

PROCESS: Specification	ISSUE DATE: 09.03.2022	DOC NO: 081246BBI Q-pulse Ref. No.: CT-PRDS29
TITLE: Hyaluronidase ≥1000 u/mg	REVISION: 5	Page: 1 of 1
AUTHORISED: QC Laboratory Supervisor		APPROVED: SQR Leader

Product Code: 081246BBI

EC no.: 3.2.1.35

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

Aspect	Description	Units	Limits	Method
Form	White to yellowish, freeze-dried powder.	N/A	N/A	N/A
Preparation	Bovine testes	N/A	N/A	HBEP
Activity	Assay	U/mg material	≥1000	BP6.2.2-WI204
Additional Data	Appearance of solution	N/A	≤ Ref III	BP6.2.2-WI103
	pH	N/A	4.5 – 7.5	BP6.2.2-WI117
Associated Material	Lactose	N/A	As Required to Standardise	N/A
Recontrol	Re-assay	Months	24	N/A
Storage	Temperature	°C	-20	N/A
Shipping	Temperature	°C	2 - 8	N/A
Packaging	• Polyainers	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 “Material for research & further manufacture only” 	N/A	N/A	N/A
	<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 “Material for research & further manufacture only” 	°C °C	-20 2 – 8	
Samples	Retention	1 g	2	N/A
	Quality Control	1 g	1	
Special Instructions	None			