

[REDACTED]

Dtd. Shillong, the 6th Sept., 2023

[REDACTED]

Dt. Shillong, the 04.08.23

Sir/Madam,

Kindly find herewith the analytical report of the following Survey Sample of Drugs. This has a reference to the letter cited above.

The details of the report are also enclosed for necessary.

Registration No.	Name of samples	Manufacturer	Batch No.	Mfg. Date	Exp. Date
[REDACTED]	Maxclave 156.25 mg	[REDACTED]	23BS174	07/23	12/24
[REDACTED]	Maxclave 156.25 mg	[REDACTED]	23BS173	07/23	12/24
[REDACTED]	Maxmo	[REDACTED]	23BS175	07/23	06/24

[REDACTED]

Dtd. Shillong, the 6th Sept., 2023

Copy to:

1. [REDACTED]
 2. Managing Director, MMDSL, Department of Health & Family Welfare, DHS Complex, Laitumkhrach, Shillong.
- [REDACTED]

Name of the sample and content:

MAXCLAVE 156.25mg

Each 5ml of Reconstituted Suspension contains:

Amoxicillin Trihydrate IP

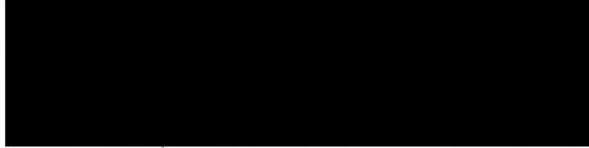
Eq. to Amoxicillin.....125mg

Potassium Clavulanate IP

Equivalent to Clavulanate Acid.....31.25mg

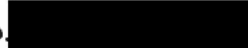
Excipients..... q.s.

Manufacturer's name & address:



Date received: 07.08.2023

REGISTRATION No.



Batch No. 23BS174

Mfg. Date 07/23

Exp. Date 12/24

Permitted
Limits

Description: Fine micro-crystalline amorphous powder, off-white light in colour with an unpleasant odour.

Uniformity of Weights: Conform to specifications prescribed in IP.

Weight/ml: Conform to specifications prescribed in IP.

pH = 7.2

3.8-6.6

Identification Test: Conform to specifications prescribed in IP.

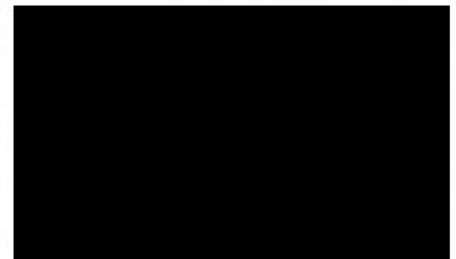
ASSAY:

- | | |
|--------------------------------------------------------------------|---------|
| 1. <u>Amoxicillin</u> : % Content of active component = 98.6% | 90-120% |
| 2. <u>Clavulanic Acid</u> : % Content of active component = 161.9% | 90-125% |

Stability Test:

- | | |
|--------------------------------------------------------------------|-------|
| 1. <u>Amoxicillin</u> : % Content of active component = 86.7% | > 80% |
| 2. <u>Clavulanic Acid</u> : % Content of active component = 119.6% | > 80% |

REMARKS: SAMPLE PASSED THE TESTS PERFORMED EXCEPT THAT THE CONCENTRATION OF CLAVULANIC ACID IS TOO HIGH AND CROSSES THE PERMISSABLE LIMIT CLAIMED BY IP



Dated: Shillong

The 6/9/23

Name of the sample and content:

MAXCLAVE 156.25mg

Each 5ml of Reconstituted Suspension contains:

Amoxicillin Trihydrate IP

Eq. to Amoxicillin.....125mg

Potassium Clavulanate IP

Equivalent to Clavulanate Acid.....31.25mg

Excipients..... q.s.

Manufacturer's name & address:



Date received: 07.08.2023

REGISTRATION No.



Batch No. 23BS173

Mfg. Date 07/23

Exp. Date 12/24

Permitted
Limits

Description: Fine micro-crystalline amorphous powder, off-white light in colour with an unpleasant odour.

Uniformity of Weights: Conform to specifications prescribed in IP.

Weight/ml: Conform to specifications prescribed in IP.

pH = 7.2

3.8-6.6

Identification Test: Conform to specifications prescribed in IP.

ASSAY:

- | | |
|-------------------------------------------------------------------|---------|
| 1. <u>Amoxicillin:</u> % Content of active component = 97.8% | 90-120% |
| 2. <u>Clavulanic Acid:</u> % Content of active component = 142.1% | 90-125% |

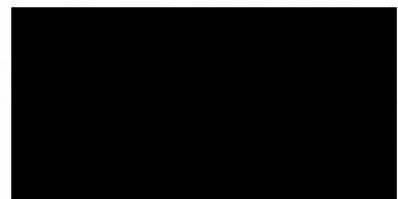
Stability Test:

- | | |
|-------------------------------------------------------------------|-------|
| 1. <u>Amoxicillin:</u> % Content of active component = 93.3% | > 80% |
| 2. <u>Clavulanic Acid:</u> % Content of active component = 123.1% | > 80% |

REMARKS: SAMPLE PASSED THE TESTS PERFORMED EXCEPT THAT THE CONCENTRATION OF CLAVULANIC ACID IS TOO HIGH AND CROSSES THE PERMISSABLE LIMIT AS CLAIMED BY IP

Dated: Shillong

The 6/9/23



501111
5.1020
Name of the sample and content:

MAXMO

Each 5ml of reconstituted suspension contains:
Amoxicillin Trihydrate IP
Eq.to Amoxicillin.....125mg
Colour: Sunset Yellow FCF

Manufacturer's name & address:



Date received: 07.08.2023

REGISTRATION No.



Batch No. 23BS175

Mfg. Date 07/23

Exp. Date 06/24

Permitted
Limits

Description: Micro crystalline powder, white in colour. When reconstituted the suspension becomes orange in colour.

Uniformity of Weights: Conform to specifications prescribed in IP.

Weight/ml: Conform to specifications prescribed in IP.

pH = 6.5

5.0-7.5

Identification Test: Conform to specifications prescribed in IP.

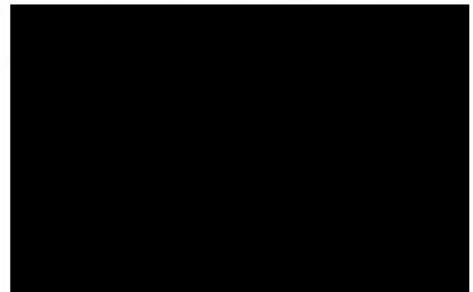
ASSAY: % Content of active component = 85.6%

90-120%

Stability tests: % Content of active component = 81.2%

> 80%

REMARKS: **SAMPLE FAILED IN THE ASSAY**



Dated: Shillong

The 6/9/23