Colloidal Silicon Dioxide

1 Nonproprietary Names

BP: Colloidal anhydrous silica
PhEur: Silica colloidalis anhydrica
USPNF: Colloidal silicon dioxide

2 Synonyms

Aerosil; *Cab-O-Sil*; *Cab-O-Sil M-5P*; colloidal silica; fumed silica; light anhydrous silicic acid; silicic anhydride; silicon dioxide fumed; *Wacker HDK*.

3 Chemical Name and CAS Registry Number

Silica [7631-86-9]

4 Empirical Formula and Molecular Weight

SiO_2 60.08

5 Structural Formula

SiO_2

6 Functional Category

Adsorbent; anticaking agent; emulsion stabilizer; glidant; suspending agent; tablet disintegrant; thermal stabilizer; viscosity-increasing agent.

7 Applications in Pharmaceutical Formulation or Technology

Colloidal silicon dioxide is widely used in pharmaceuticals, cosmetics, and food products; *see* Table I. Its small particle size and large specific surface area give it desirable flow characteristics that are exploited to improve the flow properties of dry powders in a number of processes such as tableting.[1–3]

Colloidal silicon dioxide is also used to stabilize emulsions and as a thixotropic thickening and suspending agent in gels and semisolid preparations.[4] With other ingredients of similar refractive index, transparent gels may be formed. The degree of viscosity increase depends on the polarity of the liquid (polar liquids generally require a greater concentration of colloidal silicon dioxide than nonpolar liquids). Viscosity is largely independent of temperature. However, changes to the pH of a system may affect the viscosity; *see* Section 11.

In aerosols, other than those for inhalation, colloidal silicon dioxide is used to promote particulate suspension, eliminate hard settling, and minimize the clogging of spray nozzles. Colloidal silicon dioxide is also used as a tablet disintegrant and as an adsorbent dispersing agent for liquids in powders.[5] Colloidal silicon dioxide is frequently added to suppository formulations containing lipophilic excipients to increase viscosity, prevent sedimentation during molding, and decrease the release rate.[6,7]

Table I: Uses of colloidal silicon dioxide.

Use	Concentration (%)
Aerosols	0.5–2.0
Emulsion stabilizer	1.0–5.0
Glidant	0.1–0.5
Suspending and thickening agent	2.0–10.0

8 Description

Colloidal silicon dioxide is a submicroscopic fumed silica with a particle size of about 15 nm. It is a light, loose, bluish-white-colored, odorless, tasteless, nongritty amorphous powder.

9 Pharmacopeial Specifications

See Table II.

Table II: Pharmacopeial specifications for colloidal silicon dioxide.

Test	PhEur 2002	USPNF 20
Identification	+	+
Characters	+	—
pH (4% w/v dispersion)	3.5–5.5	3.5–5.5
Arsenic	—	⩽8 ppm
Chloride	⩽250 ppm	—
Heavy metals	⩽25 ppm	—
Loss on drying	—	⩽2.5%
Loss on ignition	⩽5.0%	⩽2.0%
Organic volatile impurities	—	+
Assay (on ignited sample)	99.0–100.5%	99.0–100.5%

10 Typical Properties

Acidity/alkalinity: pH = 3.5–4.4 (4% w/v aqueous dispersion)
Density (bulk): 0.029–0.042 g/cm^3
Density (tapped): *See* Tables III to V.
Flowability: 35.52% (Carr compressibility index)
Moisture content: *See* Figure 1.[8,9]
Particle size distribution: 7–16 nm. *See also* Figure 2.
Refractive index: 1.46
Solubility: practically insoluble in organic solvents, water, and acids, except hydrofluoric acid; soluble in hot solutions of alkali hydroxide. Forms a colloidal dispersion with water.
Specific gravity: 2.2

Specific surface area: 200–400 m^2/g (Stroehlein apparatus, single point); 50–380 m^2/g (BET method). *See also* Tables III to V.

Several grades of colloidal silicon dioxide are commercially available, which are produced by modifying the manufacturing process. The modifications do not affect the silica content, specific gravity, refractive index, color, or amorphous form. However, particle size, surface areas, and densities are affected. The physical properties of three commercially available colloidal silicon dioxides, *Aerosil* (Degussa), *Cab-O-Sil* (Cabot Corporation), and *Wacker HDK* (Wacker-Chemie GmbH) are shown in Tables III to V, respectively.

Table III: Physical properties of *Aerosil.*

Grade	Specific surface area[a] (m^2/g)	Density (tapped) (g/cm^3)
130	130 ± 25	0.05
130vs	130 ± 25	0.12
200	200 ± 25	0.05
200vs	200 ± 25	0.12
300	300 ± 30	0.05
380	380 ± 30	0.05

[a] BET method.

