

Title

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Certificate of Analysis Finished Product

3Product Name	OCTREOCAN Injection	A.R. No.	NL/FP/24/038
Generic Name	Octreotide Acetate Injection 1ml	Sampled qty.	45 Ampoules
Batch No.	A23652A	Sampled by	Aakash
Batch Size	3024 Ampoules	Sampled on	23/04/2024
Mfg. Date	03/2024	Date of Testing	23/04/2024
Exp. Date	02/2026	Date of Conditionally Release	04/05/2024

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	4.77
6.	Particulate Matter		
	(a.) Sub-Visible particle count		
	(1.) Particles $\geq 10\mu\text{m}$	NMT-6000/Ampoule	28/Ampoule
	(2.) Particles $\geq 25\mu\text{m}$	NMT-600/Ampoule	0/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	50 mcg	53.98 mcg	107.96%	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 *Umita*

Checked by *Sujjan*

Approved by *[Signature]*