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Pace Biotech

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

Title	:	Certificate of Analysis Finished Product

3Product Name	**OCTREOCAN 100mcg** Injection	**A.R. No.**	NL/FP/24/198
Generic Name	Octreotide Acetate Injection 100mcg/ml	**Sampled qty.**	60 Ampoules
Batch No.	A24043E	**Sampled by**	Aakash
Batch Size	10,024 Ampoules	**Sampled on**	03/07/2024
Mfg. Date	05/2024	**Date of Testing**	03/07/2024
Exp. Date	04/2026	**Date of Conditionally Release**	11/07/2024

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	4.35
6.	Particulate Matter		
	(a.) Sub-Visible particle count (1.) Particles ≥10µm (2.) Particles ≥25µm	NMT-6000/Ampoule NMT-600/Ampoule	81/Ampoule 1/Ampoule
	(b.) Visual	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	Complies
7.	Sterility	No microbial growth should be observed.	Under process
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	108.16 mcg	108.16%	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

PACE BIOTECH PAONTA SAHIB (H.P.)