

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/24/262
Generic Name	Octreotide Acetate Injection 50mcg/ml	Sampled qty.	45 Ampoules
Batch No.	A24156E	Sampled by	Aakash
Batch Size	9710 Ampoules	Sampled on	12/08/2024
Mfg. Date	07/2024	Date of Testing	12/08/2024
Exp. Date	06/2026	Date of Release	27/08/2024

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	4.27		
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.	15/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		50 mcg	54.01 mcg	108.02%	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

