

Pace

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/26/100
Generic Name	Octreotide Acetate Injection 1ml	Sampled qty.	60 Ampoules
Batch No.	A26084B	Sampled by	Vineet
Batch Size	600 Ampoules	Sampled on	18/06/2026
Mfg. Date	06/2026	Date of Testing	23/06/2026
Exp. Date	05/2028	Date of Release	03/07/2026

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	4.42
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.	47/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	50 mcg	51.17103 mcg	102.34%	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: FIROJ KHAN	Checked by NAME: SUFIYAN ANSARI	Qualification : M.Sc. Clinical Microbiology Registration No. : 580406039593 NAME: MRS. SWATI DHAWAN Punjab Technical University
---------------------------------	------------------------------------	--