Table IV: Physical properties of *Cab-O-Sil.*[10]

Grade	Specific surface area[a] (m^2/g)	Density (tapped) (g/cm^3)
LM-5	130 ± 25	0.04
LM-50	150 ± 25	0.04
M-5	200 ± 25	0.04
H-5	325 ± 25	0.04
EH-5	390 ± 40	0.04
M-7D	200 ± 25	0.10

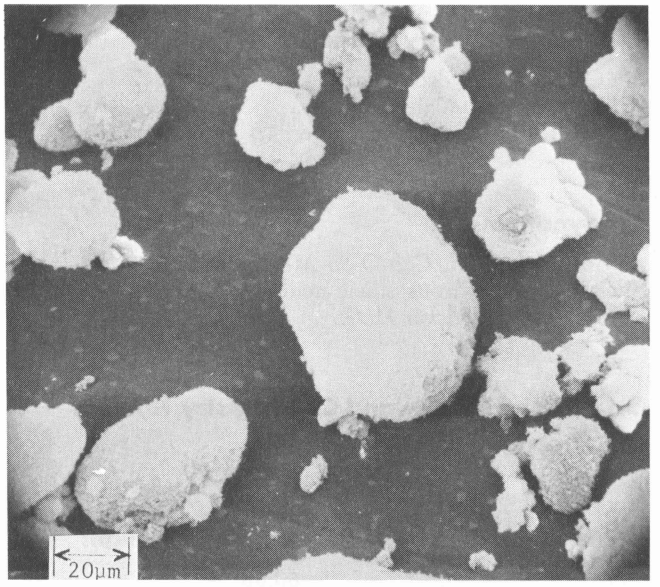
[a] BET method.

Table V: Physical properties of *Wacker HDK.*[11]

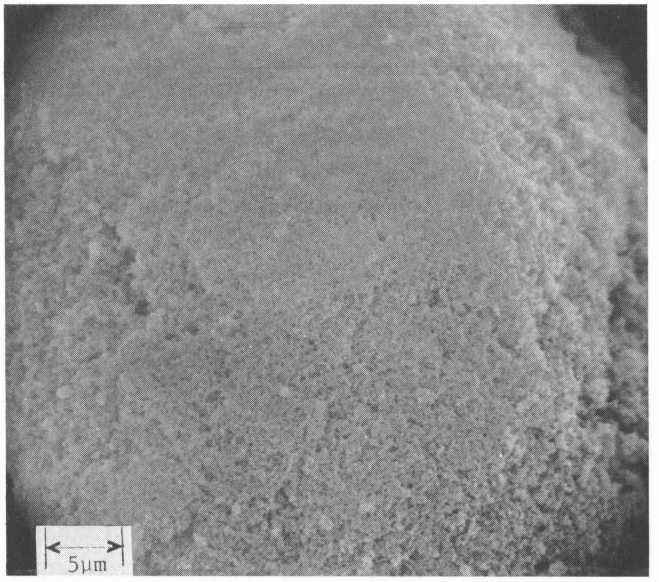
Grade	Specific surface area[a] (m^2/g)	Density (tapped) (g/cm^3)
S13	125 ± 15	0.05
V15	150 ± 20	0.05
N20	200 ± 30	0.04
T30	300 ± 30	0.04
T40	400 ± 40	0.04
H15	120 ± 20	0.04
H20	170 ± 30	0.04
H30	250 ± 30	0.04
H2000	140 ± 30	0.22
H3004	210 ± 30	0.08
H2015	110 ± 30	0.20
H2050	110 ± 30	0.20

[a] BET method.

SEM: 1
Excipient: Colloidal silicon dioxide (*Aerosil A-200*)
Manufacturer: Degussa
Lot No.: 87A-1 (04169C)
Magnification: 600×
Voltage: 20 kV



SEM: 2
Excipient: Colloidal silicon dioxide (*Aerosil A-200*)
Manufacturer: Degussa
Lot No.: 87A-1 (04169C)
Magnification: 2400×
Voltage: 20 kV



11 Stability and Storage Conditions

Colloidal silicon dioxide is hygroscopic but adsorbs large quantities of water without liquefying. When used in aqueous systems at a pH 0–7.5, colloidal silicon dioxide is effective in increasing the viscosity of a system. However, at a pH greater than 7.5 the viscosity-increasing properties of colloidal silicon

dioxide are reduced; and at a pH greater than 10.7 this ability is lost entirely since the silicon dioxide dissolves to form silicates.[10] Colloidal silicon dioxide powder should be stored in a well-closed container.

Some grades of colloidal silicon dioxide have hydrophobic surface treatments that greatly minimize their hygroscopicity.

