



Works: 515/3, Village Kondi, PO Thana, Baddi, Distt.-Solan (H.P.) Corp. Office: Plot No-213, Industrial Area Phase-I, Chandigarh-160002

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

(The Drugs and cosmetics Act 1940 and the rules there under)

Format No. OC/006/F002-02

Generic Name	Desmopressin Nasal Spray BP 0.01% w/v, 50 Metered Doses		
Product Name	Desmopressin Nasal Spray 50 MD	A. R. No.	FNS-12/10/21
Batch No	NSZ102	Date of Receipt	23/11/2021
Mfg. Date	10/2021	Batch Size	1100 Vial
Exp. Date	09/2023	Sample Qty.	35 Vial

S. No.	Test	Specifications	Results
1.	Description	A clear colorless solution filled in amber colour glass bottle fitted with spray dispenser.	A clear colorless solution filled in amber colour glass bottle fitted with spray dispenser.
2.	Identification a) By HPLC	In the Assay, the principal peak in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2).	Complies
3.	Nominal No. of Sprays	50 Sprays	51 Sprays
4.	pH	3.5 to 5.5	4.48
5.	Related Substances a) The area of any secondary peak b) Total area of any such peaks	NMT 4.0% NMT 5.0%	0.25 % 0.36 %
6.	Uniformity of delivered doses	Meets the requirement	Complies
7.	Particulate Matter	Should be free from any visible foreign particles	Complies
8.	Assay (BY HPLC) Each Spray delivers: Desmopressin Acetate BP 10 mcg	NLT 9.0 mcg to NMT 11.0 mcg (90.00 % to 110.00 %)	10.64 mcg/spray (106.40 %)

Remarks: The product referred to above complies / does not comply / with L.P./ BP / USP / In-House Specifications.

UNCONTROLLED COPY

Analyzed By 24/1

Checked By

Approved By