Edward Food Research & Analysis Centre Limited

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 : EFRAC/2023/DRG/RG/03639
ISSUE DATE : 24/11/2023
CUSTOMER REFERENCE : TRF
DATE : 17/11/2023
PAGE NO : 1 of 2

SAMPLE DETAILS

SAMPLE REGISTRATION DETAILS

Sample Name : Tab Amlodipine 2.5mg
Sample Receipt Date : 17/11/2023
Registration No : EFRAC/2023/DRG/RG/03639
Name of Manufacturer : N/A
Batch No. : MMDSL QC-0014
Date of Mfg. : Sep-2023

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 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)

Authorized Signatory
Ashok Singh Kushawaha
Senior Chemist

Edward Food Research & Analysis Centre Limited

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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	Disintigration	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 madethere 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-

Authorized Signatory
Ashok Singh Kushawaha
Senior Chemist

Research & Analysis Centre: Subhas Nagar PO: Nilgunj Bazar Barasat Kolkata 700 121
Phone +91 33 7112 2800 Fax: +91 33 7112 2801 Email: efraclab@efrac.org
www.efrac.org