td>
<td>Automatic coffee powder dispensing Snacks’ powdered flavors Powdered egg whites</td>
</tr>
<tr>
<td>END PRODUCT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LIPID SUBSTITUTION, TEXTURE, AESTHETIC APPEAL: CAB-O-SIL food-grade fumed silica facilitates the substitution of up to 40% of fat contained in foods, by: a) providing a more homogeneous lipid distribution to enhance the fat’s effectiveness; and b) acting as an effective stabilizer of Pickering emulsions that replace fat fractions. In both cases, the organoleptic properties of the final product are preserved.</td>
<td>Yes</td>
<td>Extruded snacks Baked cookies Low calorie frozen foods Pickering emulsions for fat substitution</td>
</tr>
</tbody>
</table>

### CAB-O-SIL Food-Grade Fumed Silica Benefits

- Liquid adsorption
- Anti-settling
- Improved flow
- Improved dispersability
- Increased storage stability
- Improved aesthetic appeal
- Liquid thickening
- Microencapsulation
- Transparency
- Conditioning agent
- Increased drying rates
- Flavor masking
- Lipid substitution
- Improved process efficiency

### Selection Guide

<table>
<thead>
<tr>
<th></th>
<th>CAB-O-SIL M-5F Fumed Silica</th>
<th>CAB-O-SIL EH-5F Fumed Silica</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adsorption</td>
<td>***</td>
<td>*****</td>
</tr>
<tr>
<td>Microencapsulation</td>
<td>***</td>
<td>*****</td>
</tr>
<tr>
<td>Dispersability</td>
<td>*****</td>
<td>***</td>
</tr>
<tr>
<td>Anti-settling</td>
<td>***</td>
<td>***</td>
</tr>
<tr>
<td>Anti-caking</td>
<td>***</td>
<td>***</td>
</tr>
<tr>
<td>Transparency</td>
<td>*****</td>
<td>*****</td>
</tr>
<tr>
<td>Surface Area</td>
<td>200 m²/g</td>
<td>380 m²/g</td>
</tr>
</tbody>
</table>

Performance: Best = ***** Good = ***

### Health & Safety

- High purity, food grade silica quality.
- Colorless, odorless, tasteless.
- No Genetically Modified Organisms.
- Products do not contain common food allergens.
- Food Grade Statement provided by Cabot Corp.

### Regulatory Compliance

CAB-O-SIL M-5F and EH-5F fumed silica are silicon dioxide that:

- Are approved food additives (E551) per listing in EC Regulation N° 1333/2008.
- Are labeled according to EC Regulation N° 1333/2008.
- Meet the purity criteria of E551 monograph as laid out in EU Regulation 231/2012.
- Are determined as US FDA GRAS per scientific procedure established under 21 CFR70.30 (b)

Cabot GmbH, Rheinfelden plant is a registered food ingredients supplier and is HACCP, Kosher and Halal certified.
CAB-O-SIL® M-5F AND EH-5F FUMED SILICA

FOR FOOD APPLICATIONS

APPLICATION GUIDE

CARRIER

Liquid, semisolid, or pasty substances can be converted into dry flowing powders by adding CAB-O-SIL M-5F fumed silica. Improved carrier performance occurs at higher adsorption values.

Oil Adsorption Values (g/100g of Silica)

- Orange Oil: 830
- Lemon Oil: 430
- Silica Gel: 820
- CAB-O-SIL M-5F: 390

FREE FLOW

CAB-O-SIL M-5F fumed silica offers equivalent performance as a flow aid when compared to precipitated silica, with the advantage that it does not dull the natural food color (whereas precipitated silica does). This is thanks to its low refractive index advantage that it does not dull the natural food color (whereas precipitated silica does). For illustration purposes only.

LIPID SUBSTITUTION

CAB-O-SIL EH-5F fumed silica lowers moisture loss, reduces lipid oxidation, and provides stabilization against staling, all while reducing the required lipid fraction. Example: low-calorie soft cookies.

