March 2018

Pharma Grade Statement
CAB-O-SIL® M-5P and M-5DP Fumed Silicas for Pharmaceutical Applications

CAB-O-SIL®M-5P and M-5DP fumed silicas are high purity silicon dioxide products manufactured via a high-temperature combustion process.

- CAB-O-SIL® M-5P and M-5DP fumed silicas meet all the requirements for *Colloidal Silicon Dioxide* as described in the US Pharmacopoeia National Formulary.
- CAB-O-SIL® M-5P and M-5DP fumed silicas meet the requirements of *Silica Colloidal, Anhydrous* (aka *Silica Colloidalis Anhydricas*) as described in the European Pharmacopoeia
- CAB-O-SIL® M-5P fumed silica meets the requirements of the *Light Anhydrous Silicic Acid* as described in the Japanese Pharmacopoeia

CAB-O-SIL®M-5P and M-5DP fumed silicas are expected to be used as excipients in medicinal products for administration via oral route and for topical application in cream, oils and lotions. Appendix 1 shows the list of Pharmacopoeia Monograph parameters that are tested on each lot.

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United States, European and Japanese Pharmacopoeia

General monographs requirements are applicable to all products in the given class, irrespective of whether there is individual monograph for the product in pharmacopoeia, unless otherwise specified in preamble. The applicability of the general monograph requirements is explained below in each relevant section.

1. General Monograph (GM) – Substance for pharmaceutical use

EP < 2034 > on substance for pharmaceutical use applies to excipients. They must be manufactured by procedures that are designed to ensure a consistent quality and comply with the requirements of the individual monograph or approved specification.

2. General Texts – Control of impurities in substances for pharmaceutical use

As part of our Product Stewardship continuous improvement plan, Cabot periodically undertakes a complete review our life science silica grades and their compliance scheme. Robust risk assessment including testing program is part of this program.

The *USP Chapter <1086> Impurities for drug substances and drug products* mentioned that impurities to be tested are specifically called out in individual *monograph Colloidal Silicon Dioxide*. Please refer to Appendix 1 attached to this Statement. The following categories of impurities listed in *general notice 5.60. Impurities and Foreign Substances* are controlled when applicable.

- Other impurities – if applicable, listed in individual monograph.
- Residual solvents – see paragraph 3
- Elemental impurities – see paragraph 4

Per *European Pharmacopoeia - EP Chapter 5.10*, requirements on control of impurities given in *General Monograph < 2034 > on substance for pharmaceutical use* and individual *monograph Silica Colloidal, Anhydrous* are complementary. Impurities referenced in this individual monograph are tested on each lot, please refer to Appendix 1 attached to this Statement. The following generic categories of impurities listed in general monograph are controlled when applicable:

- Related substances do not apply to excipients.
- Residual solvents – see paragraph 3
- Elemental impurities – see paragraph 4
- Microbial quality – see paragraph 15
- Sterility – not applicable
- Bacteria endotoxins and pyrogens – not applicable as CAB-O-SIL® fumed silica products are not designed for parenteral administration

3. General Texts – Residual Solvents

Chemical Test <467> Residual Solvents contained in the current United States Pharmacopoeia 40/National Formulary 35 states: "Testing of drug substances, excipients, and drug products for residual solvents should be performed when production or purification processes are known to result in the presence of such residual solvents. It is only necessary to test for residual solvents that are used or produced in the manufacture or purification processes."

European Pharmacopoeia Chapter 5.4 on residual solvents and current EMA[1] Guideline for Residual Solvents (EMA_CHMP_ICH_82260_2006) states "Testing in drug substances, excipients, and in drug products should be performed for residual solvents when production or purification processes are known to result in the presence of such solvents. It is only necessary to test for solvents that are used or produced in the manufacture or purification of drug substances, excipients, or drug product."

*Japanese Pharmacopoeia Chapter 2.46 on residual solvent*s states "Testing should be performed for residual solvents when production or purification processes are known to result in the presence of such solvents. It is only necessary to test for solvents that are used or produced in the manufacture or purification of drug substances, excipients, or drug products."

Cabot has reviewed its manufacturing processes and has concluded that no Class I, II or III solvents or other organic solvents are used or produced in the manufacture of CAB-O-SIL® M-5P and M-5DP fumed silicas.

