

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

ISSUE DATE 22/11/2023

CUSTOMER REFERENCE TRF

DATE PAGE NO 17/11/2023

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SAMPLE DETAILS

SAMPLE REGISTRATION DETAILS

Sample Name

: Tab Albendazole 400mg

Sample Quantity Received

60.00 Tablets

Sample Registration Date Sample Submitted/Drawn by 17/11/2023 Client

Batch Size

≅ N/A

Date of Expiry

: Mar-2026

Sample Receipt Date

Registration No

17/11/2023

Name of Manufacturer

N/A

Batch No.

MMDSL QC-0017

Date of Mfg.

: Oct-2023

SAMPLE ANALYSIS DETAILS

Analysis Starting Date

18/11/2023

Analysis Completion Date

20/11/2023

TEST RESULT										
SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	UOM	ACCEPTANCE LIMIT	RESULTS				
1	Description	Indian Pharmacopoeía 2022			Orange colour biconvex oval shaped uncoated tablet having red specs on whole body, one side plain and other side breakline chewable tablet.	Orange colour biconvex oval shaped uncoated tablet having red specs on whole body, one side plainand other sidebreakline chewable tablet.				



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SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	UOM	ACCEPTANCE LIMIT	RESULTS
2	Identification A	Indian Pharmacopoeia 2022	20	F -	The principal spot in the chromatogram obtained with the test solution should correspond to that in the chromatogram obtained with the reference solution.	The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution.
3	Identification B	Indian Pharmacopoeia 2022	2.53	S=3	Should Comply	Complies
4	Disintegration test	Indian Pharmacopoeia 2022	€8	Min./Sec.	NMT 15 Mins	Min: 04 Min36 Sec, Max: 04 Min58 Sec
5	Dissolution	Indian Pharmacopoeia 2022	400 mg/Tab	% of L.C.	NLT 85.0	Avg :95.88 , Min :95.51 , Max : 96.12
6	Uniformity of the weight	Indian Pharmacopoeia 2022	*	%	(±)5.0	Avg wt :872.67 mg , (-) Dev : 0.58, (+) Dev : 0.82
7	Assay	Indian Pharmacopoeia 2022	400 mg/Tab	% of L.C.	370.0 - 430.0 mg/Tab i.e. 92.5 - 107.5	395.44 mg/Tab i.e. 98.86

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:



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CUSTOMER REFERENCE 3: TRF

DATE

17/11/2023

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Date

: 22/11/2023

MOU

: 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

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-END OF THE TEST REPORT-
