

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	:	FLUTIHEAL AZ NF		
Generic name	:	Azelastine Hydrochloride and Fluticasone Propionate Nasal Spray		
Product Code	:	1854-G	A.R.No.	: FP/24/5142
Batch No.	:	2411101	Batch Size	: 61.0 Ltr
Manufacturing Date	:	11/2024	Expiry Date	: 10/2027
Sample Quantity	:	30 x 7 ml	Pack Size	: 1 x 7 ml (70 MD)
Date of Sampling	:	04/12/2024	Date of Analysis	: 04/12/2024
Ref.Doc. No.	:	FP/1854	Date of Release	: 11/12/2024
Mfg.LIC.No.	:	MNB/06/440		

S.No.	TESTS	SPECIFICATIONS	RESULTS
01.	Description	White to off white suspension filled in 15 ml HDPE snap on bottle screwed with a nasal spray pump of 0.1 ml delivery and fitted with an actuator and a protection cap.	White suspension filled in 15 ml HDPE snap on bottle screwed with a nasal spray pump of 0.1 ml delivery and fitted with an actuator and a protection cap.
02.	Identification By HPLC	The retention time of the Azelastine hydrochloride, Fluticasone propionate, Phenylethyl alcohol, and Benzalkonium chloride peak in chromatogram of test solution corresponds to that of the chromatogram obtained with reference solution.	Complies
03.	Net content	Not less than 7.00 ml	9.1ml
04.	pH	Between 5.80 to 6.80	6.31
05.	Weight per ml	Between 0.900 g/ml to 1.100 g/ml	1.004g/ml
06.	No of deliveries per container	Not less than 70	74
07.	Content delivered per actuation		
	Azelastin Hydrochloride IP.....140mcg	Between 112.00 mcg to 168.40 mcg/ actuation (NLT 80.0% and NMT 120.0% of the labeled amount)	140.24 mcg/actuation 100.2%
	Fluticasone propionate IP.....50mcg	Between 40.00 mcg to 60.00 mcg/ actuation (NLT 80.0% and NMT 120.0% of the labeled amount)	48.72 mcg/actuation 97.5%
08.	Assay		
	Azelastine hydrochloride IP.....0.14% w/v	Between 0.126% w/v to 0.154% w/v (NLT 90.0% and NMT 110.0% of the labeled amount).	0.13947% w/v 99.6%
	Fluticasone propionate IP.....0.05% w/v	Between 0.045% w/v to 0.055% w/v (NLT 90.0% and NMT 110.0% of the labeled amount).	0.04785% w/v 95.7%

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Name	Lalita	Shantanu	Vijay Singh
Signature			
Date	11/12/2024	11/12/2024	11/12/2024

Form no.: QC013-F05-05

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	Benzalkonium chloride IP.....0.01% w/v	Between 0.008% w/v to 0.012% w/v (NLT 80.0% and NMT 120.0% of the labeled amount).	0.00962% w/v 96.2%
	Phenylethyl alcohol IP.....0.25% w/v	Between 0.200% w/v to 0.300% w/v (NLT 80.0% and NMT 120.0% of the labeled amount).	0.23990% w/v 95.7%
09.	Microbial Limit Test		
	1. Total Aerobic viable count 2. Total Fungal Count Pathogens: 1. <i>Pseudomonas aeruginosa</i> 2. <i>Staphylococcus aureus</i> 3. <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~~ meets the specification of **FLUTIHEAL AZ NF** and hence is/~~is not~~ of standard quality.

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Name	Salita	Shankant	Ujjwal Singh
Signature			
Date	11/12/2024	11/12/2024	11/12/2024

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