

Location : CTO HPAI-Unit I

Dr.Reddy's 

Factory : Plot No.137,138,145 & 146, S V.Co-op Industrial estate, Bollaram village ,Jinnaram mandal, Sangareddy District.,
Telangana State.,INDIA-502325 Phone No : 08458-280600 & Fax Number : 08458-279623

CERTIFICATE OF ANALYSIS

Product : Lomustine Ph.Eur.		Customer Name : Customer Name : Galenicum Health SLU	
Batch No.: AJNH001396		Date of Manufacture : September 2020	
Batch Quantity : 3.518 Kg		Expiry : August 2024	
Analytical Report No: 1001FP20004276		Date of analysis : 07.10.2020	
Reference : Ph.Eur.		Specification No.: S-08-LSM3-Ph.Eur/04	
Storage : Store in a tightly closed container at 2-8°C temperature, protected from light.			
S.No.	Test	Result	Specification
1.0	Appearance	Yellow crystalline powder	Yellow crystalline powder
2.0	Solubility	Complies	Practically insoluble in water, freely soluble in acetone and methylene chloride, soluble in alcohol.
3.0	Identification by IR	Complies	To match with standard spectrum.
4.0	Related substances by HPLC		
4.1	Unspecified impurities	0.02%	Not more than 0.10%
4.2	Total impurities	0.07%	Not more than 0.2%
5.0	Chlorides	Less than 500 ppm	Not more than 500 ppm
6.0	Loss on drying	0.26 % w/w	Not more than 1.0% w/w
7.0	Assay on dried basis	100.0 % w/w	Not less than 99.0% and not more than 101.0% w/w
8.0	Formic acid content by HPLC	Not detected	Not more than 5000 ppm
9.0	Residual solvents by GC-MS		
9.1	Methanol	Not detected	Not more than 3000 ppm
9.2	Acetone	206 ppm	Not more than 5000 ppm
9.3	Dichloromethane	Not detected	Not more than 600 ppm
9.4	Toluene	Not detected	Not more than 890 ppm

Remark : The product CONFORMS to above specifications.

Compiled by : <i>P.S.S</i>	Checked by : <i>edg</i>	Approved by : <i>[Signature]</i>
Date : <i>17/12/2020</i>	Date : <i>17/12/2020</i>	Date : <i>17/12/2020</i>

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Dr. Reddy's Laboratories Ltd.
Chemical Tech Ops-Unit-I
Plot Nos. 137, 138, 145 & 146,
S.V. Co-operative Industrial Estate,
IDA, Bollaram, Jinnaram Mandal,
Sangareddy District,
Telangana - 502 325

Tel : 08458 280600 / 283200
Fax : 08458-279623
Email : mail@drreddys.com

Date: December 28, 2020

CERTIFICATE OF CONFORMANCE

To

M/s. Galenicum Health S.L.

We, **Dr. Reddy's Laboratories Limited, Chemical Tech Ops-Unit-1**, Plot No.137, 138,145 & 146, S.V.Co-operative Industrial Estate,IDA Bollaram, Jinnaram Mandal, Sangareddy District, Telangana -502325, manufacturer of Active pharmaceutical Ingredient **LOMUSTINE** herewith conform that below mentioned batches were manufactured as per the standard operating procedures, product specifications and in compliance with cGMP as well as applicable regulatory guidelines. No OOS/OOT & incidents were reported during the manufacturing of below batches.

S. No.	Batch No.	Date of manufacture
01	AJNH001396	September-2020

For Dr. Reddy's Laboratories Limited,

A handwritten signature in black ink, with the date '28/12/20' written below it.

Dattatraya A. Shinde.

Team Member, Quality Assurance.