BIODEAL PHARMACEUTICALS LIMITED

NALAGARH – ROPAR ROAD, VILLAGE SAINIMAJRA, NALAGARH, DIST.SOLAN (HP) INDIA.

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	:	**CALCICAN N.S.**			
Generic name	:	Calcitonin (Salmon) Nasal solution USP			
Product Code	:	1665-BP	A.R.No.	:	FP/26/6931
Batch No.	:	2608328C	Batch Size	:	4.0 Ltr.
Manufacturing Date	:	09/2026	Expiry Date	:	08/2028
Sample Quantity	:	35 x 3.7 ml	Pack Size	:	1 x 3.7 ml
Date of Sampling	:	01/10/2026	Date of Analysis	:	03/10/2026
Ref.Spec. No.	:	FP/1665	Date of Release	:	23/10/2026
Mfg.LIC.No.	:	MB/06/441			

S.No.	TESTS	SPECIFICATIONS	RESULTS
01.	Description	Clear solution filled in amber coloured glass bottle fitted with 100 mcl pump, actuator and dust cap.	Clear solution filled in amber coloured glass bottle fitted with 100 mcl pump, actuator and dust cap.
02.	Identification		
	A. Calcitonin(salmon) (By HPLC)	A. The retention time of the peak obtained in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation as obtained in the assay.	Complies
	B. Benzalkonium Chloride solution IP (By HPLC)	B.The retention time of the peak obtained in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation as obtained in the assay.	Complies
	C. Phenylethyl alcohol IP (By HPLC)	C.The retention time of the peak obtained in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation as obtained in the assay.	Complies
03.	Net content	NLT 3.7 ml	4.0 ml
04.	pH at 25°C	3.5-4.5	4.00
05.	Weight per ml at 25°C	0.9000 – 1.1000 g/ml	1.007 g/ml
06.	Average Weight per actuation	Individual weight should not differ by ±15 % of the target weight and mean weight should not differ by ±10 % of the target. (100 mg /actuation)	Min :- +0.1% Max :-+3.7%

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Name	Shivani Kapoor	Shalini Raut	UH Singh
Signature			
Date	23/10/2026	23/10/2026	23/10/2026

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07.	No. of metered doses/bottle	NLT 30	35
08.	Content Delivered per actuation	160 IU – 240 IU/actuation (80.0 %-120.0 %of the labeled claim)	Avg:- 107.1%, Min.:- 105.6%, Max.:- 108.6%
09.	Preservative content		
	Benzalkonium Chloride IP.....0.01%w/v	0.008% w/v - 0.0115% w/v (80.0 % to 115.0 % of the label claim)	0.01147% w/v 114.7%
	Phenylethyl alcohol IP.....0.2%w/v	0.16% w/v - 0.23% w/v (80.0 % to 115.0 % of the label claim)	0.207%w/v 103.6%
10.	Assay (By HPLC)		
	Calcitonin (Salmon) IP.....2200 IU/ml	1760 IU - 2420 IU/ml (80.0% to 110.0% of the label claim)	2254.63 IU/ml 102.5%
11.	Microbial Limits test		
	1. Toatal Bacterial count 2. Total Fungal count Pathogens: *1. Pseudomonas aeruginosa* *2. Staphylococcus aureus*	Not more than 10^2 cfu /ml Not more than 5×10^1 cfu /ml To be absent per ml To be absent per ml	<10 cfu /ml <10 cfu /ml Absent/ml Absent/ml

Remarks: The product ~~meets/does not meets~~ the specification of **CALCICAN N.S.** and hence ~~is/is not~~ of standard quality.

Responsibility	**PREPARED BY**	**CHECKED BY**	**APPROVED BY**
Name	Shivam Kapoor	Shashikant	Uttam Singh
Signature			
Date	23/10/2026	23/10/2026	23/10/26

Form no: QC013-F05-07