

Sample Name AMOXYCILLIN ORAL SUSPENSION-IP.250mg./5ml. **Mfg Lic No** [REDACTED]
Submitted By Quality Control Advisor. (MMDSL) Shillong. **Report No** [REDACTED]
Address DHS LaitumkhranhNM, EastKhasi Hills Meghalaya. **Receipt Date** 21-Aug-24
Mfg By N.S. **Report Date** 19-Sep-24
Supplied By N.S. **Ref No** N.S.
Batch No MMDSL/QC-0429 **Mfg. Date** 06/2024 **Exp Date** 11/2025 **Batch Size** N.S. **Sample Qty** 12 BOTTLES.

TEST RESULTS

Date / Period of Performance of test 21/08/2024 to 19/09/2024.

Reference to protocol :- I.P-2022.

Description :- White powder filled in white plastic bottles which gives orange coloured suspension upon reconstitution with water.

Identification (by HPLC) :- Complies.

| | | | | | |
|--|--|---------------|---------------|---------------|------------|
| | | Limit | | | |
| | | Lower | Upper | | |
| pH | :- 6.08 | 5.0 | 7.5 | | |
| (Of reconstituted suspension) | | | | | |
| Average net weight | :- 9.0869gm. | | | | |
| Uniformity of weight | :- Within limit. | | | | |
| Weight per ml. | :- 1.0843gm/ml. | | | | |
| Microbial contamination | :- | Limit | | | |
| Total aerobic viable count | :- Less than 10 cfu/gm | NMT 100cfu/gm | | | |
| Total fungal count | :- Less than 10 cfu/gm | NMT 10cfu/gm | | | |
| E.coli | :- Absent/gm | Absent/gm | | | |
| Assay (by HPLC) | :- Each 5ml of reconstituted suspension contains:- | | | | |
| | | Limit | | | |
| | | Lower | Upper | | |
| Content of Amoxicillin Trihydrate eq. to Amoxicillin | Obtained :- 248.08mg | Claim 250.0mg | Lower 225.0mg | Upper 300.0mg | Method IP. |

NOTE:- SAMPLE CONSUMED IN TESTING.

Report: In Opinion of the undersigned, The sample is as defined in the Act and the rules made there under per IP. with respect above test only.

