METAPHARMACEUTICAL IND SL
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LOMUSTINE (EUR. PH.)

PRODUCT CODE: 00095	CAS Nº: 13010-47-4	ANALYSIS Nº: 156/24	
MANUFACTURER BATCH:	AJQH001431	CERTIFICATE ID:	42.475
SUPPLIER BATCH:	----	MANUFACTURING DATE:	23/12/2023
METAPH BATCH:	0020624	EXPIRY DATE:	22/12/2027

ATTRIBUTES	SHOULD BE	IS
Appearance	Yellow, crystalline powder	Yellow crystalline powder
Solubility	Practically insoluble in water, freely soluble in acetone and in methylene chloride, soluble in ethanol (96 %)	Complies (*)
Identification	Complies	Complies
Related substances		
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.2 %	< 0.05 %
Chlorides	=< 500 ppm	< 500 ppm
Loss on drying	=< 1.0 %	0.1 %
Assay	99.0 - 101.0 %	100.5 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliances with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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

(*) Data adapted from the manufacturer's certificate of analysis.

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.

STORAGE

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

Analysis date: 14/06/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000908