efrac
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/03656
ISSUE DATE : 23/11/2023
CUSTOMER REFERENCE : TRF
DATE : 17/11/2023
PAGE NO : 1 of 3

SAMPLE DETAILS

SAMPLE REGISTRATION DETAILS

Sample Name : Tab Metformin 500mg
Sample Receipt Date : 17/11/2023
Registration No : EFRAC/2023/DRG/RG/03656
Name of Manufacturer : N/A
Batch No. : MMDSL QC-0015
Date of Mfg. : Oct-2023

Sample Quantity Received : 100.00 Tablets
Sample Registration Date : 20/11/2023
Sample Submitted/Drawn by : Client
Batch Size : N/A
Date of Expiry : Sep-2025

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 biconvex caplet shaped uncoated tablet having breakline in one side and plain on other side.	White colour biconvex caplet shaped uncoated tablet having breakline in one side and plain on other side.
2	Identification A	Indian Pharmacopoeia 2022	-	—	The IR spectrum obtained with the sample should concordant with the reference spectrum of metformin HCL	The IR spectrum obtained with the sampleis concordant with the reference spectrum of metformin HCL

Authorized Signatory
Ashok Singh Kushawaha
Senior Chemist

Research & Analysis Centre: Subhas Nagar PO: Nilgunj Bazar Barasat Kolkata 700 121
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TEST RESULT

SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	UOM	ACCEPTANCE LIMIT	RESULTS
3	Identification B	Indian Pharmacopoeia 2022	-	—	An orange-red colour should produced which darkens on keeping	An orange-red colour produced which darkens on keeping
4	Identification C	Indian Pharmacopoeia 2022	-	—	A curdy white ppt should formed which should not soluble in HNO3 but soluble in dilute ammonia solution.	A curdy white pptis formed which insoluble in HNO3 but soluble in dilute ammonia solution.
5	Uniformity of weight	Indian Pharmacopoeia 2022	-	%	(±)5.0	Avg wt : 751.67 mg , (-) Dev : 1.03 , (+) Dev : 2.02
6	Disintigration	Indian Pharmacopoeia 2022	-	Min./Sec.	NMT 15 Minutes	Min : 02 Min 25 Sec , Max : 03 Min 12 Sec
7	Dissolution	Indian Pharmacopoeia 2022	500 mg/Tab	% of L.C.	NLT 75.0	Avg : 89.11 , Max : 90.54 , Min : 88.19
8	Assay	Indian Pharmacopoeia 2022	500 mg/Tab	% of L.C.	475.0 - 525.0 mg/Tab i.e. 95.0 - 105.0	486.75 mg/Tab i.e. 97.34
9	Related Substances	Indian Pharmacopoeia 2022	-	%	Dicyandiamide impurity : NMT 0.02 ,Any other impurities : NMT 0.1	Dicyandiamide impurity :0.0029, Any other impurities : 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~~:

Authorized Signatory
Ashok Singh Kushawaha
Senior Chemist

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MFG. LICENCE No :		PAGE NO	: 3 of 3

Date : 23/11/2023

UOM : Unit of Measurement

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

Note :

-END OF THE TEST REPORT-

Authorized Signatory
Ashok Singh Kushawaha
Senior Chemist

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