

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

ISSUE DATE

16/10/2023

CUSTOMER REFERENCE | Mail

DATE

28/09/2023

PAGE NO

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SAMPLE DETAILS

SAMPLE REGISTRATION DETAILS

Sample Name

: Cap Omeprazole 20mg

Sample Quantity Received

80.00 Capsules

Sample Registration Date Sample Submitted/Drawn by 09/10/2023 Client

Batch Size

N/A

Date of Expiry

3 Jun-2025

Sample Receipt Date

: 28/09/2023 Registration No

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 Pharmacopoeía 2022	60	:09	When Examined in the range 230nm to 360nm,the resulting Solution should shows absorption maxima at 276nm and 305nm.	AfterExamined 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	3	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					

QA.15.0.0.3

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SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	иом	ACCEPTANCE LIMIT	RESULTS
4	uniformity of the weight	Indian Pharmacopoeia 2022	3.00	%	NMT (±) 10.0	Avg : 197.04, (+) Dev : 2.1, (-) 2.5
5	Assay	Indian Pharmacopoeia 2022	20mg/ċap	% 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 here under for the reasons given below:

Date

: 16/10/2023

иом

: 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-