

Date: 01/20/18

Location : CTO HPAI-Unit 1

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. : 08458283209

CERTIFICATE OF ANALYSIS

Product : Lomustine Ph.Eur.	Customer Name : Galenicum Health SL
Batch No.: AJLH000127	Date of Manufacture : January 2018
Batch Quantity : 3.365 Kg	Expiry : December 2021
Analytical Report No: 40001055096	Date of analysis : 30.01.2018
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	0.03%	Not more than 0.10%
4.2	Total impurities	0.03%	Not more than 0.2%
5.0	Chlorides	Less than 500 ppm	Not more than 500 ppm
6.0	Loss on drying	0.07% w/w	Not more than 1.0% w/w
7.0	Assay on dried basis	99.8% 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-HS		
9.1	Methanol	Not detected	Not more than 3000 ppm
9.2	Acetone	166 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>adw</i>	Checked by : <i>Vineet</i>	Approved by : <i>K. H. Reddy</i>
Date : 30/01/18	Date : 30/01/18	Date : 30/01/18