

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

Generic Name :	Amoxicillin and Potassium Clavulanate Tablets IP	Format No :		
Sample Name :	Amoxicillin and Potassium Clavulanate Tablets 500mg+125mg	Mfg. Lic.No. :		
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	Report No. :		
Mfd. By :	NS	Date of Receipt :	18/04/2024	
Supplied By :	NS	Report Date :	01/05/2024	
Ref.No. :	NS	Period of Analysis :	18/04/2024-01/05/2024	
		Stability Condition :		
Batch No.	Mfg. Date	Exp. Date	Batch Size	Sample Qty.
MMDSL/QC-0195	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	1098.48mg				
Uniformity of weight	-4.50 to +2.87%	±5.0%			
Uniformity of Content (by HPLC)					
For Potassium Clavulanate Eq. to Clavulanic Acid	0.00	NMT 15.0			
Disintegration time	12 to 13 Minutes	NMT 30 minutes			
Dissolution (by HPLC)					
For Amoxicillin Trihydrate Eq. to Amoxicillin	95.8 to 96.0% (Avg.95.9%)	NLT 85.0% (Q)			
For Potassium Clavulanate Eq. to Clavulanic Acid	91.2 to 91.4% (Avg.91.3%)	NLT 80.0% (Q)			
Water	4.81%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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Generic Name : Amoxicillin and Potassium Clavulanate Tablets IP

Sample Name : Amoxicillin 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

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Stability Condition :

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MMDSL/QC-0195	02/2024	07/2025	NS	60 Tablets

RESULTS OF ANALYSIS

		<u>Claim</u>	<u>Lower</u>	<u>Upper</u>	<u>Method</u>
Amoxicillin Trihydrate eq. to Amoxicillin	510.34mg	500.00 mg	450.00 mg	600.00 mg	IP
Potassium Clavulanate eq. to Clavulanic Acid	124.20mg	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