Pacé
Add Pace To Health

Pace Biotech

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

Title	:	Certificate of Analysis Finished Product

Product Name	**OCTREOCAN** Injection	**A.R. No.**	NL/FP/26/191
Generic Name	Octreotide Acetate Injection 1ml	**Sampled qty.**	60 Ampoules
Batch No.	A26192F	**Sampled by**	Vineet
Batch Size	6,000 Ampoules	**Sampled on**	26/08/2026
Mfg. Date	08/2026	**Date of Testing**	27/08/2026
Exp. Date	07/2028	**Date of Release**	10/09/2026

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	4.55
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.	 3/Ampoule 0/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	50 mcg	49.96522 mcg	99.93%	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
10/09/26	10/09/26	10/09/26
NAME: FIROJ KHAN	NAME: SURJEET KAUR	NAME: MRS. SWATI DHAWAN

Name : Mrs. Swati Dhawan
Designation : QC HOD
Qualification : M.Sc. Clinical Microbiology
Registration No. : 00244-[illegible]
Punjab Technical University, Jalandhar