



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/03402
Meghalayan Medical Drugs And Services Limited	ISSUE DATE :	31/10/2023
New colony shillong, DHS, Iaitumkhrah, Office of the mission director,NHM, Shillong, East Khasi Hills Meghalaya, 793003	CUSTOMER REFERENCE :	TRF
Shillong - 793003	DATE :	28/09/2023
MFG. LICENCE No :	PAGE NO :	1 of 2

SAMPLE DETAILS


SAMPLE REGISTRATION DETAILS			
Sample Name	: Cap Omeprazole- 40mg	Sample Quantity Received	: 80.00 Capsule
		Sample Registration Date	: 26/10/2023
		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/03402		
Name of Manufacturer	: N/A		
Batch No.	: MMDSL/QC-0003		
Date of Mfg.	: Jul-2023		
SAMPLE ANALYSIS DETAILS			
Analysis Starting Date	: 27/10/2023	Analysis Completion Date	: 31/10/2023

TEST RESULT

SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	UOM	ACCEPTANCE LIMIT	RESULTS
1	Assay	Indian Pharmacopoeia 2022	40 mg/Cap	% of L.C.	90.0 - 110.0	98.41
2	Uniformity of Weight	Indian Pharmacopoeia 2022	-	%	(±) 7.5	Avg wt : 257.17 mg , (-) Dev : 2.7 , (+) Dev : 4.1
3	Dissolution	Indian Pharmacopoeia 2022	40 mg/Cap	% of L.C.	Acid stage : NMT 10.0 , Buffer stage : NMT 75.0	For acid stage : Avg : 0.0 , Min : 0.0 , Max : 0.0 , For Buffer stage : Avg : 99.30 , Min : 99.00 , Max : 99.55



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 Authorized Signatory
 Ashok Singh Kushawaha
 Senior Chemist



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TEST RESULT

SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	UOM	ACCEPTANCE LIMIT	RESULTS
4	Identification	Indian Pharmacopoeia 2022	-	—	The principal peak in the chromatogram obtained with the test solution should correspond to the peak due to omeprazole in the chromatogram obtained with the reference solution.	The principal peak in the chromatogram obtained with the test solution corresponds to the peak due to omeprazole in the chromatogram obtained with the reference solution.
5	Disintegration test	Indian Pharmacopoeia 2022	-	Min./Sec.	NMT 30 Minutes	Min : 07 Min 30 Sec , Max : 09 Min 23 Sec

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 : 31/10/2023

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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