

Product Data Sheet

LUZENAC PHARMA M

Luzenac Pharma M is micronized talc originating from one of Rio Tinto Minerals' European deposits. It is bacteria controlled and complies with European, US and Japanese Pharmacopoeia specifications. It is produced according to the IPEC GMP guidelines for bulk pharmaceutical excipients.

Luzenac Pharma M is an excipient ideal for use in pharmaceutical tablet coating application. It is also recommended in cosmetics for its spreadability, smoothness, optical properties and perfume retention.

Typical Properties

Whiteness (Minolta CR300, illuminant D65/2°) Y	92.5
B.E.T. (DIN 66131/2)	4.6 m ² /g
Density (ISO 787/10)	2.78 g/cm ³
Tapped bulk density (ISO 787/11)	0.63 g/cm ³
Loose bulk density (EN 1097/3)	0.28 g/cm ³
Hardness (Mohs scale)	1
Moisture (105°C) (ISO 787/2)	< 0.2%
Oil absorption	45 ml/100g

Pharmacopoeia

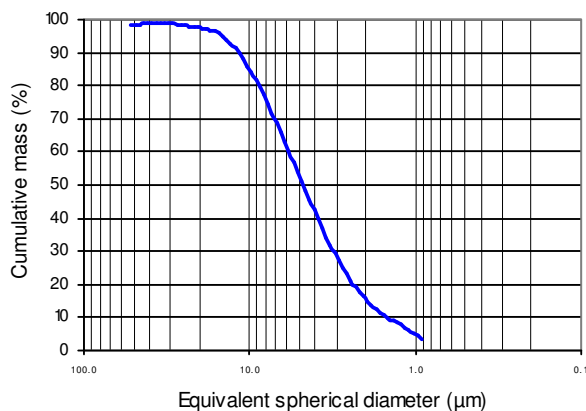
European (Talc monograph 04/2005:0438)	Compliant
US (Talc monograph USP30 – NF25)	Compliant
Japanese (Talc monograph 14)	Compliant

Hegmann fineness (Grind gauge)

Particle Size Distribution by Sedigraph

Sedimentation analysis, Stoke's Law (ISO 13317-3)

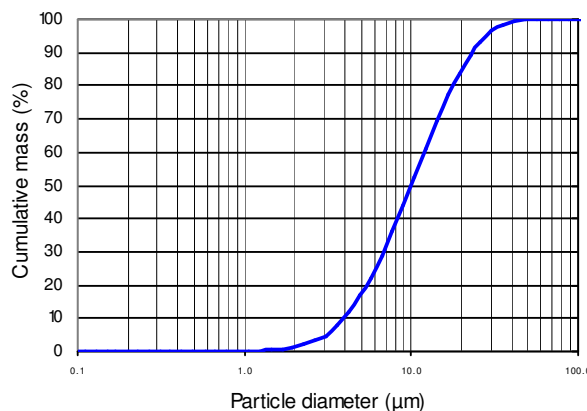
Median Diameter: 4.7 µm



by Laser Mastersizer

Laser diffraction, Mie Theory (ISO 13320-1)

Median Diameter: 10.5 µm



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EUROPEAN PHARMACOPOEIA (Talc monograph 04/2005 :0438)

Identification A, B & C.....	Compliant
Absence of asbestos, B.....	Compliant
Alkalinity / Acidity.....	Compliant
Water soluble substances	≤ 0.2%
Aluminium.....	≤ 2%
Calcium	≤ 0.9%
Acid soluble iron	≤ 0.25%
Magnesium	17.0 – 19.5%
Acid soluble lead	≤ 10 ppm
Loss on ignition (1050°C – 1100°C)	≤ 7%

Microbiology (cfu/g)

Total viable aerobic count.....	≤ 100 cfu/g (topical); ≤ 1000 (oral)
Combined mold and yeast.....	≤ 50 cfu/g (topical); ≤ 100 (oral)
Gram negatives	none detected

US PHARMACOPOEIA (Talc monograph USP30 – NF25)

Identification A, B & C.....	Compliant
Absence of asbestos, B.....	Compliant
Alkalinity / Acidity.....	Compliant
Water soluble substances	≤ 0.1%
Aluminium.....	≤ 2%
Calcium	≤ 0.9%
Acid soluble iron	≤ 0.25%
Magnesium	17.0 – 19.5%
Acid soluble lead	≤ 10 ppm
Loss on ignition (1050°C – 1100°C)	≤ 7%

Microbiology (cfu/g)

Total viable aerobic count.....	≤ 100 cfu/g (topical); ≤ 1000 (oral)
Combined mold and yeast.....	≤ 50 cfu/g (topical); ≤ 100 (oral)
Gram negatives	none detected

JP PHARMACOPOEIA (Talc monograph 14)

Identification	Compliant
Loss on drying (450 – 550°C)	≤ 5%
Acid soluble substances	≤ 2%
Water soluble substances	≤ 4 mg
Water soluble iron.....	Compliant
Arsenic	≤ 4 ppm
Storage	Compliant

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