Spray Drying Thermal Efficiency

- Efficiency (%)
- 0.0% 0.2% 0.4% 0.6%
- 64 73 9 thermal efficiency increase

THICKENING

Increased CAB-O-SIL EH-5F fumed silica concentrations can lead to a substantial increase in viscosity. Mixing at low shear forces achieves the best results, as high blending speeds fragment the network formed by CAB-O-SIL fumed silica, reducing viscosity.

Spray Drying Aid

CAB-O-SIL EH-5F fumed silica can improve spray-drying thermal efficiency by up to 10%, prevent clogs in the atomizer and deliver higher powder recovery. It also can increase higher throughput, as spray dryers can be operated with a lower outlet temperature.

Spray Drying Thermal Efficiency

- Viscosity (cP)
- 15,000 10,000 5,000 0
- 0.5% 1.0% 1.5% 2.0% 2.5% 3.0%
- % CAB-O-SIL EH-5F fumed silica (g/100 g oil)

FIND PRODUCT STORAGE STABILITY

CAB-O-SIL EH-5F fumed silica can improve the texture of extruded foods, as measured by breaking strength, which is a proxy for crispiness or brittleness.

Hardness value of low-calorie cookies

- Bubble Size = Force (g) \rightarrow Hardness (lower is better)
- % CAB-O-SIL EH-5F fumed silica

- 0.0% 1.0% 2.0% 3.0%
- 5% 10% 15% 20%
- % Oil

- 250 Lowering oil content makes cookie become harder
- 410 Adding CAB-O-SIL EH-5F makes low-calorie cookie softer
- 280

70% Wheat Starch / 30% Gluten Extrudate

Shear

- Force (N) \rightarrow Crispiness / Brittleness

- 0.0% 0.5% 1.0% 1.5% 2.0%
- 0 200 600 1000

**CAB-O-SIL** is a registered trademark of Cabot Corporation.

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**CAB-O-SIL® MULTIFUNCTIONAL EXCIPIENT FOR PHARMACEUTICALS**

**APPLICATION OVERVIEW**

**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**

<table>
<thead>
<tr>
<th>CAB-O-SIL fumed silica</th>
<th>Surface Area</th>
<th>Tapped Density</th>
<th>Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>M-5P</td>
<td>200 m²/g</td>
<td>&lt; 60 g/l</td>
<td>Easy to disperse</td>
</tr>
</tbody>
</table>

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.

**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.

**PERFORMANCE REQUIREMENTS**

<table>
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<th>Purity</th>
<th>Ease of Use / Dusting</th>
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<tbody>
<tr>
<td>Untreated Fumed Silica</td>
<td></td>
</tr>
<tr>
<td>Low bulk density</td>
<td></td>
</tr>
<tr>
<td>CAB-O-SIL M-5P Fumed silica</td>
<td></td>
</tr>
<tr>
<td>Higher</td>
<td></td>
</tr>
<tr>
<td>More Difficult</td>
<td></td>
</tr>
</tbody>
</table>

| Precipitated Silica |
| High bulk density |
| Cabot Product |
| Competitive Product |
| Lower |
| Easier |

**CAB-O-SIL FUMED SILICA**

<table>
<thead>
<tr>
<th>Product</th>
<th>Product Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>M-5P</td>
<td>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.</td>
</tr>
</tbody>
</table>

**Regulatory Compliance:**

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

- USP 37/NF 32 colloidal silicon dioxide monograph.

**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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CAB-O-SIL® Fumed Silica
for Pharmaceutical and Nutraceutical Applications
Cabot Corporation has been a global manufacturer of specialty chemicals and performance products since 1882. We continue to innovate and find applications for our materials in new fields, where they help improve existing products and create exciting new offerings. Cabot is committed to the reliable delivery of pharmaceutical materials of the highest quality and consistency. Our global reach enables us to partner closely with our ever-growing list of customers in order to become their supplier of choice for quality materials, performance and service.

