

UNTREATED FUMED SILICA



CAB-O-SIL® M-5P

CAB-O-SIL M-5P untreated fumed silica is a synthetic, amorphous silica that complies with the pharmacopoeia monographs:

"Colloidal Silicon Dioxide" in the U.S. Pharmacopeia/National Formulary

"Silica, Colloidal Anhydrous" in the European Pharmacopoeia

"Light Anhydrous Silicic Acid" in the Japanese Pharmacopoeia

Application Information:

Tablets:

For tableting CAB-O-SIL M-5P functions as a glidant or free-flow additive to provide improved tablet production efficiencies and improved tablet uniformity and strength.

In the tableting process the use of CAB-O-SIL M-5P results in more consistent feed rate of the powders into the tablet press allowing higher press operating speeds while maintaining tablet uniformity.

With the use of CAB-O-SIL M-5P lower press compression force is required reducing equipment wear and yielding uniform tablets at lower tablet hardness.

The use of CAB-O-SIL M-5P in the formulation results in tablets that have:

- Increased hardness and strength hence reduced breakage.
- Decreased weight variation.
- Increased consistency of thickness and density.



Liquids, gels and semi-solids:

CAB-O-SIL M-5P is an efficient thickener of non-polar liquids and can be used to thicken liquids or make gels and semi-solids. At 1.46 the refractive index of fumed silica is close to that of many oils and hydrocarbon solvents, therefore, CAB-O-SIL M-5P can be used to make clear liquids and gels. The thickening mechanism of fumed silica is not strongly temperature dependent, so CAB-O-SIL M-5P can be used to make non-melting gels and semi-solids such as suppositories.

Capsules:

CAB-O-SIL M-5P improves the free-flow of powders and granulations facilitating filling of capsules. For soft-gel capsules, CAB-O-SIL M-5P provides anti-settling for insoluble ingredients in the liquid or gel prior to and during filling of the soft-gel capsules.





Pharmacopoeia Compliance:

Certificates of Analysis for every lot of CAB-O-SIL M-5P fumed silica contain results of compliance testing for the current monograph requirements in the U.S. Pharmacopoeia/National Formulary, European Pharmacopoeia and Japanese Pharmacopoeia. Compliance testing is performed at an external laboratory certified Good Laboratory Practices (cGLP). CAB-O-SIL M-5P is manufactured using Good Manufacturing Practices as appropriate for a pharmaceutical excipient at Cabot's Tuscola, Illinois, USA and Rheinfelden, Germany facilities.

Performance Comparisons:

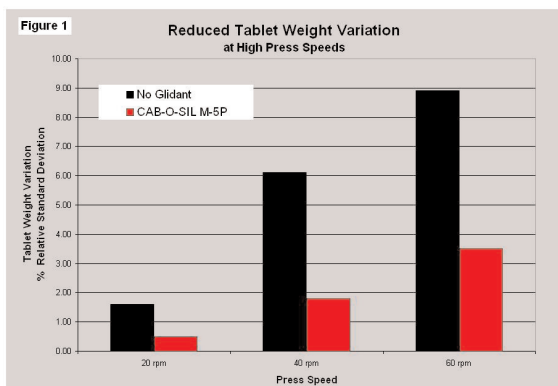
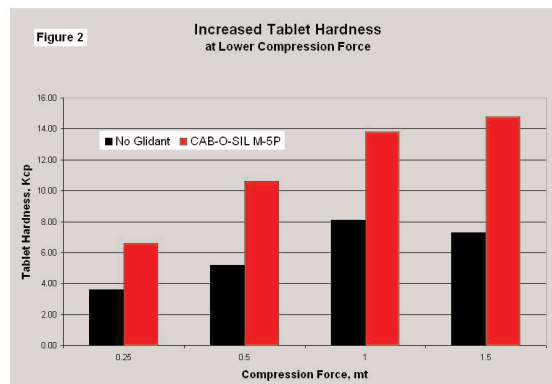


Figure 1 compares the weight variation of Ibuprofen tablets containing 0.5% by weight CAB-O-SIL M-5P to Ibuprofen tablets not containing a glidant. Tablets containing CAB-O-SIL M-5P have significantly lower weight variation especially at higher press speeds. At high press speeds tablets not containing a glidant have unacceptably large weight variation. The use of CAB-O-SIL M-5P allows faster press speeds while achieving tablet weights within acceptable tolerances.

Figure 2 compares hardness of Ibuprofen tablets containing either 0.25% CAB-O-SIL M-5P or no glidant. Regardless of compression force, tablets containing CAB-O-SIL M-5P have significantly higher hardness than without a glidant. With the use of CAB-O-SIL M-5P lower press compression force is required reducing equipment wear and yielding uniform tablets at lower tablet hardness.



Packaging Options:

CAB-O-SIL M-5P is packaged in multi-wall Kraft paper bags. In North America product is packaged in 10-lb bags and is available in 18 x 10 lb poly-shrouded units. In Europe, product is available in 10-kg bags and is available in 18 x 10 kg poly-shrouded units.

Product Sales Specifications:

Sales specifications for this product may be obtained by contacting a sales or technical service manager at the Cabot Corporation office in your region.

Material Safety Data Sheet:

A Material Safety Data Sheet for this product may be obtained by contacting the Cabot Corporation office in your region or can be downloaded from our website:

www.cabot-corp.com

Consult our website for current information on the following for this product:

[Bovine Spongiform Encephalopathy](#)
[Allergens](#)
[Nutritional Value Solvents](#)
[Genetically Modified Organisms](#)
[Microbial Contamination](#)
[Product Shelf-Life](#)
[Food and Cosmetics usage](#)

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