

Product Data Sheet

# LUZENAC PHARMA UM

Luzenac Pharma UM talc is bacteria controlled and complies with European, US and Japanese Pharmacopoeia and CTPA and CTFA specifications.

Luzenac Pharma UM is an excipient ideal for use in pharmaceutical applications as a lubricant. It is also recommended in cosmetics for its optical properties (matting effect, covering power).

**Typical Properties**

Whiteness (Minolta CR300, illuminant D65/2°) Y .....	94.0
B.E.T. (ISO 9277) .....	13.2 m <sup>2</sup> /g
Density (ISO 787/10) .....	2.78 g/cm <sup>3</sup>
Tapped bulk density (ISO 787/11) .....	0.20 g/cm <sup>3</sup>
Loose bulk density (EN 1097/3).....	0.17 g/cm <sup>3</sup>
Hardness (Mohs scale).....	1
Moisture (105°C) (ISO 787/2) .....	< 0.4%
Oil absorption .....	70 ml/100g
Blaine 10 (Permeametry).....	50000

**Pharmacopoeia**

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

**Food additive compliance**

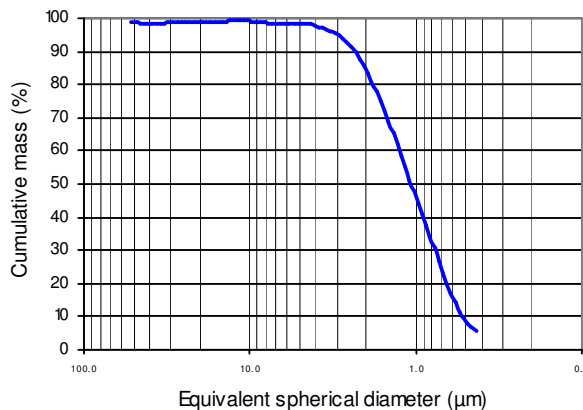
- European Directive 95/2/EC: Talc registered for use as food additive under EC number E553b (Annex IV)
- European Directive 2008/84/EC: Luzenac Pharma UM complies with required purity criteria for use as food additive\*
- Food Chemical Codex V edition: Luzenac Pharma UM complies with required purity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

(\*): Luzenac Europe ensures Luzenac Pharma UM 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) > 15µm.....** max. 0.03%

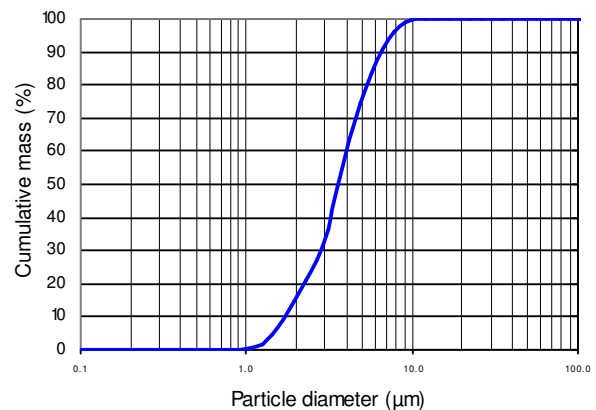
**Particle Size Distribution by Sedigraph**

Sedimentation analysis, Stokes' Law (ISO 13317-3)  
 Median Diameter: 1.1 µm



**by Laser Mastersizer**

Laser diffraction, Mie Theory (ISO 13320-1)  
 Median Diameter: 3.6 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
<b>Topical applications:</b>		
Total viable aerobic count	≤ 10 <sup>2</sup> CFU/g	≤ 100 cfu/g
Combined mold & yeast		≤ 50 cfu/g
<b>Oral applications:</b>		
Total viable aerobic count	≤ 10 <sup>3</sup> CFU/g	≤ 1000 cfu/g
Combined mold & yeast	≤ 10 <sup>2</sup> 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  
CI: 77 718  
JSCI: 41



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