



PROCESS: Specification	ISSUE DATE: 07.06.2019	DOC NO.: 181515R05
TITLE: Ribonuclease	REVISION: 3	PAGE: 1 of 2
AUTHORISED: Supply Chain Manager		APPROVED: SQR Leader

Product Code: 181515R05

EC no.: 3.1.27.5

EDQM Certificate no.: R1-CEP 2003-046-Rev 01

Aspect	Description	Units	Limits	Method
Form	White, chromatographically purified salt-free, freeze-dried powder 	N/A	N/A	N/A
Preparation	Bovine pancreas	N/A	N/A	R 2
Activity	Assay	U/mg material	≥100	BP6.2.2-WI37
Solubility	Deionised water 0,1 M Acetate Buffer pH 5,0	5 mg/ml 5 mg/ml	Soluble Soluble	BP6.2.2-WI105 BP6.2.2-WI105
Additional Data	<u>Salmonella</u> <u>Pseudomonas aeruginosa</u> <u>Staphylococcus aureus</u> <u>E. coli</u> Total Aerobic Microbial Count Total Combined Yeast & Mould Count Moisture	Count/10g Count/g Count/g Count/g cfu/g cfu/g %	0 0 0 0 ≤1000 Record ≤5	BP6.2.3-WI66 BP6.2.3-WI63 BP6.2.3-WI65 BP6.2.3-WI64 BP6.2.3-WI49 BP6.2.3-WI70 BP6.2.2-WI27
Associated Material	None	N/A	N/A	N/A
Retest Date	Re-assay	Months	60	N/A
Storage	Storage Temperature	°C	-20	N/A
Transit	Storage in Transit	°C	Ambient	N/A
Packaging	<ul style="list-style-type: none"> Amber glass bottle for samples Dependent on volume / weight 	N/A	N/A	N/A

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Aspect	Description	Units	Limits	Method
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 	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 	°C °C	-20 Ambient	
Samples	Retention	1 g 10 g	6 2	N/A
	Quality Control	1 g 200 mg	1 1	
	Microbiology	1 g 10 g	2 1	
Special Instructions	None			