



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: Meghalayan Medical Drugs And Services Limited **REPORT NO**

: EFRAC/2023/DRG/RG/03659

New colony shillong, DHS, laitumkhrah, Office of the mission

ISSUE DATE : 12/12/2023

director, NHM, Shillong, East Khasi Hills Meghalaya, 793003

CUSTOMER REFERENCE : TRF

DATE : 17/11/2023

Shillong CENCENO:

PAGE NO : 1 of 2

SAMPLE DETAILS

SAMPLE REGISTRATION DETAILS

: Amoxyucillin Syrup 125mg + Sample Name

Sample Quantity Received

: 7.00 Bottle

potassium Clavulanate 31.25mg

Sample Registration Date

: 20/11/2023

Sample Submitted/Drawn by

: Client

Batch Size Date of Expiry : N/A

: Dec-2024

Sample Receipt Date Registration No

: 17/11/2023

: EFRAC/2023/DRG/RG/03659

Name of Manufacturer

Batch No.

: MMDSL QC-0021

: Jul-2023

Date of Mfg.

SAMPLE ANALYSIS DETAILS

Analysis Starting Date : 30/11/2023 **Analysis Completion Date**

: 07/12/2023

| TEST RESULT | | | | | | | | | | | |
|-------------|----------------|---------------------------|-------------|-----|-----------------------|-----------------------|--|--|--|--|--|
| SL No. | TEST PARAMETER | TESTING / REF. PROCEDURE | LABEL CLAIM | UOM | ACCEPTANCE LIMIT | RESULTS | | | | | |
| 1 | Description | Indian Pharmacopoeia 2022 | | _ | Off white colour | Off white colour | | | | | |
| | | | | | powder. | powder. | | | | | |
| 2 | Identification | Indian Pharmacopoeia 2022 | | _ | In the assay , the | In the assay , the | | | | | |
| | | | | | retention time of the | retention time of the | | | | | |
| | | | | | two principal peaks | two principal peaks | | | | | |
| | | | | | in the | in the | | | | | |
| | | | | | chromatogram | chromatogram | | | | | |
| | | | | | obtained with the | obtained with the | | | | | |
| | | | | | test solution should | test solution | | | | | |
| | | | | | correspond to those | corresponds to | | | | | |
| | | | | | in the | those in the | | | | | |
| | | | | | chromatogram | chromatogram | | | | | |
| | | | | | obtained with the | obtained with the | | | | | |
| | | | | | reference solution. | reference solution. | | | | | |









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Shillong C793003 PAGE NO : 2 of 2

TEST RESULT

| SL No. | TEST PARAMETER | TESTING / REF. PROCEDURE | LABEL CLAIM | UOM | ACCEPTANCE LIMIT | RESULTS |
|--------|----------------|---------------------------|-------------|-----------|--|--|
| 3 | рН | Indian Pharmacopoeia 2022 | | 7- | 3.8 - 6.6 | 5.3 |
| 4 | Water | Indian Pharmacopoeia 2022 | | % | NMT 7.5 | 6.6843 |
| 5 | Assay | Indian Pharmacopoeia 2022 | 6 | % of L.C. | Amoxycillin: 90.0 to 120.0,Potassium Clavulanate: 90.0 to 125.0 | Amoxycillin: 98.38 , Potassium Clavulanate : 98.88 |

In the opinion of the undersigned, the Sample referred to above <u>is of Standard Quality</u> / <u>is not of Standard Quality</u> as defined in the Act or the Rules made there under for the reasons given below:

Date : 12/12/2023

UOM : Unit of Measurement

REMARKS : The sample is tested as per test procedure shared by client and Opinion on Quality is drawn against the result obtained for

tested parameter only

Note :

-END OF THE TEST REPORT-