4. General Texts – Elemental (Metal) Impurities and Metal Catalysts/Reagents

The *US Pharmacopoeia - USP Chapter <232>* sets out elemental impurities (E.I.) limits in drug products. Those limits do not apply to excipients, except where specified in individual monographs. However, E.I. levels present in excipients must be known, controlled and documented.
Some default concentration limits of metals in finished drug products cannot be exceeded for excipients or active substances as per *USP Chapter <232> - Table 2*.
Pursuant to *General Notices 5.60.30 - Elemental Impurities*, General *Chapters <232> - Elemental Impurities* applies to USP Drug Products, unless *General Chapter <232>* is referenced in a particular monograph and then this *Chapter <232>* applies to the substance described in this monograph. *General Chapter <232>* follows the ICH Q3D[2] guidelines on E.I.

The *European Pharmacopoeia (EP) General Chapter 5.20* now refers to the ICH Q3D guideline for E.I. in medicinal products. This guideline prescribes a permitted daily exposure (PDE) according to the route of administration for elements of toxicological concern which may be present in medicinal products. E.I. limits do not apply to excipients, that are not medicinal products per se.
General monograph 2034 – Substances for pharmaceutical use, paragraph Test – Elemental impurities states that *EP General Chapter 5.20* applies to medicinal products. An individual monograph of a substance for pharmaceutical use therefore does not contain specifications for E.I. unless otherwise

[1] European Medicine Agency
[2] ICH – International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use.
Q3D: Q corresponds to "Quality" guideline, "3" refers to "impurity" and "D" corresponds to the type of "impurity", in this case "elemental" impurities.

required. This is why Cabot does not test every lot of CAB-O-SIL® M-5P and M-5DP fumed silicas products for heavy metals content anymore.
In line with the general principles laid out in the ICH Q3D guideline for E.I., Cabot has conducted its own risk assessment to identify all potential sources of E.I., determine which E.I. are likely to be present and whether or not current controls are adequate.

To the best of our knowledge, Cabot does not intentionally add or use any metal, metal catalyst or metal reagent in the manufacturing process of our CAB-O-SIL® M-5P and M-5DP fumed silicas. Therefore metal, metal catalyst or metal reagent residues are not expected to be present in our CAB-O-SIL® M-5P and M-5DP fumed silica products above trace concentrations (i.e., low ppm or less). In addition, a testing campaign to establish a baseline on the environmental metal contaminants has been conducted at both manufacturing sites. The presence of 24 metals were tested by Glow Discharge Mass Spectroscopy (GDMS). As a result of the testing campaign, Cabot concluded that the controls in place are adequate. Cabot will not implement lot-to-lot routine testing for those 24 metal impurities as they are not expected to be present above trace concentrations (i.e. low ppm or less). To help our customers in making their own risk assessment on E.I., Cabot offers the following information:

Table 1 – Metal elemental impurities levels in CAB-O-SIL® M-5P and M-5DP fumed silicas

Metal	Max. content for each element (ppm)
Pb	<0.5
Tl	<0.8
Hg	<1
Cd	
As	<1.5
Co	<5
Ir **V** **Os** **Pt** **Pd** **Rh** **Ru** **Ag** **Ba** **Li** **Au***	<10
Se	<15
Ni	<20
Cr **Cu** **Mo** **Sn** **Sb**	<50

* Based on historical data. We cannot test for gold as the crucibles used for the measurement are made of gold.

5. Genotoxicity

Silicon Dioxide has been tested in the ECETOC[3] program - Joint Assessment of Commodity Chemicals (JACC Report n°51 - Sept.2006) and for REACH registration purposes. Silicon dioxide has demonstrated no mutagenic activity in Salmonella typhimurium or Escherichia coli with and without metabolic activation (microorganism gene mutation test in vitro). In addition, no clastogenic activity has been observed in the chromosome aberration test in Chinese hamster ovary (CHO) cells.

To the best of our knowledge, based on these tests, Cabot believes CAB-O-SIL® M-5P and M-5DP fumed silicas have no genotoxic activity.

