


<b>PROCESS:</b> Specification	<b>ISSUE DATE:</b> 05.09.2022	<b>DOC NO:</b> 081246H02 <b>Q-pulse Ref. No.:</b> CT-PRDS31
<b>TITLE:</b> Hyaluronidase $\geq 1000$ u/mg	<b>REVISION:</b> 7	<b>Page:</b> 1 of 2
<b>AUTHORISED:</b> Laboratory Supervisor		<b>APPROVED:</b> SQR Leader

Product Code: 081246H02

EC no.: 3.2.1.35

CEP (FOR TSE ONLY) #R1-CEP 2001-085-REV02

Aspect	Description	Units	Limits	Method
<b>Form</b>	White to yellowish, salt-free, freeze-dried powder.	N/A	N/A	N/A
<b>Preparation</b>	Bovine testes	N/A	N/A	HBEP
<b>Activity</b>	Assay	U/mg material	$\geq 1000$	BP6.2.2-WI204
<b>Additional Data</b>	Loss on drying (LOD)	N/A	$\leq 5.0\%$	BP6.2.2-WI27
	Identification	N/A	Positive	BP6.2.2-WI140
	Appearance of solution	N/A	$\leq$ Ref Sol. III	BP6.2.2-WI103
	pH	N/A	4.5 – 7.5	BP6.2.2-WI117
	Melamine	Record	Record	Outsourced
	Residual Solvents	Record	Record	Outsourced
	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	24	N/A
<b>Storage</b>	Temperature	$^{\circ}\text{C}$	-20	N/A
<b>Shipping</b>	Temperature	$^{\circ}\text{C}$	2 - 8	N/A
<b>Packaging</b>	<ul style="list-style-type: none"> <li>• Polytainers</li> </ul> 	N/A	N/A	N/A

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Aspect	Description	Units	Limits	Method
<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	
<b>Samples</b>	Retention	1 g	6	N/A
	Quality Control	1g	2	
	Microbiology	1 g	1	
<b>Special Instructions</b>	None	N/A	N/A	N/A