[redacted]

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** : [redacted]
**ISSUE DATE** : 23/11/2023
**CUSTOMER REFERENCE** : TRF
**DATE** : 17/11/2023
**PAGE NO** : 1 of 3

### SAMPLE DETAILS

**SAMPLE REGISTRATION DETAILS**

Sample Name : Tab Metformin 500mg
Sample Receipt Date : 17/11/2023
Registration No : [redacted]
Name of Manufacturer : N/A
Batch No. : MMDSL QC-0015
Date of Mfg. : Oct-2023

Sample Quantity Received : 100.00 Tablets
Sample Registration Date : 20/11/2023
Sample Submitted/Drawn by : Client
Batch Size : N/A
Date of Expiry : Sep-2025

**SAMPLE ANALYSIS DETAILS**

Analysis Starting Date : 21/11/2023
Analysis Completion Date : 23/11/2023

### TEST RESULT

| SL No. | TEST PARAMETER | TESTING / REF. PROCEDURE | LABEL CLAIM | UOM | ACCEPTANCE LIMIT | RESULTS |
|---|---|---|---|---|---|---|
| 1 | Description | Indian Pharmacopoeia 2022 | - | — | White colour biconvex caplet shaped uncoated tablet having breakline in one side and plain on other side. | White colour biconvex caplet shaped uncoated tablet having breakline in one side and plain on other side. |
| 2 | Identification A | Indian Pharmacopoeia 2022 | - | — | The IR spectrum obtained with the sample should concordant with the reference spectrum of metformin HCL | The IR spectrum obtained with the sampleis concordant with the reference spectrum of metformin HCL |

[redacted]

[redacted]

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** : [redacted]
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**PAGE NO** : 2 of 3

**TEST RESULT**

| SL No. | TEST PARAMETER | TESTING / REF. PROCEDURE | LABEL CLAIM | UOM | ACCEPTANCE LIMIT | RESULTS |
|---|---|---|---|---|---|---|
| 3 | Identification B | Indian Pharmacopoeia 2022 | - | — | An orange-red colour should produced which darkens on keeping | An orange-red colour produced which darkens on keeping |
| 4 | Identification C | Indian Pharmacopoeia 2022 | - | — | A curdy white ppt should formed which should not soluble in HNO3 but soluble in dilute ammonia solution. | A curdy white pptis formed which insoluble in HNO3 but soluble in dilute ammonia solution. |
| 5 | Uniformity of weight | Indian Pharmacopoeia 2022 | - | % | (±)5.0 | Avg wt : 751.67 mg , (-) Dev : 1.03 , (+) Dev : 2.02 |
| 6 | Disintigration | Indian Pharmacopoeia 2022 | - | Min./Sec. | NMT 15 Minutes | Min : 02 Min 25 Sec , Max : 03 Min 12 Sec |
| 7 | Dissolution | Indian Pharmacopoeia 2022 | 500 mg/Tab | % of L.C. | NLT 75.0 | Avg : 89.11 , Max : 90.54 , Min : 88.19 |
| 8 | Assay | Indian Pharmacopoeia 2022 | 500 mg/Tab | % of L.C. | 475.0 - 525.0 mg/Tab i.e. 95.0 - 105.0 | 486.75 mg/Tab i.e. 97.34 |
| 9 | Related Substances | Indian Pharmacopoeia 2022 | - | % | Dicyandiamide impurity : NMT 0.02 ,Any other impurities : NMT 0.1 | Dicyandiamide impurity :0.0029, Any other impurities : Not detected |

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~~:

[redacted]

[redacted]

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/03656 |
| | **ISSUE DATE** | : | 23/11/2023 |
| | **CUSTOMER REFERENCE** | : | TRF |
| | **DATE** | : | 17/11/2023 |
| | **PAGE NO** | : | 3 of 3 |

**Date** : **23/11/2023**

**UOM** : **Unit of Measurement**

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

**Note** :

**-END OF THE TEST REPORT-**

[redacted]