

XYSIL® 380P

Hydrophilic Fumed Silica

TECHNIQUE DATA SHEET

XYSIL® 380P (Pharmaceutical grade) is a hydrophilic Fumed Silica with a specific surface area of 380m²/g, and also known as

Synthetic, Amorphous, Colloidal Silicon Dioxide, manufactured by a continuous flame hydrolysis process of silicon tetrachloride.

Characteristic physico-chemical data

Properties	Units	Guarantee Value	Standardization
Xysil200P tested according to Ph.Eur.,USP/NF,Monograph0434, JP, ChP and GB			
Specific surface area (BET)	m²/g	380±25	GB/T10722
pH-value (in 4% dispersion)		3.8-4.5	Ph.Eur. ,USP/NF
Loss on drying, ex works(2h @ 105℃)	wt%	<1.5	Ph.Eur. ,USP/NF
Loss on ignition(2h @ 1000,based on material dried for 2h @ 105℃)	wt%	<2.5	Ph.Eur.,USP/NF,
Chlorides	ppm	<250	Ph.Eur.
		<110	USP/NF
Arsenic	Ug/g	<8.0	USP/NF
Heavy metals	ppm	<25	Ph.Eur.
Sieve residue (45µm)	%	<0.05	GB/T5211.14
Assay-SiO2 content (based on the substance heated at 1000 ℃ for 2 h)	wt%	99.0-100.5	Ph.Eur.,USP/NF
Tamped density (based on material dried for 2h @ 105℃)	g/L	25~60	GB/T5211.4
Identification		Pass	Ph.Eur.
Residual Solvents	ppm	Pass	USP/NF
Appearance	Fine, white, amorphous powder		

Applications and Properties

Application:

Pharmacy, all types of dosage forms (XYSIL380P shows identical application properties to XYSIL380).

Functions:

- > Free flow and anti-caking agent to improve powder properties
- Improve tablet properties such as hardness and friability as viscosity increasing agent to thicken and thixotropize liquids
- Dessicant for moisture-sensitive actives
- > Improves distribution of active pharmaceutical ingredients
- > Used as anti-setting, thickening and anti-sagging agent
- > High purity, low humidity content
- No influence on taste
- Does not alter natural colour of powder formulations

Registrations(substance or product components)

Chemical Name CAS NO. REACH(EU) KKDIK K-REACH TSCA Customs Tariff Number Silicon Dioxide 112945-52-5, 7631-86-9 Registered Registered Registered Registered 281122(Internet); 2811229000(China)

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Packaging and Storage

XYSIL® 380P is packaged in multiple layer kraft paper 10kg bags or 180Kg FIBCs on pallet, and should be stored in the original packaging in dry storage areas for protecting the material from volatile substance.,and should be used in two years from prodution.

Transportation:

20'GP: 1800KG, 10 pallets, 180KG/pallet. 40'GP: 3600KG, 20 pallets, 180KG/pallet. 40'HQ: 4000KG, 20 pallets, 200KG/pallet. Road Transportation: by requirement

Reversion 11 on Jan 25th, 2022