

AR. No. : F0000000943		<b>FINISH PRODUCT CERTIFICATE OF ANALYSIS</b>	
<b>QUALITY CONTROL DEPARTMENT</b>			
<b>Product Name</b>	: CALCICAN NASAL SPRAY	<b>Batch Size</b>	: 1111 VIAL
<b>Generic Name</b>	: Calcitonin Salmon Nasal Solution USP	<b>Report No.</b>	: F0000000943
<b>Batch No.</b>	: MND0157A	<b>Report Date</b>	: 31/03/2024
<b>Mfg. Dt</b>	: Mar. 2024		
<b>Exp.Dt</b>	: Feb. 2026		

TEST	RESULTS	LIMITS
Description	Clear colourless liquid filled in Amber glass vials crimped with nasal spray pumps and fitted with an actuator and a cap	Clear colourless liquid filled in Amber glass vials crimped with nasal spray pumps and fitted with an actuator and a cap
Identification	A Complies	In the assay, the principle peak in the chromatogram obtained with standard solution shows a peak with the same retention time as that in the chromatogram obtained with sample solution (Calcitonin (Salmon) IP)
	D Complies	Should complies by Assay (Sodium chloride IP)
pH at 25°C	3.94	3.50 to 4.50
Number of Deliveries per container	35.00	NLT 30.00
Average weight/actuation	104.63 mg per actuation	80-120 mg per actuation
Weight/ml at 25°C	1.0114 g/mL	0.9000 to 1.1000g/mL
Colour index	0.005	Not More Than 0.10 (at 420nm)
Foreign Particle	Complies	No any particle observe
Particulate matter of solution By light obscuration	(A) Particle of size >10 µm : 281 per Vial (B) Particle of Size >25 µm : 11 per Vial	(A) Particle of size >10 µm : NMT 6000 per Vial (B) Particle of Size >25 µm : NMT 600 per Vial
Assay	<b>OBTAINED</b> <b>CLAIM</b>	<b>Limits</b>
SODIUM CHLORIDE IP	A      7.97mg      7.50mg 106.27%	6.00mg/ml to 9.00mg/ml 80% to 120%
CALCITONIN (SALMON) IP	D      2240.8300IU      2200.0000IU 101.86%	1760.0000IU/ml to 2530.0000IU/ml 80% to 115%

**Remarks:**The sample complies as per specification. FP/1500000869/F (Pack: 1 X 3.7 ML)

**Special Remarks :** : Above Product Release based on Chemical Analysis and Microbial Test Under Process, Temporary Change Control No.: T/DCR/027/24

	Prepared By	Checked By	Approved By
<b>Name</b>	Monali N. Patel	Himesh Shah	Dr. Manojkumar Dubey
<b>Date</b>	31/03/2024	31/03/2024	31/03/2024
<b>Designation</b>	Sr. Executive Q.C.	Team Manager Q.C.	G.M. Q.C.

Printed By: Dr. Manojkumar Dubey

Date : 31/03/2024

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