

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 N.S	
Generic name	:	Fluticasone Nasal Spray IP	
Product Code	:	1853-G	A.R.No. : FP/24/5002
Batch No.	:	2410260	Batch Size : 74.0 Ltr.
Manufacturing Date	:	10/2024	Expiry Date : 09/2027
Sample Quantity	:	30 x 10 ml	Pack Size : 1 x 10 ml (100 MD)
Date of Sampling	:	26/11/2024	Date of Analysis : 26/11/2024
Ref.Spec. No.	:	FP/1853	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 screw bottle 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 screw bottle with a nasal spray pump of 0.1 ml delivery and fitted with an actuator and a protection cap.
02.	Identification		
	By TLC	The principle spot in the chromatogram obtained with the solution (1) corresponds in position and color to that of the chromatogram obtained with solution (2).	Complies
	By HPLC	In the assay, the retention time of the principle peak in the chromatogram obtained with solution (1) is similar to that of the principal peak in the chromatogram obtained with solution (2).	Complies
03.	Net Content	Not less than 10	12.2ml
04.	No. of deliveries per container	Not less than 100	111
05.	pH	Between 5.00 to 7.00	6.05
06.	Average weight per actuation	Between 90.00 mg to 110.00 mg	101.6mg
07.	Weight per ml	Between 0.9000 g/ml and 1.1000 g/ml	1.012g/ml
08.	Related substances		
	A. Single impurity	NMT 0.5%	0.088%
	B. Total impurities	NMT 2.0%	0.426%

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Name	POONAM THAKUR	SHARVANT	CHANDAN SINGH
Signature			
Date	11/12/2024	11/12/2024	11/12/2024

Form no.: QC013-F05-05

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S.No.	TESTS	SPECIFICATIONS	RESULTS
09.	Content of Fluticasone propionate delivered per actuation	Between 40.00 mcg to 60 mcg/actuation NLT 80.0% & NMT 120.0% of the labeled amount.	48.42mcg/actuation 96.8 %
10.	Assay (By HPLC)		
	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.	0.0490% w/v 98.0%
	Phenylet hyl Alcohol IP.....0.25% w/v	Between 0.20% w/v to 0.30% w/v NLT 80.0% and NMT 120.0% of the labeled amount.	0.2391% w/v 95.6%
	Benzalkonium Chloride IP.....0.01% w/v	Between 0.008% w/v to 0.012% w/v NLT 80.0% & NMT 120.0% of the labeled amount.	0.0096% w/v 96.3%
11.	Microbial Limits:		
	1.Total Aerobic viable count 2. Total Fungal Count Pathogens: 1. <i>Escherichia coli</i> 2. <i>Salmonella Species</i> 3. <i>Pseudomonas aeruginosa</i> 4. <i>Staphylococcus aureus</i> 5. <i>Enterobacteriaceae</i>	NMT 100 cfu/ml NMT 10 cfu/ml Should be Absent/ml Should be Absent/10ml Should be Absent/ml Should be Absent/ml NMT 10 cfu/ ml	20 cfu /ml <10 cfu /ml Absent/ml Absent/10ml Absent /ml Absent/ml <10 cfu /ml

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

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Name	POONAM TAPKUR	Sharu Kant	V Hem Singh
Signature			
Date	11/12/2024	11/12/2024	11/12/2024

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