6. Ingredients origin

CAB-O-SIL® M-5P and M-5DP fumed silicas are **synthetic** amorphous silica products manufactured by a chemical process that does not use human, animal or vegetal origin raw materials. In addition, these products are not manufactured using a fermentation process or a recombinant DNA technology.

7. Information on contaminants, chemicals and additives

CAB-O-SIL® fumed silica products are not routinely analyzed for the presence of the below listed substances. To the best of our knowledge, Cabot believes these substances are not present in the raw materials used in the manufacture of our CAB-O-SIL® fumed silica products nor are these substances used in our production and handling processes. Therefore, they are not expected to be present in CAB-O-SIL® fumed silica products above trace concentrations (i.e., low ppm or less).

a. Genetically Modified Organism (GMO) products or materials, nor do they come into contact with any GMO product or material during our manufacture and handling processes;

b. Products of animal origin, nor do they contain any animal product associated with Transmissible Spongiform Encephalopathy (TSE), Bovine Spongiform Encephalopathy (BSE) or Creuzfeldt-Jakobs Disease (CJD). The regulated chemicals that typically are associated with the development of TSE, BSE or CJD are not involved in our production and handling processes;

c. Products of human origin such as blood, human stem cells, nor do they come into contact with any human stem cell products or materials during their manufacture and handling;

d. Food Allergens regulated by US FDA (Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)) and listed in Annex II of Regulation (EU) No 1169/2011 on the provision of food information to consumers (formerly in annex IIIa of the EU Directive 2000/13/EC) and amendments. Specifically, CAB-O-SIL®M-5P and M-5DP fumed silica products do not contain

[3] European Centre for Ecotoxicology and Toxicology of Chemicals

allergenic proteins derived from crustacean shellfish (e.g., crab, crayfish, lobster, shrimp, etc.), fish, egg, milk, peanuts, soy, cereals containing gluten including wheat, tree nuts (e.g., almonds, Brazil nuts, cashews, hazelnuts/filberts, macadamia nuts, pecans, pine nuts, pistachios, walnuts, etc.) and also celery, mustard, sesame seeds, sulfur dioxide and sulphites, lupin and products thereof.

Based on our knowledge of the manufacturing process and the products, there is no risk of cross contact of CAB-O-SIL® M-5P and M-5DP fumed silica product(s) with unintended allergens during the production process.

e. Corn and corn derivatives. Cabot does not use any corn and corn derivatives as raw material in our manufacturing process. Our paper bags are sealed with a mix of corn and potato starch glue, we cannot exclude a potential contact of fumed silica with the glue.

f. Mycotoxins including aflatoxin. Those substances are the main contaminants of plant origin material (e.g., grains, cereals, nuts, oilseeds, and spices) and Cabot does not use any plant origin material as raw material in our high-temperature manufacturing process. Therefore, such mycotoxins are not expected to be present in CAB-O-SIL® M-5P and M-5DP fumed silica products.

g. Melamine. Cabot does not use melamine in the manufacturing process of our CAB-O-SIL® M-5P and M-5DP fumed silicas. Based on our knowledge of the production and handling processes, Cabot does not expect melamine to be present in CAB-O-SIL® M-5P and M-5DP fumed silica products above trace levels.

h. Contaminants: Fungi and mycoplasma. Cabot does not use fungi or mycoplasma in the manufacturing process of our CAB-O-SIL® M-5P and M-5DP fumed silicas. Based on our knowledge of the production and handling processes, Cabot does not expect these substances to be present in CAB-O-SIL® M-5P and M-5DP fumed silica products above trace levels.

i. EU cosmetic allergens. Cabot does not use any of the 26 cosmetic allergens in the manufacturing process of our CAB-O-SIL® M-5P and M-5DP fumed silicas. Based on our knowledge of the production and handling processes, Cabot does not expect any of the 26 allergen ingredients currently listed in Annex III of the REGULATION (EC) No 1223/2009 on Cosmetic Products to be present in CAB-O-SIL® M-5P and M-5DP fumed silica products.

j. World Anti-Doping Agency (WADA)'s 2018 Prohibited Substances. Cabot does not use any WADA prohibited substances in the manufacturing process of our CAB-O-SIL® M-5P and M-5DP fumed silicas. Based on our knowledge of the production and handling processes, Cabot does not expect CAB-O-SIL® M-5P and M-5DP fumed silica products to come into contact with any banned/prohibited substance on the WADA 2018 Prohibited List.

