

QA.15.0.0.3

FORM 39

[RULE 150 - E(F)] APPROVAL NUMBER: T-22/DC

TEST REPORT

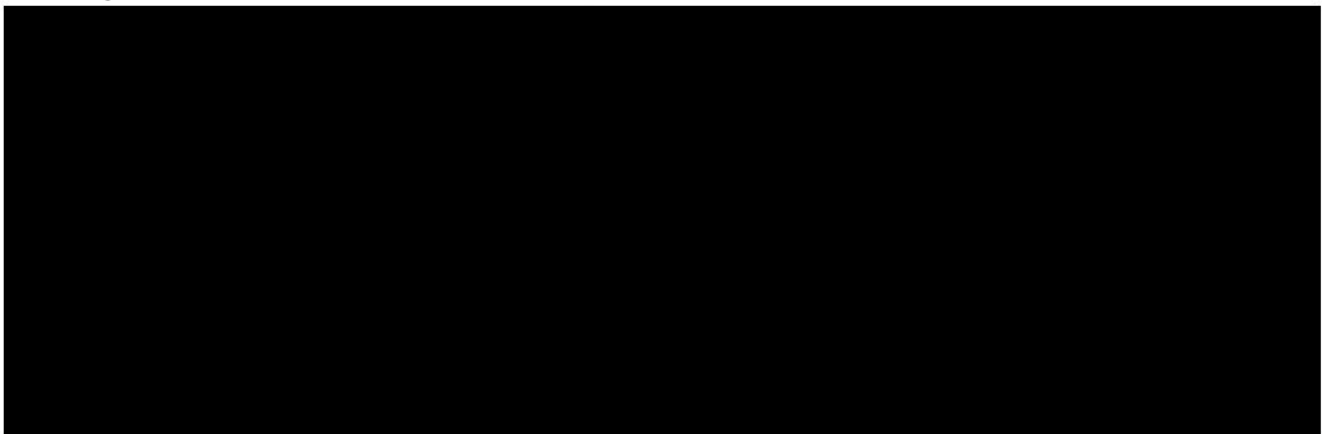
ISSUED TO : Meghalayan Medical Drugs And Services Limited New colony shillong, DHS, Iaitumkhrah, Office of the mission director, NHM, Shillong, East Khasi Hills Meghalaya, 793003 Shillong - 793003 MFG. LICENCE No :	REPORT NO : ██████████ ISSUE DATE : 17/10/2023 CUSTOMER REFERENCE : Mail DATE : 28/09/2023 PAGE NO : 1 of 3
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SAMPLE DETAILS

SAMPLE REGISTRATION DETAILS	
Sample Name : Cap Nifedipine Smg	Sample Quantity Received : 80.00 Capsules
	Sample Registration Date : 09/10/2023
	Sample Submitted/Drawn by : Client
	Batch Size : N/A
	Date of Expiry : Jun-2025
Sample Receipt Date : 28/09/2023	
Registration No : ██████████	
Name of Manufacturer : N/A	
Batch No. : MMDSL/QC-0001	
Date of Mfg. : Jul-2023	
SAMPLE ANALYSIS DETAILS	
Analysis Starting Date : 17/10/2023	Analysis Completion Date : 17/10/2023

TEST RESULT

SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	UOM	ACCEPTANCE LIMIT	RESULTS
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TEST RESULT

SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	UOM	ACCEPTANCE LIMIT	RESULTS
1	Identification	Indian Pharmacopoeia 2022		—	In the chromatogram obtained with the test solution the principal band appearing as a compact light orange band against a yellow background should correspond to that in the chromatogram obtained with reference solution (a). The band obtained with reference solution (b) appears as a single band under both visualisation procedure.	In the chromatogram obtained with the test solution the principal band appearing as a compact light orange band against a yellow background corresponds to that in the chromatogram obtained with reference solution (a). The band obtained with reference solution (b) appears as a single band under both visualisation procedure.
2	Disintegration test	Indian Pharmacopoeia 2022		Min./Sec.	NMT 30 Minutes	Min : 11 Min 43 Sec , Max : 12 Min 15 Sec
3	Dissolution Test	Indian Pharmacopoeia 2022	5 mg/Cap	% of L.C.	NLT 75.0	Avg : 96.28 , Min : 90.10 , Max : 100.03
4	Uniformity of the weight	Indian Pharmacopoeia 2022		%	(±) 7.5	Avg wt : 271.08 mg , (-) Dev : 4.7 , (+) Dev : 4.4
5	Assay	Indian Pharmacopoeia 2022	5 mg/Cap	% of L.C.	4.5 to 5.5 mg/Cap i.e. 90.0 - 110.0	4.97 mg/Cap i.e. 99.37

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In the opinion of the undersigned, the Sample referred to above is of Standard Quality / is not of Standard Quality
as defined in the Act or the Rules made there under for the reasons given below:

Date : 17/10/2023

UOM : Unit of Measurement

REMARKS : The sample is tested as per test procedure shared by client and Opinion on Quality is drawn against the results obtained for tested parameters only.

Note : This Report is valid only for use in Indian (Domestic) Market & is Not valid for use in any International Market.

-END OF THE TEST REPORT-