efrac
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 :
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 : EFRAC/2023/DRG/RG/03640
ISSUE DATE : 22/11/2023
CUSTOMER REFERENCE : TRF
DATE : 17/11/2023
PAGE NO : 1 of 3

SAMPLE DETAILS

SAMPLE REGISTRATION DETAILS

Sample Name : Tab Albendazole 400mg
Sample Receipt Date : 17/11/2023
Registration No : EFRAC/2023/DRG/RG/03640
Name of Manufacturer : N/A
Batch No. : MMDSL QC-0017
Date of Mfg. : Oct-2023

Sample Quantity Received : 60.00 Tablets
Sample Registration Date : 17/11/2023
Sample Submitted/Drawn by : Client
Batch Size : N/A
Date of Expiry : Mar-2026

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 Pharmacopoeia 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.

Authorized Signatory
Ashok Singh Kushawaha
Senior Chemist

Edward Food Research & Analysis Centre Limited

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TEST RESULT

SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	UOM	ACCEPTANCE LIMIT	RESULTS
2	Identification A	Indian Pharmacopoeia 2022	-	—	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	-	—	Should Comply	Complies
4	Disintegration test	Indian Pharmacopoeia 2022	-	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 madethere under for the reasons given below~~:

Authorized Signatory
Ashok Singh Kushawaha
Senior Chemist

Edward Food Research & Analysis Centre Limited

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		DATE	: 17/11/2023
MFG. LICENCE No :		PAGE NO	: 3 of 3

Date : 22/11/2023

UOM : Unit of Measurement

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

Note :

-END OF THE TEST REPORT-

Authorized Signatory
Ashok Singh Kushawaha
Senior Chemist

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