

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, Iaitumkhrach, Office of the mission director, NHM, Shillong, East Khasi Hills Meghalaya, 793003 Shillong - 793003 MFG. LICENCE No :	REPORT NO : [REDACTED] ISSUE DATE : 23/11/2023 CUSTOMER REFERENCE : TRF DATE : 17/11/2023 PAGE NO : 1 of 3
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SAMPLE DETAILS

SAMPLE REGISTRATION DETAILS

Sample Name : Tab Metformin 500mg	Sample Quantity Received : 100.00 Tablets
	Sample Registration Date : 20/11/2023
	Sample Submitted/Drawn by : Client
	Batch Size : N/A
Sample Receipt Date : 17/11/2023	Date of Expiry : Sep-2025
Registration No : [REDACTED]	
Name of Manufacturer : N/A	
Batch No. : MMDSL QC-0016	
Date of Mfg. : Oct-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 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 sample is concordant with the reference spectrum of metformin HCL

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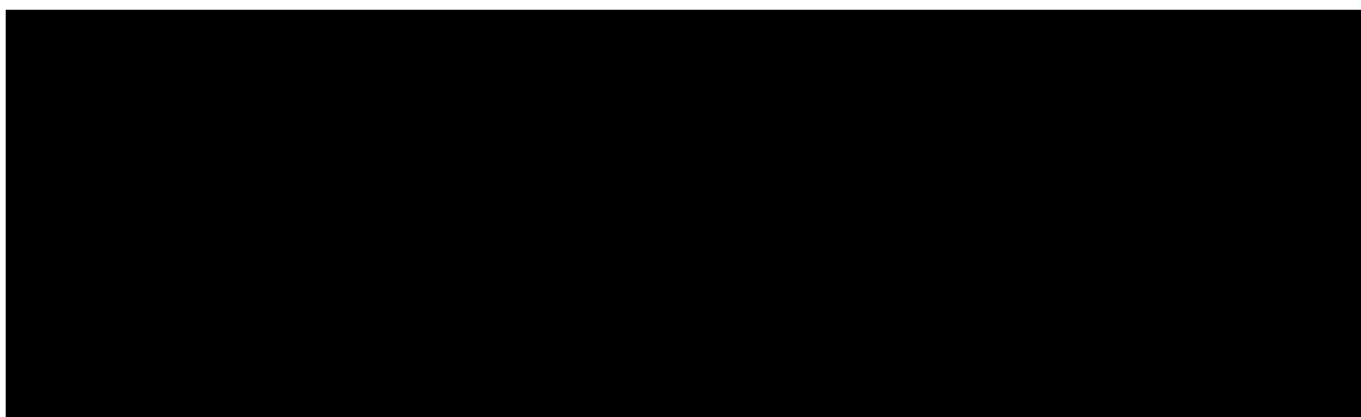
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TEST RESULT

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 HNO ₃ but soluble in dilute ammonia solution.	A curdy white ppt is formed which insoluble in HNO ₃ but soluble in dilute ammonia solution.
5	Uniformity of weight	Indian Pharmacopoeia 2022	-	%	(±)5.0	Avg wt : 750.85 mg , (-) Dev : 0.87 , (+) Dev : 1.00
6	Disintegration	Indian Pharmacopoeia 2022	-	Min./Sec.	NMT 15 Minutes	Min : 02 Min 15 Sec , Max : 3 Min 10 Sec
7	Dissolution	Indian Pharmacopoeia 2022	500 mg/Tab	% of L.C.	NLT 75.0	Avg : 88.43 , Min : 87.86 , Max : 89.53
8	Assay	Indian Pharmacopoeia 2022	500 mg/Tab	% of L.C.	475.0 - 525.0 mg/Tab i.e. 95.0 - 105.0	490.7 mg/Tab i.e. 98.14
9	Related Substances	Indian Pharmacopoeia 2022	-	%	Dicyandiamide impurity :NMT 0.02 ,Any other impurities :NMT 0.1	Dicyandiamide impurity : 0.0028, 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 made there under for the reasons given below:



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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-