



Edward Food Research & Analysis Centre Limited



QA.15.0.0.3

FORM 39

[RULE 150 - E(F)] APPROVAL NUMBER: T-22/DC

TEST REPORT

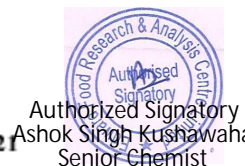
| | | |
|---|----------------------|-------------------------|
| ISSUED TO : | REPORT NO : | EFrac/2023/DRG/RG/03641 |
| Meghalayan Medical Drugs And Services Limited | ISSUE DATE : | 22/11/2023 |
| New colony shillong, DHS, Iaitumkhrah, Office of the mission director,NHM, Shillong, East Khasi Hills Meghalaya, 793003 | CUSTOMER REFERENCE : | TRF |
| Shillong - 793003 | DATE : | 17/11/2023 |
| MFG. LICENCE No : | PAGE NO : | 1 of 3 |

SAMPLE DETAILS

| | |
|---|--|
| SAMPLE REGISTRATION DETAILS | |
| Sample Name : Tab Albendazole 400mg | Sample Quantity Received : 60.00 Tablets |
| | Sample Registration Date : 17/11/2023 |
| | Sample Submitted/Drawn by : Client |
| | Batch Size : N/A |
| Sample Receipt Date : 17/11/2023 | Date of Expiry : Mar-2026 |
| Registration No : EFRAC/2023/DRG/RG/03641 | |
| Name of Manufacturer : N/A | |
| Batch No. : MMDSL QC-0018 | |
| 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 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 plain and other side breakline chewable tablet. |





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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 Min 26 Sec , Max : 05 Min 05 Sec |
| 5 | Dissolution | Indian Pharmacopoeia 2022 | 400 mg/Tab | % of L.C. | NLT 85.0 | Avg : 96.16 , Min : 95.74 , Max : 96.30 |
| 6 | Uniformity of the weight | Indian Pharmacopoeia 2022 | - | % | (±)5.0 | Avg wt : 872.25 mg , (-) Dev : 0.65, (+) Dev : 0.80 |
| 7 | Assay | Indian Pharmacopoeia 2022 | 400 mg/Tab | % of L.C. | 370.0 - 430.0 mg/Tab i.e. 92.5 - 107.5 | 392.08 mg/Tab i.e. 98.02 |

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:




 Authorized Signatory
 Ashok Singh Kushawaha
 Senior Chemist



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| Shillong - 793003 | PAGE NO : | 3 of 3 |
| MFG. LICENCE No : | | |

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-

ELECTRONIC COPY



Authorized Signatory
Ashok Singh Kushawaha
Senior Chemist