Sample Name AMOXYCILLIN ORAL SUSPENSION-IP.250mg./5ml. Submitted By Quality Control Advisor. (MMDSL) Shillong. DHS LaitumkhrahNHM, EastKhasi Hills Meghalaya. Address

Mfg Lic No Report No

N.S. Mfg By

Receipt Date 21-Aug-24 Report Date 19-Sep-24 N.S.

Supplied By N.S.

Ref No

Batch No MMDSL/QC-0427 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 5.0

Upper 7.5

:- 6.13

(Of reconstituted suspension)

Average net weight

:- 9.0775gm.

Uniformity of weight Weight per ml.

:- Within limit. :- 1.0832 gm/ml.

Microbial contamination

:-

Limit

Total aerobic viable count :- Less than 10 cfu/gm Total fungal count

:- Less than 10 cfu/gm

NMT 100cfu/gm NMT 10cfu/gm

E.coli

:- Absent/gm

Absent/gm

Assay (by HPLC)

:- Each 5ml of reconstituted suspension contains:

Limit

Content of

Obtained

Claim

Lower

Upper

Method

Amoxycillin Trihydrate eq. to Amoxycillin

:- 248.37mg

250.0mg

225.0mg

300.0mg

IP.

NOTE: - SAMPLE CONSUMED IN TESTING.

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