



TECHNICAL DATA SHEET

00095-TDS-ENG-2022

LOMUSTINE (EP)		
DESCRIPTION DCI: LOMUSTINE		DESCRIPTION DOE: LOMUSTINA
CAS N°: 13010-47-4	EC N°: 235-859-2	AEMPS CODE: 378A
MOL. WEIGHT: 233.70	MOL. FORMULA: C ₉ H ₁₆ CIN ₃ O ₂	ARTICLE CODE: 00095

ATTRIBUTES	SHOULD BE
Appearance	Yellow, crystalline powder
Solubility	Practically insoluble in water, freely soluble in acetone and in methylene chloride, soluble in ethanol (96 %)
Identification	Complies
Related substances	
Unspecified impurities	= < 0.10 %
Total impurities	= < 0.2 %
Chlorides	= < 500 ppm
Loss on drying	= < 1.0 %
Assay	99.0 - 101.0 %
Formic Acid	= < 5000 ppm
Residual solvents	
Methanol	= < 3000 ppm
Acetone	= < 5000 ppm
Methylene Chloride	= < 600 ppm
Toluene	= < 890 ppm

COMPLIES WITH

European Pharmacopoeia 10.0

STORAGE

Store in a tightly closed container between 2 - 8°C. Protect from direct light.

REMARKS

Lomustine is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.