

Product Data Sheet

LUZENAC PHARMA

Natural talc, stable, physically and chemically inert, with a lamellar structure, Luzenac Pharma complies with European and US purity criteria for use as a food additive. Bacteria controlled and compliant with European, US and Japanese Pharmacopoeia specifications, Luzenac Pharma is specifically adapted for use as an additive in food calling for such requirements.

Typical Properties

Whiteness (Minolta CR300, illuminant D65/2°) Y	92.5
B.E.T. (ISO 9277)	3.5 m ² /g
Density (ISO 787/10)	2.78 g/cm ³
Tapped bulk density (ISO 787/11)	0.94 g/cm ³
Loose bulk density (EN 1097/3).....	0.50 g/cm ³
Hardness (Mohs scale).....	1
Moisture (105 °C) (ISO 787/2)	< 0.2%

Pharmacopoeia

European (Talc monograph 01/2009:0438)	Compliant
US (Talc monograph USP32 – NF27)	Compliant
Japanese (Talc monograph XV)	Compliant

Food additive compliance

- European Directive 95/2/EC: Talc registered for use as food additive under EC number E553b (Annex IV)
- European Directive 2008/84/EC: Luzenac Pharma complies with required purity criteria for use as food additive*
- Food Chemical Codex V edition: Luzenac Pharma complies with required purity criteria for use as food additive*

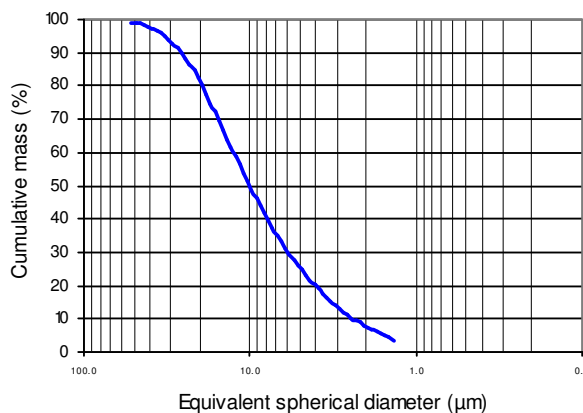
(*): Luzenac Europe ensures Luzenac Pharma compliance with purity criteria required for use as a food additive as defined in “Luzenac Management of food additive compliance” (document available on request).

Screen residue (Alpine airjet) ≥ 75µm..... Max.0.2%

Particle Size Distribution by Sedigraph

Sedimentation analysis, Stokes' Law (ISO 13317-3)

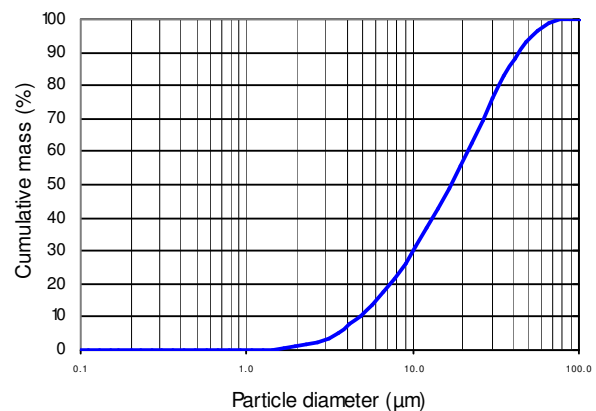
Median Diameter: 10.0 µm



by Laser Mastersizer

Laser diffraction, Mie Theory (ISO 13320-1)

Median Diameter: 19.3 µm



Notice: Although the data listed are typical, they are not production specifications. The supplier provides the data in good faith, however it makes no warranty or representation of any kind, express or implied, regarding the information given or product described, including any warranty of suitability for a particular purpose.

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EUROPEAN PHARMACOPOEIA (Talc monograph 01/2009:0438)/ **US PHARMACOPOEIA** (Talc monograph USP32-NF27)

Identification A, B & C.....	Compliant
Absence of asbestos, B.....	Compliant
Alkalinity / Acidity.....	Compliant
Water soluble substances	≤ 0.2%
Aluminium.....	≤ 2%
Calcium	≤ 0.90%
Acid soluble iron	≤ 0.25%
Magnesium	17.0 – 19.5%
Acid soluble lead	≤ 10.0 ppm
Loss on ignition (1050°C – 1100°C)	≤ 7%

Microbiology	European Pharmacopoeia	US Pharmacopoeia
Topical applications:		
Total viable aerobic count	≤ 10 ² CFU/g	≤ 100 cfu/g
Combined mold & yeast		≤ 50 cfu/g
Oral applications:		
Total viable aerobic count	≤ 10 ³ CFU/g	≤ 1000 cfu/g
Combined mold & yeast	≤ 10 ² CFU/g	≤ 100 cfu/g
Gram negatives		none detected

JP PHARMACOPOEIA (Talc monograph XV)

Identification	Compliant
Loss on ignition (450 – 550°C, 3 hours)	≤ 5.0%
Acid soluble substances	≤ 2.0%
Acidity / Alkalinity.....	Compliant
Water soluble substances	≤ 4.0 mg
Water soluble iron.....	Compliant
Arsenic	≤ 4 ppm
Storage.....	Compliant

NOMENCLATURE

INCI name: Talc
CAS n° 14807-96-6
EINECS n° 238-877-9
Cl: 77 718
JSCI: 41



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