



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 :	REPORT NO :	EFrac/2023/DRG/RG/03244
Meghalayan Medical Drugs And Services Limited	ISSUE DATE :	16/10/2023
New colony shillong, DHS, Iaitumkhrah, Office of the mission director,NHM, Shillong, East Khasi Hills Meghalaya, 793003	CUSTOMER REFERENCE :	Mail
Shillong - 793003	DATE :	28/09/2023
MFG. LICENCE No :	PAGE NO :	1 of 2

SAMPLE DETAILS

SAMPLE REGISTRATION DETAILS	
Sample Name : Cap Omeprazole 20mg	Sample Quantity Received : 80.00 Capsules
	Sample Registration Date : 09/10/2023
	Sample Submitted/Drawn by : Client
	Batch Size : N/A
Sample Receipt Date : 28/09/2023	Date of Expiry : Jun-2025
Registration No : EFRAC/2023/DRG/RG/03244	
Name of Manufacturer : N/A	
Batch No. : MMDSL/QC-0002	
Date of Mfg. : Jul-2023	
SAMPLE ANALYSIS DETAILS	
Analysis Starting Date : 10/10/2023	Analysis Completion Date : 15/10/2023

TEST RESULT

SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	UOM	ACCEPTANCE LIMIT	RESULTS
1	Identification	Indian Pharmacopoeia 2022	-	—	When Examined in the range 230nm to 360nm, the resulting Solution should show absorption maxima at 276nm and 305nm.	After Examined in the range 230 nm to 360 nm, the resulting Solution show absorption maxima at, 276.0 = 0.207, 305.0 = 0.379
2	Disintegration test	Indian Pharmacopoeia 2022	-	Min./Sec.	NMT 30	Max : 07 min, 19 sec Min : 06 min, 15 sec
3	Dissolution Test	Indian Pharmacopoeia 2022	20 mg/cap	% of L.C.	Acid stage : NMT 10.0, Buffer stage : NLT 75.0	Acid Stage Avg : 1.17, Min : 0.90, Max : 1.39 Buffer stage : Avg : 98.06, Min : 97.80, Max : 98.45



Authorized Signatory
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Senior Chemist

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TEST RESULT

SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	UOM	ACCEPTANCE LIMIT	RESULTS
4	uniformity of the weight	Indian Pharmacopoeia 2022	-	%	NMT (\pm) 10.0	Avg : 197.04, (+) Dev : 2.1, (-) 2.5
5	Assay	Indian Pharmacopoeia 2022	20mg /cap	% of L.C.	90.0 - 110.0	99.38

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 : 16/10/2023

UOM : Unit of Measurement

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



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