k. Chemical additives such as biocides, colorants, stabilizers, pigments, preservatives, antioxidants, complexing agents, UV filter, scents, and parabens.

l. Other: Intentionally added sugars (lactose, glucose, etc.), gluten, alcohol, latex, hormones, antibiotics, vitamins, alkaloids, palm oil, enzymes, flavors, Jatropha-derived glycerin and related materials.

m. Foreign particles: refers to foreign particles and technically unavoidable particles under the scope of International Pharmaceutical Excipient Council (IPEC) TUPP – Technically Unavoidable Particle Profile guide, not resulting from contamination or adulteration.

Based on design of our completely closed manufacturing process, our knowledge of the operating conditions and strict control during maintenance/repair activities, the presence of foreign particles is not expected. We cannot totally exclude the presence of those particles in case of unexpected failure of our equipment/material. However, failure in our material would be clearly noticeable by "irregularities" in the production process control parameters. For a period after maintenance or repairs in the facility, the final product is controlled more thoroughly than during normal operation.

As part of our regular control process, two tests are conducted in-house for the detection of foreign particles

- **A19-Test**: Dark spots/particles are detected to confirm they are not present after maintenance/repairs activities.
- **Mesh residue (45µm)**: In addition to foreign particles, also unexpectedly bigger silicon dioxide agglomerates are detected.

Referring to the design of our equipment, the extremely light pyrogenic (fumed) silica is conveyed upwards via an air-stream after the burner area through the cooling section. This set-up functions as gravity separator with the heavier foreign particles accumulating at the bottom of the loop. No foreign particles have been detected using this process.
In addition, in finished product conic silos, gravity would cause heavier foreign particles to fall to the bottom of each silo. No foreign particles have been detected at the bottom of the silos.

Foreign particles from the materials of construction of the process equipment would not be detected with a magnet separator, therefore Cabot's Rheinfelden facility does not use a magnetic particles separator in the processes.

The manufacturing processes used for the product of CAB-O-SIL® M-5P and M-5DP fumed silica are regularly audited by regulatory agencies and our customers. The measures taken in our processes to prevent foreign particles in CAB-O-SIL® M-5P and M-5DP fumed silica products have always met audit standards.

8. Halogens such as chlorine, iodine, bromine

CAB-O-SIL® fumed silica products are not routinely analyzed for the presence of halogens. Cabot manufactures CAB-O-SIL® M-5P and M-5DP fumed silicas by flame hydrolysis of chlorosilanes. Based on our knowledge of the production processes, Cabot cannot totally exclude the presence of halogens (chlorine, bromine, iodine) in CAB-O-SIL® M-5P and M-5DP fumed silica products.

9. Cations content for drug notice

Cabot does not routinely test CAB-O-SIL® M-5P and M-5DP fumed silicas for sodium, magnesium, calcium and potassium content. To the best of our knowledge, Cabot believes that sodium, magnesium, calcium and potassium are not being used as raw materials in the manufacture of our CAB-O-SIL® M-5P and M-5DP fumed silica products; and accordingly; are not expected to be present in those products above trace concentrations (i.e., low ppm or less).

Based on GDMS data on these products and similar products, the maximum amount of sodium, magnesium, calcium and potassium should not exceed 20ppm each. These values are given for information only and do not represent a specification of our products.

10. Use as an additive in Dietary/Food Supplements

Silicon dioxide is authorized as an ingredient of dietary/food supplements per listing in Annex II.B – Minerals of the European Directive 2002/46/EC and amendments.
Per Article 4.3 of the above Directive, the purity criteria for the authorized substances that are specified in a Community Legislation related to foodstuffs shall apply.

To help our customers in meeting their legal obligations associated with dietary/food supplements production, we provide the following information:

CAB-O-SIL® M-5P and M-5DP fumed silicas are not routinely tested for E551 purity criteria of the Commission Regulation (EU) N° 231/2012 laying down specifications for food additives. However, based on our knowledge of the manufacturing process for these products and an analysis performed on these products and similar products, the E551 purity criteria are not expected to be exceeded for CAB-O-SIL® M-5P and M-5DP fumed silicas.

