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

Title	:	Certificate of Analysis Finished Product

Product Name	**OCTREOCAN** Injection	**A.R. No.**	NL/FP/26/257
Generic Name	Octreotide Acetate Injection 1ml	**Sampled qty.**	60 Ampoules
Batch No.	A26248J	**Sampled by**	Vineet
Batch Size	10,000 Ampoules	**Sampled on**	06/10/2026
Mfg. Date	09/2026	**Date of Testing**	07/10/2026
Exp. Date	08/2028	**Date of Release**	21/10/2026

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	4.12
6.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test		
	(1.) Particles ≥10µm	NMT 6000/Ampoule	93/Ampoule
	(2.) Particles ≥25µm	NMT 600/Ampoule	1/Ampoule
	(B.) Visual Particle	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection.	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	104.59343 mcg	104.59%	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
21/10/26	21/10/26	21/10/26
NAME: SHAHRUKH KHAN	NAME: SURJEET KAUR	NAME: MRS. SWATI DHAWAN

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