

PROCESS: Product Specifications	ISSUE DATE: 22.01.2019	DOC NO: 081240H03
TITLE: Hyaluronidase	REVISION: 17	PAGE: 1 of 1
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Product Code: 081240H03

EC No.: 3.2.1.35

EDQM Certificate no.: R1-CEP 2001-085-Rev 02

Aspect	Description	Units	Limits	Method
Form	White to white with yellowish or brownish tint lyophilised amorphous powder.	N/A	N/A	N/A
Preparation	Bovine Testes	N/A	N/A	N/A
Activity	Assay Specific Activity	IU/mg material IU/mg	300-650 ≥300	BP6.2.2-WI204
Solubility	Soluble in water, practically insoluble in Acetone and in Ethanol.	N/A	N/A	BP6.2.2-WI105
Additional Data	Loss on Drying Identification Clarity (1% Aqueous solution) Colour (1% Aqueous solution) pH (0.5% Aqueous solution) Protein Bacterial Endotoxins <i>Enterobacteriaceae</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> Total Microbial Count	% N/A N/A N/A N/A Mg/mg EU/IU cfu/1g cfu/g cfu/g cfu/g	≤5 Positive ≤ Soln II ≤ Y ₄ 4.5-7.5 ≥0.70 <0.2 0 0 0 ≤1000	BP6.2.2-WI27 BP6.2.2-WI140 BP6.2.2-WI103 BP6.2.2-WI81 BP6.2.2-WI117 BP6.2.2-WI43 BP6.2.3-WI57 Outsourced BP6.2.3-WI63 BP6.2.3-WI65 BP6.2.3-WI49
Retest Date	Re-assay	Months	24	N/A
Storage	Storage Temperature, protected from light	°C	-20	N/A
Transit	Storage in Transit, protected from light	°C	Ambient	N/A
Packaging	<ul style="list-style-type: none"> • Polyainers 500ml • Box (31cm x 31cm x 24cm) 	N/A N/A	N/A N/A	N/A N/A
Labels	<u>Large Label</u> <ul style="list-style-type: none"> • Name of product • Product Code • Lot Number • Net Weight • Manufacture Date • Retest Date • Storage Temperature • Storage in Transit • Manufacturer's details <u>Small Label</u> <ul style="list-style-type: none"> • Name of Product • Product Code • Lot No. • Net Weight • Manufacture Date • Retest Date • Storage Temperature • Storage in Transit • Manufacturer's details 	N/A °C °C °C °C	N/A -20 Ambient -20 Ambient	N/A
Samples	Retention Quality Control Microbiology	1 g 1 g 1 g 50mg	8 2 2 1	N/A
Special Instructions	<ul style="list-style-type: none"> • Packaging labels with Russian text. • 150g Hyaluronidase packed into 500ml polytainer. • 18 x 500 ml polytainer packed into the box with dimensions (31cm x 31cm x 24cm). • Calculation: Specific Activity = Assay H_{ase} / Protein 			