Please note that the ingredients in dietary supplements sold or manufactured in the US must comply with the requirements of the Food Safety Modernization Act (FSMA). As of the date of this statement, CAB-O-SIL® M-5P and M-5DP fumed silicas manufactured at Cabot's Rheinfelden facility are FSMA compliant. However, CAB-O-SIL® M-5P fumed silica manufactured at Cabot's Tuscola facility is not currently FSMA compliant.

11. Nutritional content

CAB-O-SIL® M-5P and M-5DP fumed silica products have neither nutritional content nor value.

12. Manufacturing sites

CAB-O-SIL® M-5P fumed silica is manufactured in two fumed silica facilities located in Rheinfelden, Germany and in Tuscola, Illinois, United States of America. Each manufacturing site supplies their respective regional customers and distributors. Both Tuscola and Rheinfelden processes are similar and produce CAB-O-SIL® M-5P fumed silica to the same global product specification. If a change of manufacturing source would be needed, customers should consider whatever internal qualifications and/or testing they feel is appropriate for their specific application.

CAB-O-SIL® M-5DP fumed silica is manufactured only in our Rheinfelden facility.

12.1. Good manufacturing practices (GMP)

Our plants operate using the highest quality standard and are ISO 9001 certified. CAB-O-SIL® M-5P and M-5DP fumed silica products from both facilities are produced following Cabot manufacturing processes are generally consistent with good manufacturing practices that we believe are suitable for the production of this excipient. See below paragraph on quality of the excipient.

12.2 Quality of the excipient

In line with the requirements laid out in Commission Directive 2003/94/EC, Eudralex Volume 4 “Guideline Good Manufacturing Practices in respect to medicinal products” and “Guideline on the formalized risk assessment for ascertaining the appropriate good manufacturing practice for excipients” and the IPEC Good Manufacturing Practices Guide for Pharmaceutical Excipients, Cabot has conducted and continuously monitors in-house quality inspection programs and performs risk assessments. Please note there is no legally binding provisions requiring pharmaceutical excipient to be produced following GMP under US Food and Drug Act.

As required in Europe, Cabot offers a quality agreement to their direct customers and EU distributors that purchase CAB-O-SIL® M-5P and M-5DP fumed silicas manufactured at Cabot’s Rheinfelden facility. This quality agreement follows the IPEC Good Manufacturing Practices Guide for Pharmaceutical Excipients and the 2009 IPEC Quality Agreement Guide and Template.

13. Testing

Pharmacopoeias testing is conducted at external certified laboratories that operate under GLP (good laboratory practices) and which are regularly audited by Cabot and authorities.

14. Packaging information

CAB-O-SIL® M-5P and M-5DP fumed silica packaging materials are suitable for food contact applications. To the best of our knowledge, our paper bags comply with:

- Regulation (EC) No 1935/2004 of the European Parliament and the Council on materials and articles intended to come into contact with food,
- Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food,
- European Parliament and Council Directive 94/62/EC and latest amends on packaging and packaging waste and US CONEG requirements.

In addition,
For paper bags (multi wall kraft paper bags):

- The paper part complies with German BfR Recommendation XXXVI and 21 CFR 176.180
- The middle kraft paper ply is creped with polyethylene that complies with Regulation (EC) 10/2011 and 21 CFR 177.1520. The overall migration values are below the 10 mg/dm² migration limit stated in Regulation (EC) No 10/2011.
- The printing inks comply with EuPIA guidelines and 21 CFR 178.3297

Our paper bags are sealed with a mix of corn and potato starch glue; we cannot exclude a potential contact of silica material with the glue.

15. Irradiation

Neither CAB-O-SIL® M-5P and M-5DP fumed silica nor its starting raw materials (chlorosilanes, air, and hydrogen) are subject to any kind of irradiation during their manufacturing, handling, and storage processes. However, we cannot guarantee that irradiated substances will not be absorbed later due to improper transportation or storage conditions that are not under Cabot control.
Please note that Cabot's Rheinfelden facility utilizes paper bags that have been irradiated prior their use to ensure microbiological cleanliness as required to satisfy HACCP requirements.

