



TECHNICAL DATA SHEET

151399-TDS-ENG-2024

HIALURONIDASA PHARMA (EUR. PH.) (> 2000 IU/mg)		
DESCRIPTION DCI: hyaluronidase		DESCRIPTION DOE: HIALURONIDASA
CAS Nº: 9001-54-1	EC Nº: 232-614-1	AEMPS CODE: 1719A
MOL. WEIGHT: ---	MOL. FORMULA: ---	ARTICLE CODE: 151399

ATTRIBUTES	SHOULD BE
Appearance	White or yellowish-white, amorphous powder
Solubility	Soluble in water, practically insoluble in acetone and in anhydrous ethanol
Identification	Complies
Appearance of solution	Clear
pH	4.5 - 7.5
Loss on drying	=< 5.0 %
Bacterial endotoxines	< 0.2 IU/IU Hyaluronidase
Assay	> 2000 IU/mg
Tyrosine	
540 nm	=< 0.1 µg/IU
Absorbance	
260 nm	=< 0.60
280 nm	=< 0.42
Microbiological control	
TAMC	=< 100 CFU/g
TYMC	=< 100 CFU/g
Escherobacteriaceae	Absent
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Store in cool place (2 - 8°C). Keep container tightly closed in a dry and well-ventilated place.

REMARKS

Hyaluronidase is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.