

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

Generic Name : Clobazam Tablets IP
 Sample Name : Clobazam Tablets IP 10mg

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 : ██████████
 Mfg. Lic.No. : ██████████
 Report No. : ██████████
 Date of Receipt : 12/06/2024
 Report Date : 18/06/2024
 Period of Analysis : 12/06/2024-18/06/2024
 Stability Condition :

Batch No.	Mfg. Date	Exp. Date	Batch Size	Sample Qty.
MMDSL/QC-0318	04/2024	03/2026	NS	100 Tablets

RESULTS OF ANALYSIS

Reference to Protocol	I.P.-2022			
Description	White round flat uncoated tablets having scored on one side			
Test Parameters	Results	Limit		
Identification :				
(A) by IR	Complies	-		
(B) by HPLC	Complies	-		
Average weight	132.38 mg	-		
Uniformity of weight	-2.49% to +2.21%	±7.5%		
Uniformity of content (by HPLC)				
For Clobazam	3.16	NMT 15.0		
Related Substances (by HPLC)				
Clobazam Impurity A	Not detected	NMT 0.5%		
Any secondary peak	0.0029%	NMT 0.2%		
Sum of all secondary peak	0.0037%	NMT 1.0%		
Dissolution (by HPLC)				
For Clobazam	98.5% to 100.6% (Avg. 99.6%)	NLT 75.0% (Q)		
Assay (by HPLC)	Each uncoated tablet contains:			
<u>Particulars</u>	<u>Result</u>	<u>Claim</u>	<u>Lower</u>	<u>Upper</u>
				<u>Method</u>

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Format No : [REDACTED]
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RESULTS OF ANALYSIS

		<u>Claim</u>	<u>Lower</u>	<u>Upper</u>	<u>Method</u>
Clobazam IP	10.06 mg	10.0 mg	9.5 mg	10.5 mg	IP-2022

End of Report

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