


Dr. Reddy's Laboratories Ltd. Chemical Technical operations-Unit I Plot No. 137, 138, 145 & 146 Sri Venkateswara Co-operative Industrial Estate, Bollaram, Jinnaram Mandal, Sangareddy District, Telangana-502325.			
CERTIFICATE OF ANALYSIS			
Product Name: Lomustine Ph.Eur			
Batch No.	AJQH001562	Customer Name	Metapharmaceutical Industrial SL
Batch Quantity	3.496 KG	Date of Manufacture	05-01-2024
A.R. No.	1001FP25001136	Expiry date	04-01-2028
Reference	Ph.Eur	Date Of Analysis	10-05-2025
Storage condition	Store in tightly closed container at 2-8°C temperature, protected from light	Specification No.	SP-CTO10-000167 (Version : 3.0)

S. No.	TEST	SPECIFICATION	RESULT
1	Appearance	Yellow crystalline powder	Yellow crystalline powder
2	Solubility		
2.1	Solubility in water	Practically insoluble in water	Complies
2.2	Solubility in acetone	Freely soluble in acetone	Complies
2.3	Solubility in Methylene chloride	Freely soluble in Methylene chloride	Complies
2.4	Solubility in alcohol	Soluble in alcohol	Complies
3	Identification by IR	To match with standard spectrum	Complies
4	Related substances by HPLC		
4.1	Unspecified Impurities	Not more than 0.10 %	0.03 %
4.2	Total Impurities	Not more than 0.2 %	0.07 %
5	Chlorides	Not more than 500 ppm	Less than 500 ppm
6	Loss on Drying	Not more than 1.0 %w/w	0.11 %w/w
7	Assay on dried basis	Not less than 99.0 %w/w and not more than 101.0 %w/w	99.4 %w/w
8	Formic acid content by HPLC	Not more than 5000 ppm	35 ppm
9	Residual solvents by GCHS		
9.1	Methanol	Not more than 3000 ppm	Less than LOQ (44.9 ppm)
9.2	Acetone	Not more than 5000 ppm	210 ppm
9.3	Dichloromethane	Not more than 600 ppm	Not Detected
9.4	Toluene	Not more than 890 ppm	Below limit of detection (0.7 ppm)
10	N-Nitrosodicyclohexylamine (NDCHA) content by LCMS	Not more than 0.113 ppm	Not Detected

Additional Comments if Any: --

METAPHARMACEUTICAL

N DE LOTE:

0290625

Signature
25/06/2025

Remarks: APPROVED (Sample Conforms to above Specification)		
Prepared By	Reviewed By	Approved By
G S V N.PUNNARAO(Team Leader)	Bhimireddy.Jaya bharath reddy(Team Leader)	Manoj Kumar.Sharma(Head of Department)
15-05-2025 19:30	15-05-2025 19:34	15-05-2025 20:17
Printed by: Rakesh.Bhupathi		Printed on: 16-05-2025 23:33
Copy No.: 2		Page No.: 1 of 1
Note : This document has been generated electronically and is valid without signature.		
CNo.: C250001051		