

BIODEAL PHARMACEUTICALS LIMITED

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

**CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)**

Page No. 1 of 2

Product Name	:	CALCICAN		
Generic name	:	Calcitonin (Salmon) Nasal solution USP		
Product Code	:	1665-BP	A.R.No.	: FP/25/1387
Batch No.	:	2503045A	Batch Size	: 5.0 Ltr.
Manufacturing Date	:	03/2025	Expiry Date	: 02/2027
Sample Quantity	:	30 x 3.7ml	Pack Size	: 1 x 3.7 ml
Date of Sampling	:	13/03/2025	Date of Analysis	: 13/03/2025
Ref.Doc. No.	:	FP/1665	Date of Release	: 24/03/2025
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	3.8 ml
04.	pH at 25°C	3.5-4.5	4.08
05.	Weight per ml at 25°C	0.9000 – 1.1000 g/ml	1.0012 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 :- -0.4% Max :-+6.3%

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Name	Rahul	Shashikant	Uttam Singh
Signature			
Date	24/03/2025	24/03/2025	24/03/25

Form no: QC013-F05-05

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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:- 94.6%, Min.:- 83.0%, Max.:- 104.1%
09.	Preservative content		
	Benzalkonium Chloride IP.....0.02%w/v	0.016% w/v - 0.023% w/v (80.0 % to 115.0 % of the label claim)	0.0105% w/v 104.6%
	Phenylethyl alcohol IP.....0.2%w/v	0.16% w/v - 0.23% w/v (80.0 % to 115.0 % of the label claim)	0.1909%w/v 95.4%
10.	Assay (By HPLC)		
	Calcitonin (Salmon) IP.....2200 IU/ml	1760 IU - 2420 IU/ml (80.0% to 110.0% of the label claim)	2224.54 IU/ml 101.1%
11.	Microbial Limits test		
	1. Total Bacterial count	Not more than 10^2 cfu /ml	15 cfu /ml
	2. Total Fungal count	Not more than 5×10^1 cfu /ml	<10 cfu /ml
	Pathogens:		
	1. <i>Pseudomonas Aeruginosa</i>	To be absent per ml	Absent/ml
	2. <i>Staphylococcus Aureus</i>	To be absent per ml	Absent/ml
	3. <i>Burkholderia cepacia complex</i>	To be absent per ml	Absent/ml

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

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Name	Salvi	Shankant	Vijay Singh
Signature	[Signature]	[Signature]	[Signature]
Date	24/03/2025	24/03/2025	24/03/25