

CERTIFICATE OF ANALYSIS

Name of Product: Rc Trypsin (Powder)			
Batch No.	B5DS00223	Storage condition	2°C to 8°C
A.R.No	QC/FP/017/23	Date of Release	22-10-2023
Mfg. Date	10-2023	STP Number	STP006-00
Exp. Date	09-2025	Page No.	1 of 2

No.	Test	Specification	Results
1	Description	White to off-white, odorless powder	White, odorless powder
2	Solubility(10mg/ml)	Clear colorless solution	Complies
3	Loss on drying	NMT 5.0%	3.21%
4	Enzyme activity by USP method	NLT 2500 USP Units/mg of powder	4300 USP Units/mg of powder
5	Protein content by UV 280 method	95.0% ± 10.0%	98.7%
6	Specific activity	NLT 3800 USP Units/mg of protein (BAEE)	4407 USP Units/mg of protein
7	Purity by RP-HPLC	A. NLT 70% for the peak area of β - trypsin B. NMT 20% for the peak area of α - trypsin	A. 78.25% B. 12.20%
8	Yeast host cell protein residue	≤ 0.01%	Complies
9	Yeast host cell DNA residue	≤ 10.0000 ng/mg	Complies
10	Endotoxin content (LAL test)	≤ 20.0 EU/mg	Complies

	Prepared by	Reviewed by	Approved by
Name	Mansi	P. Sri Lakshmi	Srikanth
Department	Quality Assurance	Quality Assurance	Quality Assurance
Designation	Senior Executive	Assistant Manager	Head Quality
Sign & Date	KM 22-10-2023	Sri 22-10-2023	Sri 22-10-2023

PROVIS BIOLABS PVT LIMITED

No. 5-9-262/54P & 55P, First floor
 Plot No. 54 part and 55 part,
 Rajiv Gandhi Nagar, Prashanthi nagar, Kukatpally,
 Hyderabad – 500 072, Telangana, India.

Provis

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11	Microbial Limit test		
	A. Total microbial count (TVAC/TYMC)	TVAC: NMT 1000 cfu/g TYMC: NMT 100 cfu/g	Nil Nil
	B. Pathogens		
	<i>Escherichia coli</i>	Should be absent	Absent
	<i>Salmonella sp.</i>	Should be absent	Absent
	<i>Staphylococcus aureus</i>	Should be absent	Absent
	<i>Pseudomonas aeruginosa</i>	Should be absent	Absent

REMARKS: The Product Complies / ~~Does Not Comply~~ as per specification No. SPEC006-00

	Prepared by	Reviewed by	Approved by
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