



CABOT

Cabot Sanmar Limited

UNTREATED FUMED SILICA

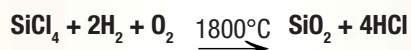
CAB-O-SIL® M-5P



Cabot Sanmar Limited is the only manufacturer of fumed silica in India, a Joint Venture with Cabot Corporation, USA.



CAB-O-SIL® M-5P untreated fumed silica (pharmaceutical grade) is a high purity, chemically inert, odourless, white, free flowing powder manufactured using state-of-the-art technology through a continuous process involving flame hydrolysis of silicon tetrachloride in an oxy-hydrogen flame.



CAB-O-SIL® M-5P fumed silica is hydrophilic due to the presence of surface hydroxyl groups. It has X-ray amorphous structure due to rapid cooling of the silica particles from the molten state to the solid state during manufacturing. It has a refractive index of 1.46 as a result of which it disappears completely in organic solvents having refractive index close to 1.46.

During the manufacturing process, silicon dioxide molecules condense to form particles. The particles collide, attach and sinter together resulting in three-dimensional branched chain aggregates of approximately 150 to 200 nanometers in length. Once the aggregates cool below the fusion point of silica (1710°C), further collisions result in mechanical entanglement of the chains, termed as agglomeration.

Fumed silica is a well-known pharmaceutical excipient since 1957 as

- Traditional glidant for solid dosage form
- Suitable for soft powder mixtures
- Thickener for pharmaceutical oils

The basic manufacturing process for pharma and non-pharma grades of CAB-O-SIL® untreated fumed silica product are almost similar. However, in response to our pharma customers' need, as a part of our commitment to the pharmaceutical industry, we manufacture the pharmaceutical grade fumed silica CAB-O-SIL® M-5P, with process control under steady state conditions and good manufacturing practices in our ISO 9001, ISO 14001 and BS OHSAS 18001 certified manufacturing facility. The product undergoes

rigorous quality tests using all major pharmacopoeia test methods and is supported by complete documentation prior to release for sales. All tests performed are included in Certificate of Analysis. Product properties comply with recent version of pharmacopoeia monographs and registered with USFDA for type-IV excipient.

Regulatory Status - Pharmaceuticals

USP/N	Colloidal Silicon Dioxide
Ph. Eur.	Silica, Colloidal Anhydrous
JP	Light Anhydrous Silicic Acid
Type IV DMF	25597

COA test Parameters

BET Surface Area ¹	Identification ^{2,3,4}
Tapped Density ¹	pH ^{2,3}
325 mesh residue ¹	Chloride ^{3,4}
	Arsenic ^{2,4}
	Heavy Metals ^{3,4}
	Loss on Drying ^{2,4}
	Loss on Ignition ^{2,3,4}
	Assay (SiO ₂ content) ^{2,3,4}
	Aluminum ⁴
	Calcium ⁴
	Iron ⁴
	Volume Test ⁴

¹ Cabot Test Method

² USP/NF Monographs

³ Ph. Eur. Monographs

⁴ JP Monographs

Typical properties of CAB-O-SIL® M-5P Product

Parameter	Typical Values
BET Surface Area, m ² /g	200
Tapped Density, g/L	Ca 40
pH, 4% aqueous dispersion	Ca 4.0
Loss on Drying, 105°C, 2hr	< 1.0 %
Loss on Ignition, Dried material, 1000°C, 2hr	< 1.0 %
SiO ₂ Content, by weight	> 99.8 %

Scanning electron micrograph of CAB-O-SIL® M-5P

CAB-O-SIL® M-5P for Pharma applications

In Solid dosage form (tablets & capsules)

- Improved powder flow and packing characteristics
- Reduces caking
- Improve tablet properties
 - Hardness
 - Weight uniformity
 - Content uniformity
 - Increased tensile strength
 - Enhanced dissolution
 - Improved tableting operation

In Semi-solid dosage form (suppositories & transdermal) acts as

- Inorganic thickener

- Viscosity enhancer
- Keeps the active ingredient uniformly distributed

In Liquid dosage form (gels, cream, suspensions)

- Thickens low polarity media
- Forms clear gel
- Helps pseudo plastic flow behaviour
- Keeps the particles in suspension
- Prevents sedimentation

Hygroscopicity

CAB-O-SIL® M-5P fumed silica particles are non-porous and typically the moisture content is less than 1% at the time of packaging, which can be removed by heating at 110°C.

Fine particle size and large number of surface hydroxyl group makes the M-5P fumed silica an **excellent desiccant**. It absorbs moisture but **will not liquefy**, which helps to **stabilize** moisture sensitive ingredients in drugs, tablets and capsules preventing agglomeration of powder blends.

Flow Properties

M-5P fumed silica is used as **glidant and anti-caking agent to improve the flow properties** of granulation in high-speed tablet and capsule machine. Particulate flow has a direct effect on **weight uniformity** and plays an important role in **solid-solid blending** and **powder homogeneity**.

- **Reduces friction** between particles
- **Improves flow** of granulations
- **Improves fill** of surface irregularities in granules
- **Prevents segregation** and **separation** of granules
- Assists in **prevention of cavitations** or **surgings** of tablet granulation in a powder blend.

