

neoFroxx GmbH

Marie-Curie-Str. 3 64683 Einhausen +49 6251 989 240

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Specification

Product	Gelatine powdered pure EP, NF (pharma grade)
Product number	LC-10003
Synonyms	Gelatina
CAS number	9000-70-8
Storage	below 25°C
Retest period (months)	48

We herewith confirm that this product meets the requirements of the European Pharmacopoeia (EP) 11.8 and National Formulary (NF) 42 (revised).

TSE/BSE declaration: The product is manufactured wholly from bovine connective tissue and does not contain any raw materials produced from or substances derived of other animal origin. Moreover this product is not derived from specific risk materials as defined in Guideline EMEA/410/01 final Rev. 03/2004. All packaging materials are not of animal origin. The product does not come in contact with animal products during storage or transportation.

Parameter	Specification
Gel strength (Bloom value) (80 - 120 % of the nominal value)	128 - 192 Bloom
Appearance (EP)	faintly yellow or light yellowish-brown solid, usually occurring as translucent sheets, shreds, granules or powder (revised)
Solubility (EP)	passes test
Identity (USP, EP)	passes test
pH (1 % in water, 55°C) (USP, EP)	3.8 - 7.6
Conductivity (USP, EP)	<= 1 mS/cm
Sulfur dioxide (USP, EP)	<= 0.005 %
Peroxides (USP, EP)	<= 0.001 %
Chromium (USP, EP)	<= 0.001 %
Zinc (USP, EP)	<= 0.003 %
Iron (USP, EP)	<= 0.003 %









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Microbial contamination (USP,	
EP)	
TAMC	<= 1000 cfu/g
TYMC	<= 100 cfu/g
E. coli	absent
Salmonella sp.	absent
Loss on drying (105°C, 16 h) (USP, EP)	<= 15 %

Einhausen, 11.12.2025





