



QA.15.0.0.3

FORM 39

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

TEST REPORT

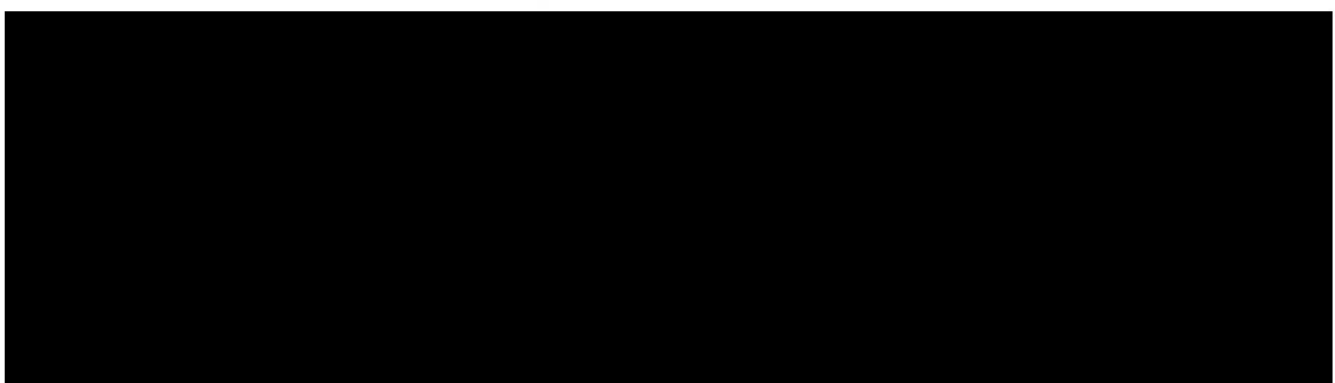
ISSUED TO : Meghalayan Medical Drugs And Services Limited New colony shillong, DHS, laitumkhrah, Office of the mission director,NHM, Shillong, East Khasi Hills Meghalaya, 793003 Shillong - 793003 MFG. LICENCE No :	REPORT NO : [REDACTED] ISSUE DATE : 24/11/2023 CUSTOMER REFERENCE : TRF DATE : 17/11/2023 PAGE NO : 1 of 2
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SAMPLE DETAILS

SAMPLE REGISTRATION DETAILS	
Sample Name : Tab Amlodipine 2.5mg	Sample Quantity Received : 200.00 Tablets
	Sample Registration Date : 17/11/2023
	Sample Submitted/Drawn by : Client
	Batch Size : N/A
	Date of Expiry : Aug-2023
Sample Receipt Date : 17/11/2023	
Registration No : [REDACTED]	
Name of Manufacturer : N/A	
Batch No. : MMDSL QC-0014	
Date of Mfg. : Sep-2023	
SAMPLE ANALYSIS DETAILS	
Analysis Starting Date : 21/11/2023	Analysis Completion Date : 23/11/2023

TEST RESULT

SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	UOM	ACCEPTANCE LIMIT	RESULTS
1	Description	Indian Pharmacopoeia 2022	-	—	White colour uncoated biconvex tablet having plain on both side.	White colour uncoated biconvex tablet having plain on both side.
2	Identification	Indian Pharmacopoeia 2022	-	—	In the assay , the principal peak in the chromatogram obtained with the test solution (b) should correspond to the peak in the chromatogram obtained with reference solution (a)	In the assay , the principal peak in the chromatogram obtained with the test solution (b) corresponds to the peak in the chromatogram obtained with reference solution (a)



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TEST RESULT

SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	UOM	ACCEPTANCE LIMIT	RESULTS
3	Uniformity of weight	Indian Pharmacopoeia 2022		%	(±)7.5	Avg wt : 194.81 mg , (-) Dev : 5.70 , (+) Dev : 4.05
4	Disintegration	Indian Pharmacopoeia 2022		Min./Sec.	NMT 15 Minutes	Min : 3 Min 15 Sec , Max : 4 Min 10 Sec
5	Dissolution	Indian Pharmacopoeia 2022	2.5 mg/Tab	% of L.C.	NLT 80.0	Avg : 99.67 , Min : 97.72 , Max : 102.0
6	Assay	Indian Pharmacopoeia 2022	2.5 mg/Tab	% of L.C.	2.25 - 2.75 mg/Tab i.e. 90.0 - 110.0	2.58 mg/Tab i.e. 103.38
7	Uniformity of Content	Indian Pharmacopoeia 2022	2.5 mg/Tab	% of L.C.	85.0 - 115.0	Avg :105.17 , Min :104.28 , Max : 106.82
8	Related Substances	Indian Pharmacopoeia 2022		%	Amlodipine impurity D : NMT 0.5 , The sum of the areas of all other secondary peaks : NMT 0.5	Amlodipine impurity D : Not detected, The sum of the areas of all other secondary peaks : Not detected

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 : 24/11/2023

UOM : Unit of Measurement

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

Note :

-END OF THE TEST REPORT-