

|   |                                 |                  |
|---|---------------------------------|------------------|
| <b>Issued To</b><br>MEGHALAYAN MEDICAL DRUGS AND SERVICES LIMITED<br>NEW COLONY SHILLONG, DHS, LAITUMKHRAH, OFFICE OF THE<br>MISSION DIRECTOR,NHM, Shillong, East Khasi Hills<br>Shillong,793003<br>Meghalaya,India | <b>Report No.</b>               | : [REDACTED]     |
|   | <b>Report Release Date</b>      | : 12/06/2024     |
|   | <b>Revision No.</b>             | : Not Applicable |
|   | <b>Revision Dated</b>           | : Not Applicable |
|   | <b>Sample Registration No.</b>  | : [REDACTED]     |
|   | <b>Sample Registration Date</b> | : [REDACTED]     |
|   | <b>Customer Reference No.</b>   | : Letter         |

| SAMPLE PARTICULARS                          |   |
|---|---|
| <b>Name of Sample<sup>#</sup></b>           | : Azithromycin Tablet 500 mg                    |
| <b>Submitted By<sup>#</sup></b>             | : MEGHALAYAN MEDICAL DRUGS AND SERVICES LIMITED |
| <b>Supplied By<sup>#</sup></b>              | : NA  |
| <b>Manufactured By<sup>#</sup></b>          | : NA  |
| <b>Batch No.<sup>#</sup></b>                | : QC/MMDSL Code MMDSL/QC-0236                   |
| <b>Batch Size<sup>#</sup></b>               | : NA  |
| <b>Pack Size<sup>#</sup></b>                | : Not Specified                                 |
| <b>Sample Quantity</b>                      | : 80 Tablets                                    |
| <b>Date of Manufacture<sup>#</sup></b>      | : 02-2024                                       |
| <b>Date of Expiry<sup>#</sup></b>           | : 01-2026                                       |
| <b>Manufacture Licence No.<sup>#</sup></b>  | : NA  |
| <b>Sample Received On</b>                   | : 22/05/2024                                    |
| <b>Sample Storage Condition<sup>#</sup></b> | : Ambient                                       |
| <b>Sample Condition</b>                     | : Good  |
| <b>Packaging Details<sup>#</sup></b>        | : Packed in original packing                    |
| <b>Any Other Information<sup>#</sup></b>    | : Not Specified                                 |

|  |              |
|--|--------------|
| <b>Reference To Protocol<sup>#</sup></b> | : IP         |
| <b>Analysis Started On</b>               | : 03/06/2024 |
| <b>Analysis Completed On</b>             | : 12/06/2024 |

| DESCRIPTION OF SAMPLE  |
|--|
| <b>Observations</b> : White coloured elongated biconvex film coated tablets having scored on one side and plain on other side. |
| <b>Requirements</b> : -  |

| S.No. | Test Parameters  | Limits  | Results                            | Method |
|-------|--|---|------------------------------------|--------|
| 1     | Identification   | The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution | Complies                           | IP     |
| 2     | Average Weight   | For information   | 705.26 mg                          | IP     |
| 3     | Uniformity of Weight   | ±5% of average weight   | Min -1.47% Max 3.59%               | IP     |
| 4     | Related Substances   | -   | -                                  | -      |
| 5     | Any Secondary Peak Eluting with an Relative Retention Time of about 1.3 due to Azihtromycin Impurity-B | NMT 2.00%   | Not detected                       | IP     |
| 6     | Sum of all the other secondary peaks   | NMT 3.00%   | 0.41%                              | IP     |
| 7     | Dissolution  | NLT 75% + 'Q' of the stated amount of Azithromycin(NLT 80%)   | Min-102.8%, Max-108.7%, Avg-105.7% | IP     |
| 8     | Disintegration Time  | NMT 15 Minutes  | 6 Minute 10 Second                 | IP     |

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|---|--|

| Each Uncoated Tablet Contains |  |        |               |          |        |
|-------------------------------|--|--------|---------------|----------|--------|
| S.No.                         | Assay Parameters                                 | Claim  | Limits        | Results  | Method |
| 1                             | Azithromycin IP eq. to Anhydrous<br>Azithromycin | 500 mg | 450 mg-550 mg | 496.6 mg | IP     |

**Symbol/s** : # Information provided by customer

**Abbreviation** : Protocol:Pharmacopeia"s Reference/BIS/Specs or STP No.

**Remarks** : In the opinion of the undersigned,the sample referred above is of standard quality as defined in the Drugs & Cosmetics Act 1940 & the rules made their under for the reasons given below.

\*\*\*\*\*End of Report\*\*\*\*\*