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Pace Biotech
Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title	:	Certificate of Analysis Finished Product		
Product Name	VALBROCAN Injection		**A.R. No.**	NL/FP/25/149
Generic Name	Valethamate Bromide Injection 1ml		**Sampled qty.**	45 Ampoules
Batch No.	A25147A		**Sampled by**	Rakesh
Batch Size	58,500 Ampoules		**Sampled on**	01/08/2025
Mfg. Date	07/2025		**Date of Testing**	01/08/2025
Exp. Date	06/2027		**Date of Release**	19/08/2025

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless solution filled in amber glass ampoule.	A clear colourless solution filled in amber glass ampoule.
2.	Identification	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies
3.	Nominal fill volume	NLT 1ml	1.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	1.1 ml
5.	pH	4.0 to 9.0	6.14
6.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles ≥10μm (2.) Particles ≥25μm (B.) Visual Particle	 NMT 6000/Ampoule NMT 600/ Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection.	 27/Ampoule 0/Ampoule Complies
7.	Sterility	No microbial growth should be observed.	Complies
8.	Bacterial Endotoxins	NMT 14.6 EU/mg of Valethamate.	Less than 14.6 EU/mg of Valethamate.
9.	Assay: (By HPLC) Each ml contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Valethamate Bromide	8 mg	8.178 mg	102.23%	90.0 to 110.0%
Sodium chloride IP	8 mg	8.0206 mg	100.26%	90.0 to 110.0%

Remarks: In the opinion of the undersigned the sample referred to above is/ is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ not complies as per IP/BP/USP/IHS.

Analysis by	Checked by	Approved by
NAME: SUFIYAN ANSARI	NAME: RAMANJEET SINGH	NAME: MRS. SWATI DHAWAN