While our CAB-O-SIL® M-5P and M-5DP fumed silica products are not directly subject to European Directive 1999/2/EC and amends, we provide the following information with respect to CAB-O-SIL® M-5P and M-5DP fumed silica products manufactured at Cabot's Rheinfelden facility:

To the best of our knowledge and based on the information received from our paper bag suppliers, we can confirm that prior to being supplied to Cabot's Rheinfelden facility, the empty paper bags have been irradiated using gamma rays from radionuclide ^{60}Co as permitted per listing in Annex II of the European Directive 1999/2/EC.

16. Microbial contamination

The production and packaging processes for CAB-O-SIL® M-5P and M-5DP fumed silica products are closed. As such, to the best of our knowledge, there is minimal potential for microbial contamination of the product. The only contact with water during production is with process steam that has a temperature in excess of 230°C.

We do not routinely test CAB-O-SIL® M-5P and M-5DP fumed silica products for the presence of microbes. Past product testing has confirmed the absence of contamination with the following results:

Test	Result
Total aerobic combined yeasts and mould content	< 100 CFU/g of product
Determination of specified microorganisms (salmonella, Escherichia coli, enterobacteria and other gram-negative bacteria – quantitative	Non-detectable

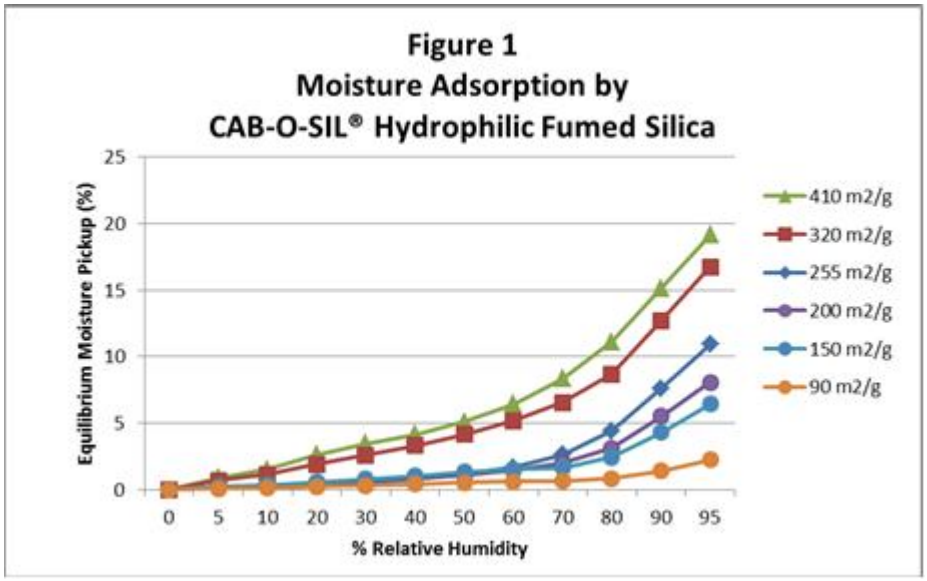
Microbe concentration is not a specification for CAB-O-SIL® M-5P and M-5DP fumed silica products, thus Cabot does not guarantee the above test results. Cabot recommends that the customer conduct its own testing should microbe concentration be a critical factor to a particular application. Please note that Cabot's Rheinfelden facility is spot-checked by independent laboratory for microbial contamination under the HACCP certification.