Current Challenges in Pharmaceutical and Nutraceutical Tablet Production

Producing tablets and capsules of uniform quality in an efficient manner can be challenging. The biggest issues tend to occur during the following stages of the production process:

- **Flow through hopper**
  - Powders may stick to metallic walls due to static charges that affect flow patterns
  - Agglomerates may form in the hopper and this may result in uneven flow as well as bridging

- **Die or capsule filling**
  The manufacture of tablets and capsules on high speed machinery requires the powder to exhibit optimal flow. If optimal flow is not achieved, the following issues can arise:
    - Segregation of active or inactive ingredients due to powder cohesiveness
    - Non-uniformity in tablet content
    - Tablet weight variation

- **Tablet compaction**
  Variable tablet hardness caused by poor powder compaction can lead to capping, lamination, chipping, and tablet breakage
CAB-O-SIL® Product Description

CAB-O-SIL M-5P (pharmaceutical grade) fumed silica is an excipient of extremely high purity used as a multi-functional additive in the pharmaceutical and nutraceutical industries.

CAB-O-SIL fumed silica acts in the following ways to address significant issues involved in tablet production:

- **Flow aid**
  - CAB-O-SIL fumed silica's **glidant** and **anti-static properties** help improve the flow properties of powders and **reduce friction and static charges** in high speed tablet and capsule machines.
  - Additionally, CAB-O-SIL fumed silica helps prevent bridging.

- **Die filling aid**
  - Uniformity in **tablet weight and active ingredient content** result from formulations that flow evenly into the die cavity during the tableting operation.

- **Compaction aid**
  - CAB-O-SIL fumed silica can aid in particle rearrangement within the die during the early stages of compression and can increase bonding strength between powder particles that form a solid tablet, helping to more effectively compact tablets/capsules.
  - **Increased tablet hardness at lower compression forces** results from formulations that are effectively compacted.

Physical-Chemical Properties

CAB-O-SIL fumed silica is compatible with many pharmaceutical ingredients. It adheres readily to hydrophilic ingredients, functioning as an excellent glidant.

<table>
<thead>
<tr>
<th>Pharmaceutical Product</th>
<th>Surface area</th>
<th>Bulk Density</th>
<th>Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAB-O-SIL M-5P fumed silica</td>
<td>200 m²/g</td>
<td>&lt;60 g/l</td>
<td>Easy to disperse</td>
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</tbody>
</table>

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Purity – CAB-O-SIL Fumed Silica versus Precipitated Silica

CAB-O-SIL fumed silica is produced through a pyrogenic process that results in one of the purest commercially available forms of synthetic amorphous silica (99.8% pure). 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 impact the product in significant ways, including:

- 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.
Regulatory Compliance

CAB-O-SIL® fumed silica is produced in a manner consistent with Good Manufacturing Practices appropriate for pharmaceutical excipients.

Pharmacopeia Status

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>CAB-O-SIL M-5P fumed silica</td>
<td>Meets all requirements of &quot;Colloidal Silicon Dioxide&quot;</td>
<td>Meets all requirements of &quot;Colloidal Anhydrous Silica&quot;</td>
<td>Meets all requirements of &quot;Light Anhydrous Silicic Acid&quot;</td>
</tr>
</tbody>
</table>

Performance

**CAB-O-SIL Fumed Silica as Flow Aid**

The formation of a powder bridge in a hopper of a tablet press can lead to a phenomenon known in powder flow as "bridging." The image to the right illustrates this phenomenon:

How is flow measured?

The angle of repose provides a useful correlation to the flow properties of powders. The relationship between the angle of repose and powder flow is shown in Table 1 on the right.

<table>
<thead>
<tr>
<th>Angle of Repose (degrees)</th>
<th>Flow</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 - 30</td>
<td>Very free flowing</td>
</tr>
<tr>
<td>30 - 38</td>
<td>Free flowing</td>
</tr>
<tr>
<td>38 - 45</td>
<td>Fair / passable flow</td>
</tr>
<tr>
<td>45 - 55</td>
<td>Cohesive</td>
</tr>
<tr>
<td>&gt;55</td>
<td>Very cohesive</td>
</tr>
</tbody>
</table>

Figure 1 illustrates the flow properties of APAP (acetaminophen or N-acetyl-p-aminophenol), ibuprofen (isobutylphenylpropanoic acid) and aspirin (acetylsalicylic acid) tablets when tested with various concentrations of CAB-O-SIL® fumed silica. The results indicate that as the concentration of CAB-O-SIL M-5P fumed silica increases, the flowability of the powder mix improves, going from ‘cohesive’ to ‘passable flow’ to ‘free flowing’.

