



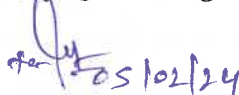
NANZ MED SCIENCE PHARMA (P) LTD.
Village - Rampur Ghat, Paonta Sahib-173025(H.P.)
(The drugs and cosmetics Act.1940 and the rules there under)
(Certificate of Analysis)

Product Name: Dandrofine S3% Lotion	
Generic Name: Clobetasol Propionate & Salicylic Acid Lotion	A.R. No.: QC/FP/N5440001/C
Batch No: N5440001	Mfg. Lice. No.: S-MNB/09/41
Mfg. Date: 01/2024	Date of Sampling: 30/01/2024
Exp. Date: 12/2025	Sample Quantity: 12×30 ml
Batch Size: 16667 Nos.	Date of Completion: 05/02/2024
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	31 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	Should be 0.0475 to 0.0575 % w/v (Should be 95.0 to 115.0 %)	0.0521 % w/v (104.2 %)
Salicylic Acid IP 3 % w/v	Should be 2.8500 to 3.3000 % w/v (Should be 95.0 to 110.0 %)	3.0386 % w/v (101.3 %)

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:	Approved By QC Manager  Date:	Released By QA Manager  Date:
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Annexure No.: NZ/QC/070/A02-00