azienda chimica e farmaceutica

SPECIFICA TECNICA

Prodotto **SILICE MICRONIZZATA USP**

NOME INCI	Silica
NOME INCI USA	Silica
CAS	7631-86-9
EINECS / ELINCS	231-545-4
FORMULA	SiO2

SPECIFICA	METODO	Lim. Inf. - Lim. Sup.	u.m.
Identificazione IR		Conforme allo standard	
Granulometria (>25 µm)		<=0,01	%
pH 5% (USP)		6,0 - 8,0	
Dimensione particellare media		2,5 - 3,7	µm
Titolo (SiO2)		>=99,00	%
Perdita all'essiccamento		<=5,0	%
Residuo all'ignizione		0,0 - 8,5	%
pH (EP)		4,0 - 7,0	
Fe2O3		<=0,020	%
Revisione Capitolato		3	
Data Approvazione		19/01/2016	

Gli eventuali metodi d'analisi non riportati sono metodi interni del produttore ottenibili su specifica richiesta

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Product Description:
Silica USP Food Additive and Pharmaceutical Excipient is a synthetic amorphous silica appearing as white free flowing powder. It has a very high purity and is taste and odor free. It meets the test requirements as published in the latest editions by U.S. Pharmacopoeia-National Formulary for Silicon Dioxide and Japanese Pharmaceutical Excipients for Hydrated Silicon Dioxide. It also meets food additive standards, such as Food Chemical Codex (FCC); the requirements for E 551, specified in the Reg. (EU) 231/2012, and D326 of the Japanese Specification and Standards for Food Additives.

Typical Properties:
The following Typical Properties data are given for informational purposes only, and are not to be interpreted as product or in-process specifications.

Property	Unit	Typical Value
Pore Volume (N2)	ml/g	1.6
Oil Adsorption (DIN EN ISO 787-5)	g/100g	300

Recommended Applications:
Silica USP Food Additive and Pharmaceutical Excipient is a fine-sized, high pore volume silica gel with a large internal surface area. Its strong affinity for moisture along with its ease of incorporation can effectively contribute to the processability, stability and shelf life of products in many pharmaceutical and food applications.

Key features are:
o Multifunctional additive, excellent compatible with active ingredients
o Highly adsorptive as carrier for liquids and actives, up to 1.6 ml of a liquid per gram
o Can keep powders dry and free flowing for a more consistent and uniform processing / dosing
o Can be highly efficient as inactive excipient for improving oral formulations especially of moisture-sensitive pharmaceutical active ingredients

Handling & Storage Recommendations:
Like all other finely powdered products Silica USP Food Additive and Pharmaceutical Excipient has a tendency to develop dust. During handling, precautions should be taken against electrostatic discharges. It should be stored in a clean, dry warehouse to protect against contamination. Its high adsorptive capacity necessitates keeping it separately from odors such as organic solvents and odorant materials during transportation, storage and handling. Open packages should be immediately resealed to prevent uptake of moisture and contamination of the product. Once a single bag is opened, it is best to place it in a PE bag shortly after. Provided the storage recommendations are followed, silica gels stored beyond the recommended shelf life are typically fit for use.

We confirm that during the manufacturing process of MICRONIZED SILICA USP phenylanine or its derivates have not been used.

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During the manufacturing process the following substances have not been used:
- Ingredients made by using Genetically Modified Organism (GMO). Therefore, the product is not a GMO material, does not contain any GMO ingredients and has not been exposed to GMO materials. The application of silica based product does not require labeling as described in Regulation (EC) No 1829/2003 on genetically modified food and feed, last amended by Regulation (EC) No 298/2008, and in Regulation (EC) No 1830/2003 concerning traceability and labeling of food and feed products made from GMO.
- Material of animal, human or viral origin; the product does not come into contact with such products
- Ingredients related to Bovine Spongiform Encephalopathy (BSE) and Transmissible Spngiform Encephalopathy (TSE). The product meets the requirement laid down in Commission Directive 1999/82/EC of 8 September 1999 amending the Annex to Council Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of medicinal products.
- Materials derived from TSE-relevant animal species as cattle, sheep, goats and animals that are naturally susceptible to infection with transmissible spongiform encephalopathy agents or suceptible to infection thorugh the oral route. Above-mentioned products meet the requirements of EMA/410/01 rev. 3 note for the guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary products.
- Ingredients, which are classified as Carcinogenic, Mutagenic and Reprotoxic (CMR)
- Constituents related to Mycotoxins
- Pesticides
- Organic solvents, residual solvents, polycyclic aromatic hydrocarbons
- Potential allergens as stated in Directive 2000/13/EC, with last amendment Directive 2008/5/EC
- Latex