

BIODEAL PHARMACEUTICALS LIMITED

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

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

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Product Name	: NOSTRIHEAL N.S		
Generic name	: Oxymetazoline Hydrochloride Nasal Solution IP		
Product Code	: 1699-AJ	A.R.No.	: FP/24/5378
Batch No.	: 2411210A	Batch Size	: 17.0 Ltr.
Manufacturing Date	: 11/2024	Expiry Date	: 10/2027
Sample Quantity	: 15x 10 ml	Pack Size	: 1 x 10 ml
Date of Sampling	: 19/12/2024	Date of Analysis	: 19/12/2024
Ref.Spec. No.	: FP/1699	Date of Release	: 25/12/2024
Mfg.LIC.No.	: MNB/06/440		

S.No.	TESTS	SPECIFICATIONS	RESULTS
01.	Description	Colourless, clear solution filled in 20 ml squeeze HDPE bottle.	Colourless, clear solution filled in 20 ml squeeze HDPE bottle.
02.	Identification By HPLC	The retention time of the major peak in the chromatogram of the sample preparation correspond to that in the chromatogram of the standard preparation, as obtained in the Assay.	Complies
03.	Net Content	Not less than 10.0 ml	10.8 ml
04.	pH	Between 4.00 to 6.50	6.11
05.	Weight per ml	Between 0.9000 to 1.1000 g/ml	1.003 g/ml
06.	Assay : Each spray delivers : Oxymetazoline HCl IP.....0.05% w/v	Between 0.045% w/v to 0.055% w/v NLT 90.0% & NMT 110.0% of L.A	0.0497% w/v 99.3% of L.A
07.	Preservative Content Each spray delivers : Benzalkonium Chloride Solution IP.....0.02% w/v	Between 0.018 %w/v to 0.022 %w/v NLT 90.0% & NMT 110.0% of L.A	0.019652%w/v 98.3% of L.A
08.	Microbial Limit Tests		
	Total Aerobic viable count Total Fungal Count Pathogens : <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> <i>Burkholderia cepacia</i> complex	NMT 100 cfu/ml NMT 10 cfu/ ml Should be absent/ml Should be absent/ml Should be absent/ml	20 cfu/ml <10 cfu/ml absent/ml absent/ml absent/ml

Remarks: The product meets/does not meet the specification NOSTRIHEAL N.S and hence is/is not of standard quality.

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Name	Lalit	Shankant	Utkarsh Singh
Signature			
Date	25/12/2024	25/12/2024	25/12/2024

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