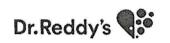
Dr. Reddy's Laboratories Ltd.
Chemical Technical operations-Unit I
Plot No. 137, 138, 145 & 146
Sri Venkateswara Co-operative Industrial Estate,
Bollaram, Jinnaram Mandal, Sangareddy District,
Telangana-502325.



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	Freely soluble in Methylene chloride	Complies	
	chloride			
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	Not more than 0.113 ppm	Not Detected	
	(NDCHA) content by LCMS			

Additional Comments if Any: --

METAPHARMACEUTICAL

N DE LOTE:

28/06/225

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)
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