Regulatory Status – Food

CAB-O-SIL® M-5P fumed silica has been approved for use as food additives as per

- EU Directive 2000/63/EC for food additive E 551
- 21 CFR (Code of Federal Regulations), § 172.480 'silicon dioxide' 'may be safely used' as an anti-caking agent with an upper limit not to exceed 2%. 'Silicon dioxide' may be used as a stabilizer in beer production (if removed later by filtration), and as an adsorbent for di-a-tocopheryl acetate and panthenal alcohol in tableted dietary supplements.

CAB-O-SIL® M-5P fumed silica has been approved for use as food contact substance.

- According to EU Directive 2002/72/EC, 'silicon dioxide' is listed for food contact use in Annex III, Section A with reference number 86240. In Appendix 2 of the Council of Europe Resolution AP (96) 5, 'silicon dioxide' is listed in List 1, Part 2, under 'Additives' (substances classified in SCF lists 0 to 4) with the reference number 86240.
- According to 21 CFR parts 174-178, 'silicon dioxide' may be used as given directly or indirectly by reference to 21 CFR § 172.480.



Microbial Contamination

CAB-O-SIL® M-5P fumed silica products are sterile immediately after manufacture because of the high temperature production process. Packaging and storage of the pharmaceutical grades are performed in accordance with good manufacturing practices.

CAB-O-SIL® M-5P fumed silica is an inert inorganic material and is not a source of microbial nutrition. At the time of packaging the moisture content is less than 1% and both gram-negative and gram positive bacteria cannot survive for more than a few hours to days depending on the type of bacteria.

The possible survival of some sporogenic microorganisms cannot be completely ruled out even under these conditions.

Microbiological testing is performed on random samples at regular intervals. We, and our partners along the distribution chain, do our utmost to ensure that CAB-O-SIL® M-5P product reaches our customers without any contamination. However, contamination is still possible during shipping and storage so we recommend customers to perform microbiological checks on the product before using it.

GMO, Allergens & TSE-BSE compliance

No materials from plant or animal origin are used during the manufacturing, packaging and storage of CAB-O-SIL® M-5P fumed silica. The production and packaging processes for CAB-O-SIL® M-5P fumed silica products are closed and as such there is no risk of genetically modified organism and any plant or animal derived allergens or precursors of disease (BSE, TSE etc.).

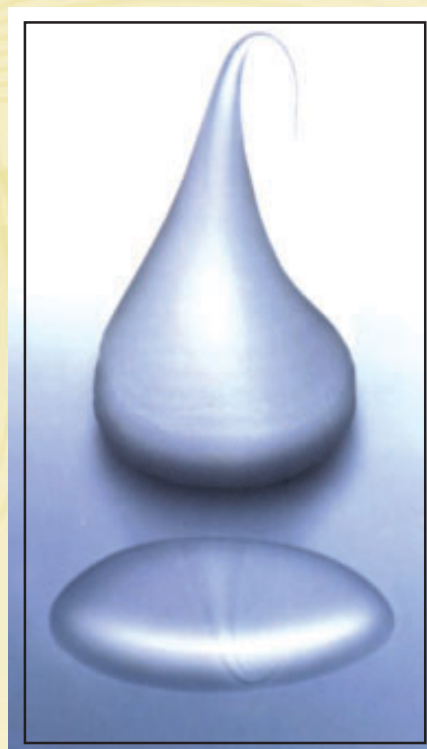
Residual Solvents

No organic solvents are used or formed as by-product during the manufacturing of Cab-O-Sil® fumed silica products.

Packaging and Storage

CAB-O-SIL® M-5P fumed silica is packed and shipped in a 3-ply 10kg Kraft paper bags with an outer LDPE liner.

Fumed Silica being a chemically inert stable metal oxide it could be theoretically stored for many years without any change in its composition. However, due to its high specific surface area, there could be adsorption of volatile



substances, moisture or other chemical vapours from the environment onto its surface. Also proper storage is critical to prevent external contamination and damage of the bags. We recommend that CAB-O-SIL® M-5P product should be stored in a clean, dry area away from heat, moisture and chemical vapours at ambient conditions. Do not store together with volatile chemicals as they may adsorb onto the product. It should be consumed within two years from its date of manufacture.

Handling

With proper equipment CAB-O-SIL® M-5P product can be handled almost completely dust-free. For more information on these services, please contact our representatives in your region.

CAB-O-SIL® M-5P product is an inert and non-toxic material. However, we recommend certain precautions, although not required, they improve the comfort level of persons working with it.

- Ventilated work area - In the laboratory, working with CAB-O-SIL® M-5P product in a powder handling booth is preferred. Wherever ventilation is not available, a dust respirator is recommended.

- Avoid continued excessive inhalation by using personal protective equipment.
- Wear appropriate eye protection.
- Wash hands after handling CAB-O-SIL® M-5P product as the product may leave a dry feeling of the skin. Use of protective skin cream and/or gloves is recommended while handling CAB-O-SIL® M-5P products
- Follow the Product Safety Data Sheet for information relevant to maximum work area concentrations and other safety aspects of the fumed silica products.
- In addition, for safety reasons it should be noted that CAB-O-SIL® M-5P product can build up static electrical charges when subjected to friction during conveyance and/or mixing. When handling near flammable or explosive liquids, be sure to take proper safety precautions, such as electrical grounding, inert atmosphere, etc.

Material Safety Data Sheets

Material Safety Data Sheets (also known as MSDS) for CAB-O-SIL® M-5P fumed silica available on request.

For additional information, contact our representatives in your region.

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