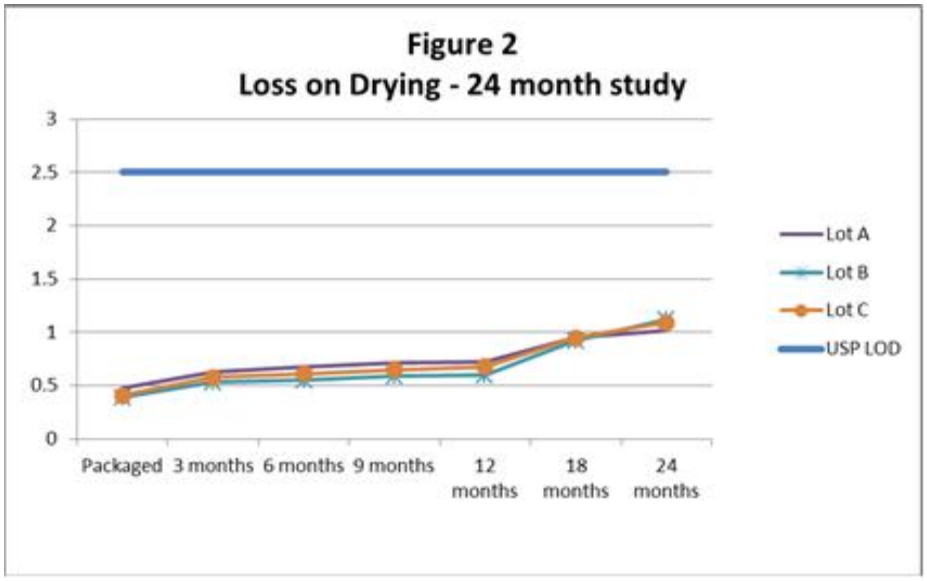
17. Stability

CAB-O-SIL® hydrophilic fumed silicas are stable products with a long history of use as a pharmaceutical excipient. However, it should be noted that hydrophilic grades will adsorb moisture and other vapors. Due to this, it is recommended that fumed silica be stored in a well ventilated, clean, dry area away from chemical vapors at ambient temperatures and within the original shrink-wrapped pallet packaging. Further, it is recommended that fumed silica packaged in paper bags be used within two years after manufacture date as bags may begin deteriorating beyond this time period.

The moisture content of hydrophilic grades of fumed silica is typically less than 1.0 % by weight at the time of packaging, but this can increase with time, depending upon temperature and relative humidity. Figure 1 reflects data collected on equilibrium moisture levels for CAB-O-SIL® hydrophilic silica grades with BET Surface Areas ranging from 90 to 410 m^2/g. The equilibrium moisture adsorption is significantly greater for higher surface area, hydrophilic silica. Adsorbed surface moisture can interfere in some applications. It is also recommended that the user determine the appropriate storage conditions, both temperature and humidity, that will assure acceptable performance of the fumed silica in the application. Adsorbed surface moisture can be removed by vacuum drying or heating the fumed silica.

In accordance with the IPEC guidelines, historical data is suitable to demonstrate stability of a product. Figure 2 represents Loss on Drying data collected on CAB-O-SIL® fumed silica having a BET Surface Area of 200 m2/g over a period of 24 months at storage conditions of nominally 25° Celsius and 60% relative humidity. An increase in moisture is noted over the 24-month period; however, moisture levels are well below the upper limit specified by the USP NSF (2.5%).





18. Certificates

ISO, OHSAS, Halal, Kosher and HACCP certificates: Please refer to the following link http://www.cabotcorp.com/responsibility/product-stewardship/ for any updated information.

19. Other information

Generic information on CAB-O-SIL® untreated fumed silica is available on Cabot's Regulatory Information Sheet available on the website

Buyer assumes full responsibility for testing and determination of suitability of a product for buyer's intended application or use according to the applicable pharmacopoeia requirements.

This information is being provided as of the date hereof. This document is valid for one year unless superseded by a newer version.

Please refer to Cabot's website – **www.cabotcorp.com** – for any updates to this information.

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Appendix 1 – Pharmacopoeia Monograph Requirements

Endpoint	US40/NF35	EP 9.5th Ed.	JP 17th Ed.
Identification	Test A meets Test B requirement	Silicates test: meets requirement	Test 1 meets Test 2 requirement Test 3
Assay	99.0–100.5%	99.0–100.5%	> 98.0%
Loss on drying	< 2.5%		< 7.0%
Loss on ignition	< 2.0%	< 5.0%	
pH	3.5–5.5	3.5–5.5	< 12.0
Arsenic	< 8 ppm		< 5 ppm
Chlorides		< 250 ppm	< 0.011%
Heavy Metals		*	< 40 ppm
Aluminum			meets requirement
Iron			< 500 ppm
Calcium			meets requirement
JP volume test			5 g sample: volume> 70ml

*See paragraph 2 – US and European Pharmacopoeia Elemental (Metal) Impurities and Metal Catalysts/Reagent Residues for more information