

neoFroxx GmbH

Marie-Curie-Str. 3
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www.neofroxx.com

Specification

Product	Gelatine powdered pure EP, NF (pharma grade)
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Product number	LC-10003 (revised)
Synonym(s)	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) and the United States National Formulary (NF).
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) (EP, NF)	128 - 192 Bloom
Identity (EP, NF)	passes test
Appearance (EP)	passes test
Solubility (EP)	passes test
pH (1 % in water w/v) at 55°C (EP, NF)	3.8 - 7.6
Conductivity (EP, NF)	max. 1 mS/cm
Sulfur oxide (EP, NF)	max. 0.005 %
Peroxides (EP, NF)	max. 0.001 %
Iron (EP, NF)	max. 0.003 %
Chromium (EP, NF)	max. 0.001 %
Zinc (EP, NF)	max. 0.003 %
Loss on drying (105°C, 16h) (EP, NF)	max. 15 %

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Parameter	Specification
TAMC (EP, NF)	max. 1000 cfu/g
TYMC (EP, NF)	max. 100 cfu/g
E. coli (EP)	Absent
Salmonella (EP)	Absent

Einhausen, 22.03.2024 (revised)