

**NANZ MED SCIENCE PHARMA (P) LTD.**

Village - Rampur Ghat, Paonta Sahib-173025(H.P.)

(The drugs and cosmetics Act.1940 and the rules there under)

(Certificate of Analysis)

Product Name: Dandrofine S3% Lotion**Generic Name:** Clobetasole Propionate & Salicylic Acid Lotion**A.R. No.:** QC/FP/N5440006/C**Batch No.:** N5440006**Mfg. Lice. No.:** S-MNB/09/41**Mfg. Date:** 07/2024**Date of Sampling :** 04/07/2024**Exp. Date:** 06/2026**Sample Quantity:** 12 × 30 ml**Batch Size:** 16667 Nos.**Date of Completion:** 09/07/2024**Mfg. For :** M/S Healing Pharma India Pvt. Ltd.**STS No.:** NZ/QC/STS/FP/0213-07**Stage:** Composite

Test	Release Specification	Observation
Description	A colourless viscous liquid.	A colourless viscous liquid.
Identification	The Retention time of major peak of in Clobetasol Propionate chromatogram of sample preparation corresponds to that in chromatogram obtained with standard preparation as obtained in assay.	Complies
Average Fill Volume	Should be NLT the label claim 30 ml	30.4 ml
Uniformity of fill volume	For 30 ml: Volume of any single container should be not less than 90 % of label amount.	100 %
Weight per ml	Should be 0.90 to 1.10 g/ml	1.02 g/ml
Assay Clobetasol Propionate IP 0.05 % w/v Salicylic Acid IP 3 % w/v	Should be 0.0475 to 0.0575 % w/v (Should be 95.0 to 115.0 %) Should be 2.8500 to 3.3000 % w/v (Should be 95.0 to 110.0 %)	0.0510 % w/v (102.0 %) 3.1107 % w/v (103.7 %)

Microbiological enumeration test and absence of specified microorganisms:

Total viable aerobic Count	Should be NMT 100 cfu/ ml	<10 cfu/ml
Total yeast/molds Count	Should be NMT 10 cfu/ml	< 10 cfu/ml
P. aeruginosa	Should be Absent/ml	absent/ml
S. aureus	Should be Absent/ml	absent/ml

Remark: In the opinion of the undersigned, the sample submitted complies/does not comply with the prescribed standards of Quality with respect to above tests as per STP No.:

NZ/QC/STP/FP/0213-07

Prepared by QC officer Date: 09/07/24	Approved by QC Manager 09/07/24	Released by QA Manager 09/07/24
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Annexure No.: NZ/QC/070/A02-00