FORM 39A |(SEE RULE 150 E (f) UNDER THE DRUGS & COSMETICS ACT 1940 & RULES THEREUNDER)

Generic Name : Amoxycillin and Potassium Clavulanate Tablets IP
Sample Name : Amoxycillin and Potassium Clavulanate Tablets 500mg+125mg
Submitted By : **M/s Meghalayan Medical Drugs and Services Limited (MMDSL)**
New Colony Shillong,DHS Laitumkhrah, Office of the Managing Director, MMDSL East Khasi Hills District Meghalaya Shillong (Assam) 793003 District Meghalaya Shillong (Assam) 793003
Mfd. By : NS
Supplied By : NS
Ref.No. : NS

Format No : [redacted]
Mfg. Lic.No. : [redacted]
Report No. : [redacted]
Date of Receipt : 18/04/2024
Report Date : 01/05/2024
Period of Analysis : 18/04/2024-01/05/2024
Stability Condition :

Batch No.	Mfg. Date	Exp. Date	Batch Size	Sample Qty.
MMDSL/QC-0197	02/2024	07/2025	NS	60 Tablets

RESULTS OF ANALYSIS

Reference to protocol	IP-2022	
Description	White elongated biconvex film coated tablet having scored on one side.	
Test Parameters	**Results**	**Limit**
Identification (by HPLC)	Complies	To Comply
Average weight	1100.90mg	
Uniformity of weight	-4.77 to +2.81%	±5.0%
Uniformity of Content (by HPLC)		
For Potassium Clavulanate Eq. to Clavulanic Acid	0.01	NMT 15.0
Disintegration time	13 to 14 Minutes	NMT 30 Minutes
Dissolution (by HPLC)		
For Amoxycillin Trihydrate Eq. to Amoxycillin	95.8 to 95.9% (Avg.95.9%)	NLT 85.0% (Q)
For Potassium Clavulanate Eq. to Clavulanic Acid	91.2 to 91.3% (Avg.91.2%)	NLT 80.0% (Q)
Water	5.12%w/w	NMT 10.0% w/w
Assay (by HPLC)	Each film coated tablet contains.	

Particulars	Result	Claim	Lower	Upper	Method

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Sample Name : Amoxycillin and Potassium Clavulanate Tablets 500mg+125mg

Submitted By : **M/s Meghalayan Medical Drugs and Services Limited (MMDSL)**
New Colony Shillong,DHS Laitumkhrah, Office of the Managing Director, MMDSL East Khasi Hills District Meghalaya Shillong (Assam) 793003 District Meghalaya Shillong (Assam) 793003

Mfd. By : NS

Supplied By : NS

Ref.No. : NS

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Date of Receipt : 18/04/2024

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Stability Condition :

Batch No.	Mfg. Date	Exp. Date	Batch Size	Sample Qty.
MMDSL/QC-0197	02/2024	07/2025	NS	60 Tablets

RESULTS OF ANALYSIS

		Claim	Lower	Upper	Method
Amoxycillin Trihydrate eq. to Amoxycillin	510.41mg	500.00 mg	450.00 mg	600.00 mg	IP
Potassium Clavulanate eq. to Clavulanic Acid	124.30mg	125.00 mg	112.5 mg	150.00 mg	IP

End of Report

Remark:In the opinion of the undersigned the sample referred to above is of STANDARD QUALITY as defined in the Act

[redacted]