

<b>PROCESS:</b> Specification	<b>ISSUE DATE:</b> 09.03.2022	<b>DOC NO:</b> 081240H02 <b>Q-pulse Ref. No.:</b> CT-PRDS23
<b>TITLE:</b> Hyaluronidase	<b>REVISION:</b> 19	<b>Page:</b> 1 of 2
<b>AUTHORISED:</b> Laboratory Supervisor		<b>APPROVED:</b> SQR Leader

**Product Code:** 081240H02

**EC no.:** 3.2.1.35

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

Aspect	Description	Units	Limits	Method
<b>Form</b>	White to yellow- coloured freeze-dried powder.	N/A	N/A	N/A
<b>Preparation</b>	Bovine testes (OIE Sources)	N/A	N/A	HOP 2
<b>Activity</b>	Assay	U/mg material	≥500	BP6.2.2-WI204
<b>Solubility</b>	Deionised water	10 mg/ml	Soluble	BP6.2.2-WI105
<b>Additional Data</b>	Loss on drying (LOD)	N/A	≤5 %	BP6.2.2-WI27
	Identification	N/A	Positive	BP6.2.2-WI140
	Appearance of solution	N/A	≤ Ref Soln.III	BP6.2.2-WI103
	pH	N/A	4.5 – 7.5	BP6.2.2-WI117
	Bacterial Endotoxins (refer to special instruction)	IU/IU	<0.2 IU/IU	BP6.2.3-WI57
	<i>E.coli</i>	cfu/g	0	BP6.2.3-WI64
	<i>Salmonella</i>	cfu/10 g	0	BP6.2.3-WI66
	<i>Pseudomonas aeruginosa</i>	cfu/g	0	BP6.2.3-WI63
Total Aerobic Microbial Count	cfu/g	≤1000 cfu/g	BP6.2.3-WI49	
Total Combined Yeast & Mould Count	cfu/g	≤100 cfu/g	BP6.2.3-WI70	
<b>Associated Material</b>	Re-assay	N/A	N/A	N/A
<b>Recontrol</b>	Re-assay	Months	48	N/A
<b>Storage</b>	Temperature	°C	-20	N/A
<b>Shipping</b>	Temperature	°C	2 - 8	N/A
<b>Packaging</b>	<ul style="list-style-type: none"> <li>Amber glass bottle for samples</li> <li>Pack product as 5 x 10 g in Polyainers</li> </ul>	N/A	N/A	N/A
<b>Labels</b>	<u>Large Label</u> <ul style="list-style-type: none"> <li>Name of product</li> <li>Product Code</li> <li>Lot Number</li> <li>Net Weight</li> <li>Manufacture Date</li> <li>Retest Date</li> <li>Storage Temperature</li> <li>Storage in Transit</li> <li>“Material for research &amp; further manufacture only”</li> </ul>	N/A	N/A	N/A
	<u>Small label</u> <ul style="list-style-type: none"> <li>Name of Product</li> <li>Product Code</li> <li>Lot No.</li> <li>Net Weight</li> <li>Manufacture Date</li> <li>Retest Date</li> <li>Storage Temperature</li> <li>Storage in Transit</li> <li>“Material for research &amp; further manufacture only”</li> </ul>	°C °C	-20 2 - 8	

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Aspect	Description	Units	Limits	Method
<b>Samples</b>	Retention	1 g 10 g 50 mg	8 2 2	N/A
	Quality Control	1 g	2	
	Microbiology	1 g 10 g	2 1	
	Endotoxins	50 mg	1	
<b>Special Instructions</b>	<ol style="list-style-type: none"> <li>1. Send customer 1 g sample in advanced for product testing.</li> <li>2. Customer's internal specifications for endotoxin &lt;0.0125 IU/IU.</li> <li>3. Customer has agreed to pay for goods even though it may not meet their internal endotoxin specification.</li> <li>4. Forward customer copies of Raw material veterinary certificate.</li> </ol>			