

**BIODEAL PHARMACEUTICALS LIMITED**

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

**CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)**

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Product Name	:	<b>NUMBON SPRAY</b>	
Generic name	:	<b>LIDOCAINE SPRAY</b>	
Product Code	:	1687-B	A.R.No. : FP/24/2061
Batch No.	:	2405219	Batch Size : 184.0 Ltr
Manufacturing Date	:	05/2024	Expiry Date : 04/2026
Sample Quantity	:	12 x 50 ml	Pack Size : 1 x 50 ml
Date of Sampling	:	31/05/2024	Date of Analysis : 06/06/2024
Ref.Spec. No.	:	FP/1687	Date of Release : 20/06/2024
Mfg.LIC.No.	:	MNB/06/440	

S.No.	TESTS	SPECIFICATIONS	RESULTS
01	Description	Clear colourless solution filled in clear bottle with spray pump and cap.	Clear colourless solution filled in clear bottle with spray pump and 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	8.0 – 11.0	9.82
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 :- 51.0 ml Maximum :- 52.0 ml Average:- 51.6 ml
05.	Assay:		
	Lidocaine IP (By HPLC)	Not less than 95.00mg and not more than 105.00 mg (95.0% to 105.0% of label claim)	96.50mg 96.5%
	Ethanol IP (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)	30.29.%v/v 99.6%

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

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Signature & date	 20/06/2024	 20/06/2024	 20/06/2024

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