

# 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	:	NUMBON SPRAY			
Generic name	:	Lidocaine spray			
Product Code	:	1687-B	A.R.No.	:	FP/25/4972
Batch No.	:	2508132	Batch Size	:	188.0 Ltr
Manufacturing Date	:	08/2025	Expiry Date	:	07/2027
Sample Quantity	:	12 x 50 ml	Pack Size	:	1 x 50 ml
Date of Sampling	:	12/09/2025	Date of Analysis	:	13/09/2025
Ref.Spec. No.	:	FP/1687	Date of Release	:	25/09/2025
Mfg.LIC.No.	:	MNB/06/440			

S.No.	TESTS	SPECIFICATIONS	RESULTS
01	Description	Clear colourless solution filled in clear bottle with spray pump & cap.	Clear colourless solution filled in clear bottle with spray pump & cap.
02.	Identification (By HPLC)	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation as obtained in the assay.	Complies
03	pH	5.0 to 7.0	6.94
04	Uniformity of volume	The average net volume of the contents of the 10 containers is not less than the labelled amount, and the net volume of the contents of any single container is not less than 91% and more than 109% of the labelled amount. If this requirement is not met, determine the net volume of the contents of the 10 additional containers. The average net volume of the contents of the 20 containers is not less than the labelled amount, and the net volume of the contents of not more than 1 of the 20 containers is less than 91% or more than 109% of the labelled amount.	Minimum :- 51.0ml Maximum :- 52.0ml Average:- 51.0ml
05.	Assay:		

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Name	Shivani Kapoor	Shamikant	Uttam Singh
Signature			
Date	25/09/2025	25/09/2025	25/09/2025

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	Each ml contains: Lidocaine IP..... 100 mg	Not less than 90.00 mg and Not more than 110.00 mg (90.0% to 110.0% of label claim)	97.15mg/ml 97.2%
	Ethanol IP.....30.4%v/v (By GC)	Not less than 27.36% v/v and Not more than 33.44% v/v of the labeled claim (90.0% to 110.0% of label claim)	29.907%v/v 98.4%
06.	Microbial Limit Tests		
	Total Aerobic viable count Total Fungal Count <i>Staphylococcus aureus</i> <i>pseudomonas aeruginosa</i>	Not more than 200 cfu/ml Not more than 20 cfu/ml Should be Absent in 1ml Should be Absent in 1 ml	20 cfu /ml <10 cfu /ml Absent/ml Absent/ml

Remarks: The product ~~meets~~/does not meet the specification **NUMBON SPRAY** and hence is/ is not of standard quality.

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Name	Shivani Kapoor	Charvi Kant	Uttam Singh
Signature			
Date	25/09/2025	25/09/2025	25/09/2025