

METAPHARMACEUTICAL

19/12/2022

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.

N DE LOTE:

0030122

Dr.Reddy's



CERTIFICATE OF ANALYSIS

Product Name: Lomustine Ph.Eur

Batch No.	AJNH002099	Customer Name	Galenicum
Batch Quantity	3.261 KG	Date of Manufacture	03-01-2021
A.R. No.	1001FP22003131	Expiry date	02-01-2025
Reference	Ph.Eur	Date Of Analysis	29-09-2022
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 %	0.04 %
4.2	Total Impurities	Not more than 0.2 %	0.05 %
5	Chlorides	Not more than 500 ppm	Less than 500 ppm
6	Loss on Drying	Not more than 1.0 %w/w	0.21 %w/w
7	Assay on dried basis	Not less than 99.0 %w/w and not more than 101.0 %w/w	100.1 %w/w
8	Formic acid content by HPLC	Not more than 5000 ppm	Not Detected
9	Residual solvents by GCHS		
9.1	Methanol	Not more than 3000 ppm	Below limit of detection (14.8 ppm)
9.2	Acetone	Not more than 5000 ppm	119 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	Below limit of detection (0.0037 %)

Additional Comments if Any: -

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)	Suresh.Kotapati(Team Leader)
13-10-2022 13:10	13-10-2022 13:36	13-10-2022 16:38
Printed by: Dattatraya.Shinde	Printed on: 14-10-2022 09:35	
Copy No.: 1	Page No.: 1 of 1	
Note : This document has been generated electronically and is valid without signature.		
CNo.: C220002909		