Figure 2 illustrates how the level of CAB-O-SIL M-5P fumed silica in an APAP mixture influences the flowability of the mixture. The results indicate that CAB-O-SIL M-5P fumed silica improved flow properties of the APAP mixture, taking it from a cohesive powder to fair/passable flow.

Figure 3 shows the different flow rates of Avicel® PH-101 Micro Crystalline Cellulose (FMC Corporation) when combined with different loading levels of CAB-O-SIL M-5P fumed silica. Note that without the addition of fumed silica, the powder does not flow.

The data in Figure 3 was measured using the Hanson’s FLODEX™ apparatus, which measures flow rates as a function of aperture diameter. The "bridging" point may be determined with this apparatus by determining the aperture diameter at which no flow of material will occur into the lower graduated cylinder.

Highly Hygroscopic Materials or Materials With Static Charge Problems
For highly hygroscopic materials or materials that exhibit poor flow due to static charge, the amount of added CAB-O-SIL M-5P fumed silica may need to be 3-4 times more than that required for materials that are less prone to static.
CAB-O-SIL® Fumed Silica as a Die Filling Aid

Uniform tablet weights and uniform doses of active ingredients are dependent on the ability of the powder mix to feed into the dies in a reproducible manner. Fumed silica can be added to the formulation in order to improve the flow properties of the material and to aid particle rearrangement within the die during the early stages of die filling and compression.

Tablet Weight and Mixing Time
Formulations that flow evenly into the die cavity during the tableting operation will result in uniform tablet weight and drug content.

Figure 4 demonstrates that the weight of APAP tablets can be influenced by the concentration of CAB-O-SIL M-5P fumed silica in the formulation, as well as the time of mixing.

Tablet Weight and Production Speeds
The addition of CAB-O-SIL M-5P fumed silica allows tablet manufacturers to produce high quality tablets at higher tablet press speeds than they otherwise could, therefore improving productivity.

Figure 5 illustrates that at high production speeds, the tablet weight of formulations that do not include fumed silica decreases by 11%, showcasing issues with the powder's flow and die filling. In contrast, tablets that include 0.25% CAB-O-SIL fumed silica preserve a more consistent weight under higher press speeds.

Note: The formulation includes: 10% APAP and balanced lactose. Bars correspond to minimum and maximum tablet weight.

Note: Ibuprofen tablets with 0.25% CAB-O-SIL fumed silica.
API Content Uniformity
Addition of fumed silica reduces segregation of active and inactive ingredients, promoting content uniformity.

The data in Figure 7 demonstrates that the presence of CAB-O-SIL M-5P fumed silica in a tablet formulation can decrease the coefficient of variation of active pharmaceutical ingredient (API) content in a batch of tablets. Very low variations in drug content were observed with APAP tablet formulations containing 0.5% CAB-O-SIL M-5P fumed silica after blending for 15 minutes. Tablets without fumed silica mixed for 15 minutes exhibited a coefficient of variation of 6%, which is 12 times higher than the variation seen in tablets that did contain CAB-O-SIL fumed silica.

**Figure 6** illustrates that at high production speeds, the addition of 0.25% CAB-O-SIL® M-5P fumed silica reduced tablet weight variation anywhere from 30% to 40% when compared to the same powder mix without a glidant.
CAB-O-SIL® Fumed Silica as Compaction Aid

Tablet Hardness

CAB-O-SIL fumed silica was added to ibuprofen tablets in order to test its influence on tablet hardness. The results of this testing under various compression force levels indicate the following conclusions and are illustrated in Figure 8 below:

- The addition of only 0.25% of CAB-O-SIL fumed silica at 0.25mt of compression force facilitates an 81% improvement in tablet hardness compared to tablets formulated without a glidant. Adding 0.25% CAB-O-SIL fumed silica increases tablet hardness by 104% when compression forces reach 0.5mt.

- The addition of CAB-O-SIL fumed silica can double tablet hardness when compared to tablets formulated without a glidant.

Figure 8 indicates that the highest tablet hardness is obtained at 1.5 metric ton of compression. This is relevant, because as the compression forces are reduced, the wear on press and dyes is reduced as well.