

CERTIFICATE OF ANALYSIS

Name of the Product	RABIES ANTISERUM, 1000 I.U. I.H.S (VINRAB)		
Stage	Finished Product	Specification No.	QCD/SPEC/017
Batch No.	08AR21013	Mfg. Date	06/2021
Batch Size	19047	Exp.Date	05/2023
A.R. No.	FP/08/07/21/002	Test Start Date	01.07.2021
No. of Containers Released	18657	Test Completion Date	15.07.2021
Date of Release	15.07.2021	Page	1 of 2

S.No.	TESTS	SPECIFICATIONS	RESULTS
01	Description	Clear and pale yellow to light brown solution. During storage it may show formation of slight turbidity or a small amount of white particulate matter.	Clear solution
02	pH	6.00 – 7.00	6.45
03	Identification	Based on virus neutralization (potency) test.	Identified as rabies antiserum based on virus neutralization
04	Total protein	Not more than 10% w/v.	3.47 % w/v
05	Foreign proteins	Should form precipitin line in between sample and Anti-Horse serum only.	Precipitin line is formed
06	Purity	Test sample should not have any additional bands compared with the reference preparation.	No additional bands were observed when compared with the reference
07	Molecular Size Distribution	The sum of the peak areas of monomer and dimer present should be NLT 85.0% of the total area of the chromatogram and the sum of the peak area of polymers and aggregates represents NMT 10.0% of the total area of the chromatogram.	87.66 % 0.99 %
08	Albumin content	Not more than 3.0%	0.10 %
09	Potency	NLT 200 I.U./mL	219 I.U./mL
10	Cresol content	≤ 0.25% v/v	0.15 %v/v
11	Content of Glycine	Between 20.25 mg/ml to 24.75 mg/mL	23.07 mg/mL
12	Osmolality	Minimum 240 mOsmol/kg.	320 mOsmol/kg

ANNEXURE: QCD0141/004.01

CIN: U24110TG1997PLC026437

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Factory: Sy.No. 117, Thimmapur (V), Kothur (Mandal), Rangareddy (Dist) - 509325, Telangana, India.

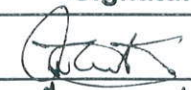
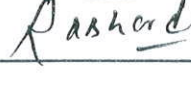


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S. No.	TESTS	SPECIFICATIONS	RESULTS
13	Extractable volume	The content of each vial should be not less than the nominal volume (i.e .not less than 5mL).	5.1 mL
14	Abnormal toxicity	None of the inoculated animals shall die or show any sign of illness in the 7 days following injection.	None of the animals is dead or ill in the 7 days following injection.
15	BET test	NMT 25 EU/mL.	< 25 EU/mL.
16	Pyrogen Test	Test sample complies if summed response does not exceed 1.15°C for 3 rabbits.	Summed response does not exceed 1.15°C for 3 rabbits
17	Sterility	No evidence of microbial growth should be observed during the incubation of 14 days.	No evidence of microbial growth is found in 14 days after sample inoculation and incubation

Note: This is certify that the product complies /does not comply as per I.P/B.P/I.H.S specifications.

	Name	Designation	Signature & Date
Prepared by	V. Nagar Rao	Sr. Executive	 15.07.21
Approved by	Raun Bhardwaj	Manager - QCD	 15.07.21

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