METAPHARMACEUTICAL

TECHNICAL DATA SHEET

00095-TDS-ENG-2026

LOMUSTINA (EUR. PH.)		
DESCRIPTION DCI: lomustine	DESCRIPTION DOE: LOMUSTINA	
CAS Nº: 13010-47-4	EC Nº: 235-859-2	AEMPS CODE: 378A
MOL. WEIGHT: 233,70	MOL. FORMULA: C9H16ClN3O2	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 %

COMPLIES WITH

European Pharmacopoeia 12.2

STORAGE

Keep the container tightly closed, in a cool, dry place. Protected from air and 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.

Metapharmaceutical Industrial S.L.U. Josep Plà, 163 2º 5ª - 08020 BARCELONA - SPAIN - telf. 93 308 99 76 e-mail: info@metaph.es - www.metaph.es
Registro Mercantil de Barcelona, Tomo 9801, Libro 8942 de la sección 2ª, folio 179, hoja 112.120, inscripción 3ª - CIF. B-58736869