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Pace Biotech

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

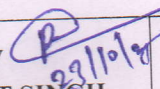
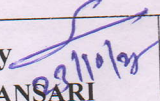

Certificate of Analysis Finished Product

Title	:		
Product Name	OCTREOCAN Injection 1ml	A.R. No.	NL/FP/25/214
Generic Name	Octreotide Acetate Injection	Sampled qty.	60 Ampoules
Batch No.	A25239A	Sampled by	Anuj Verma
Batch Size	524 Ampoules	Sampled on	07/10/2025
Mfg. Date	10/2025	Date of Testing	07/10/2025
Exp. Date	09/2027	Date of Release	23/10/2025

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless solution filled in clear colour glass ampoule.	A clear colourless solution filled in clear colour glass ampoule.
2.	Identification (By HPLC)	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 1 ml	1.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	1.1 ml
5.	pH	3.0 to 5.0	4.22
6.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (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.	11/Ampoule 1/Ampoule Complies
7.	Sterility	No microbial growth should be observe	Complies
8.	Bacterial Endotoxins	NMT 0.004 EU/mcg of Octreotide Acetate.	Less than 0.004 EU/mcg of Octreotide Acetate.
9.	Assay: (By HPLC) Each ml contains		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Octreotide Acetate	100 mcg	98.20 mcg	98.20%	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  NAME: RAMANJEET SINGH	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: MRS. SWATI DHAWAN Designation: QC HOD Qualification: M.Sc. Clinical Microbiology Registration No.: 5804063959 Panjab Technical University, Jalandhar
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