

# 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/25/074
Generic Name	Octreotide Acetate Injection 100mcg/ml	Sampled qty.	60 Ampoules
Batch No.	A25064F	Sampled by	Rakesh
Batch Size	10.000 Ampoules	Sampled on	26/05/2025
Mfg. Date	05/2025	Date of Testing	26/05/2025
Exp. Date	04/2027	Date of Release	10/06/2025

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	4.06
6.	Particulate Matter (a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$  (b.) Visual	NMT-6000/Ampoule NMT-600/Ampoule  The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	16/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: Each ml contains		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Octreotide Acetate	100 mcg	107.84 mcg	107.84%	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: SANDHYA

Checked by

NAME: SUFIYAN ANSARI

Approved by

NAME: SWATI DHAWAN