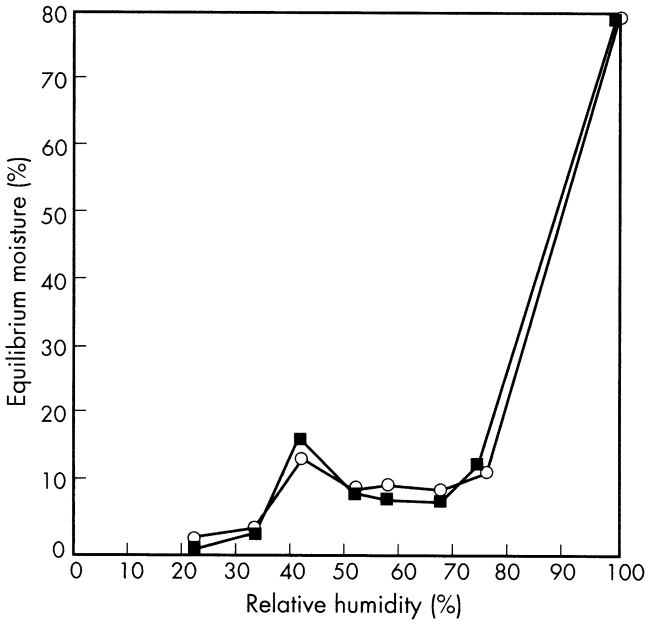


Figure 1: Sorption–desorption isotherm for colloidal silicon dioxide.
○: Sorption
■: Desorption

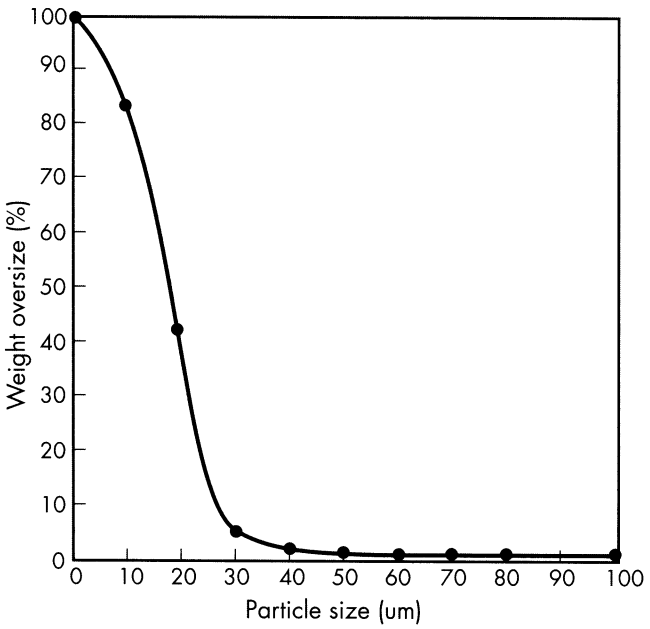


Figure 2: Particle size distribution of colloidal silicon dioxide (*Aerosil A-200*).

12 Incompatibilities

Incompatible with diethylstilbestrol preparations.[12]

13 Method of Manufacture

Colloidal silicon dioxide is prepared by the vapor hydrolysis of chlorosilanes, such as silicon tetrachloride, at 1800°C using a hydrogen–oxygen flame.

14 Safety

Colloidal silicon dioxide is widely used in oral and topical pharmaceutical products and is generally regarded as an essentially nontoxic and nonirritant excipient. However, intraperitoneal and subcutaneous injection may produce local tissue reactions and/or granulomas. Colloidal silicon dioxide should therefore not be administered parenterally.

LD_{50} (rat, IV): 15 mg/kg[13]
LD_{50} (rat, oral): 3.16 g/kg

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection and gloves are recommended. Precautions should be taken to avoid inhalation of colloidal silicon dioxide. In the absence of suitable containment facilities, a dust mask should be worn when handling small quantities of material. For larger quantities, a dust respirator is recommended.

Inhalation of colloidal silicon dioxide dust may cause irritation to the respiratory tract but it is not associated with fibrosis of the lungs (silicosis), which can occur upon exposure to crystalline silica.

16 Regulatory Acceptance

GRAS listed. Included in the FDA Inactive Ingredients Guide (oral capsules, suspensions, and tablets; transdermal and vaginal preparations). Included in nonparenteral medicines licensed in the UK.

17 Related Substances

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18 Comments

The incidence of microbial contamination of colloidal silicon dioxide is low.

The EINECS number for colloidal silicon dioxide is 231-545-4.

19 Specific References

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20 General References

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21 Authors

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22 Date of Revision

22 October 2002.