

CAB-O-SIL® M-5P Fumed Silica (Pharma Grade)

CAB-O-SIL M-5P fumed silica is synthetic, amorphous, colloidal silicon dioxide that is manufactured by high temperature flame vapor phase hydrolysis process and has extremely small particle size, enormous surface area and high purity. Its chain-forming tendencies set it apart in a class of its own. Used as an excipient of extremely high purity that is used as a multi-functional additive in the pharmaceutical industries. Compatible with many pharmaceutical ingredients and can acts as a flow additive to reduce common issues in tablets and capsules production including poor flow through hopper, active/inactive ingredient segregation and tablet breakage during compaction.



Flow Aid

CAB-O-SIL M-5P fumed silica's glidant and anti-static properties can reduce the friction and static charge in high speed tablet and capsule machines. The addition of CAB-O-SIL M-5P fumed silica can enable better spacing between the powder particles, reduce moisture bridging and reduce static charge, helping to improve flow and prevent bridging in hopper.

Die Filling Aid

CAB-O-SIL M-5P fumed silica can improve the flow properties of the mixture and aid particle rearrangement within the die during the early stage of the die filling and compression, promoting uniform tablet weight and active ingredient content.

Compaction Aid

CAB-O-SIL M-5P fumed silica can also increase tablet hardness/strength by facilitating particle flow and rearrangement during the early stages of compression process, which can increase the bonding strength between powder particles. This can help prevent subsequent tablet defects like chipping, capping, lamination and breaking.

Typical Chemical & Physical Properties

<u>Property Description and Units</u>	<u>Test Method</u>	<u>Values</u>
pH	CTM 100	3.85 – 4.15
BET Specific Surface area, m ² /g.	CTM 203	185 - 215
325 mesh residue, %w/w	CTM 120	0.02 Max
Loss on Drying*, % w/w	CTM 231	1.0 Max
Tamped Density, g/l	CTM 211	60 Max

* at the time of packaging

Pharmacopoeia Compliances

CAB-O-SIL M-5P fumed silica is tested for compliances to latest pharmacopoeia monographs

- USP/NF monograph for Colloidal Silicon Dioxide
- EP monograph for Silica Colloidal Anhydrous
- JP monograph for Light Anhydrous Silicic Acid and
- BP/IP monograph for Colloidal Silicon Dioxide

Colloidal Silicon Dioxide (USP/NF)

Identification A: Deep yellow colour is produced	Must Conform
Identification B: Greenish blue spot is produced	Must Conform
pH Value <791>	3.5 – 5.5
Arsenic, Method 1 <211>	≤ 8 ppm
Loss on Drying <731>	≤ 2.5 %
Loss on Ignition <733>	≤ 2.0 %
Assay	99.0 – 100.5 %

Colloidal Anhydrous Silica (Ph Eur.) & Colloidal Silicon Dioxide (BP/IP)

Description: Light, fine, white, amorphous powder. It has a particle size of about 15 nm.	
Solubility: Practically insoluble in water and in mineral acids except hydrofluoric acid. It dissolves in hot solutions of alkali hydroxides. When 1 g is shaken vigorously with 20 ml of carbon tetrachloride for 3 minutes; a transparent gel is produced.	Must Conform
Identification: About 20mg gives the reaction of silicates (EP/BP/IP 2.3.1)	Must Conform
pH Value (EP/BP 2.2.3 & IP 2.4.24)	3.5 – 5.5
Chlorides (EP/BP 2.4.4 & IP 2.3.12)	≤ 250 ppm
Heavy Metals (IP 2.3.13)	≤ 25 ppm
Arsenic (IP 2.3.10)	≤ 8 ppm
Loss on ignition at 900°C for 2hr (IP 2.4.20)	≤ 5%
Assay	99.0 – 100.5 %

Light Anhydrous Silicic Acid (JP)

Description: White to bluish white, light, fine powder. Odorless and tasteless, and smooth to touch. Practically insoluble in water, in ethanol (95%) and in diethyl ether. It dissolves in hydrofluoric acid, in hot potassium hydroxide test solutions and in hot sodium hydroxide test solutions, and does not dissolve in dilute hydrochloric acid.	Must Conform
Identification 1: Precipitate does not dissolve in hydrochloric acid	Must Conform
Identification 2: Precipitate has a blue color	Must Conform
Identification 3: Resulting bead upon cooling becomes opaque and acquires a reticulated appearance.	Must Conform
Solubility – Soluble only in HF & hot solutions of alkali hydroxides	Must Conform
Chlorides <1.03>	≤ 0.011%
Heavy Metals <1.07>	≤ 40 ppm
Aluminium	Must Conform
Iron <1.10>	≤ 500 ppm
Calcium	Must Conform
Arsenic <1.11>	≤ 5 ppm
Loss on Drying <2.41>	≤ 7.0 %
Loss on Ignition <2.43>	≤ 12.0 %
Volume Test	≥ 70 ml
Assay	≥ 98.0%

Packaging Options

CAB-O-SIL® M-5P fumed silica is packaged in 10kg multi-wall Kraft paper bags.

Material Safety Data Sheet

A Material Safety Data Sheet for this product may be obtained from your local Cabot Sanmar representative.



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