



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 :<br>Meghalayan Medical Drugs And Services Limited<br>New colony shillong, DHS, Iaitumkhrah, Office of the mission<br>director, NHM, Shillong, East Khasi Hills Meghalaya, 793003<br>Shillong - 793003<br>MFG. LICENCE No : | REPORT NO : EFRAC/2023/DRG/RG/03243<br>ISSUE DATE : 17/10/2023<br>CUSTOMER REFERENCE : Mail<br>DATE : 28/09/2023<br>PAGE NO : 1 of 3 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|

**SAMPLE DETAILS**

|                                           |                                           |
|-------------------------------------------|-------------------------------------------|
| <b>SAMPLE REGISTRATION DETAILS</b>        |                                           |
| Sample Name : Cap Nifedipine 5mg          | Sample Quantity Received : 80.00 Capsules |
|                                           | Sample Registration Date : 09/10/2023     |
|                                           | Sample Submitted/Drawn by : Client        |
|                                           | Batch Size : N/A                          |
|                                           | Date of Expiry : Jun-2025                 |
| Sample Receipt Date : 28/09/2023          |                                           |
| Registration No : EFRAC/2023/DRG/RG/03243 |                                           |
| Name of Manufacturer : N/A                |                                           |
| Batch No. : MMDSL/QC-0001                 |                                           |
| Date of Mfg. : Jul-2023                   |                                           |
| <b>SAMPLE ANALYSIS DETAILS</b>            |                                           |
| Analysis Starting Date : 17/10/2023       | Analysis Completion Date : 17/10/2023     |

**TEST RESULT**

| SL No. | TEST PARAMETER | TESTING / REF. PROCEDURE | LABEL CLAIM | UOM | ACCEPTANCE LIMIT | RESULTS |
|--------|----------------|--------------------------|-------------|-----|------------------|---------|
|--------|----------------|--------------------------|-------------|-----|------------------|---------|





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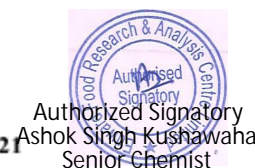
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|--------------------------------------------------------------------------------------------------------------------------|----------------------|-------------------------|
| ISSUED TO :                                                                                                              | REPORT NO :          | EFRAC/2023/DRG/RG/03243 |
| Meghalayan Medical Drugs And Services Limited                                                                            | ISSUE DATE :         | 17/10/2023              |
| New colony shillong, DHS, Iaitumkhrah, Office of the mission director, NHM, Shillong, East Khasi Hills Meghalaya, 793003 | CUSTOMER REFERENCE : | Mail                    |
| Shillong - 793003                                                                                                        | DATE :               | 28/09/2023              |
| MFG. LICENCE No :                                                                                                        | PAGE NO :            | 2 of 3                  |

**TEST RESULT**

| SL No. | TEST PARAMETER           | TESTING / REF. PROCEDURE  | LABEL CLAIM | UOM       | ACCEPTANCE LIMIT                                                                                                                                                                                                                                                                                                                           | RESULTS                                                                                                                                                                                                                                                                                                                              |
|--------|--------------------------|---------------------------|-------------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1      | Identification           | Indian Pharmacopoeia 2022 | -           | -         | In the chromatogram obtained with the test solution the principal band appearing as a compact light orange band against a yellow background should correspond to that in the chromatogram obtained with reference solution (a). The band obtained with reference solution (b) appears as a single band under both visualisation procedure. | In the chromatogram obtained with the test solution the principal band appearing as a compact light orange band against a yellow background corresponds to that in the chromatogram obtained with reference solution (a). The band obtained with reference solution (b) appears as a single band under both visualisation procedure. |
| 2      | Disintegration test      | Indian Pharmacopoeia 2022 | -           | Min./Sec. | NMT 30 Minutes                                                                                                                                                                                                                                                                                                                             | Min : 11 Min 43 Sec ,<br>Max : 12 Min 15 Sec                                                                                                                                                                                                                                                                                         |
| 3      | Dissolution Test         | Indian Pharmacopoeia 2022 | 5 mg/Cap    | % of L.C. | NLT 75.0                                                                                                                                                                                                                                                                                                                                   | Avg : 96.28 , Min :<br>90.10 , Max : 100.03                                                                                                                                                                                                                                                                                          |
| 4      | Uniformity of the weight | Indian Pharmacopoeia 2022 | -           | %         | (±) 7.5                                                                                                                                                                                                                                                                                                                                    | Avg wt : 271.08 mg ,<br>(-) Dev : 4.7 , (+)<br>Dev : 4.4                                                                                                                                                                                                                                                                             |
| 5      | Assay                    | Indian Pharmacopoeia 2022 | 5 mg/Cap    | % of L.C. | 4.5 to 5.5 mg/Cap<br>i.e. 90.0 - 110.0                                                                                                                                                                                                                                                                                                     | 4.97 mg/Cap i.e.<br>99.37                                                                                                                                                                                                                                                                                                            |





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| director, NHM, Shillong, East Khasi Hills Meghalaya, 793003  | DATE               | : 28/09/2023              |
| Shillong - 793003                                            | PAGE NO            | : 3 of 3                  |
| MFG. LICENCE No :                                            |                    |                           |

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:

Date : 17/10/2023

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 : *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-**



Authorized Signatory  
Ashok Singh Kushawaha  
Senior Chemist