



TECHNICAL DATA SHEET

151415-TDS-ENG-2024

TEMOZOLOMIDE (EUR. PH.)		
DESCRIPTION DCI: TEMOZOLOMIDE		DESCRIPTION DOE: TEMOZOLOMIDA
CAS Nº: 85622-93-1	EC Nº: 630-358-9	AEMPS CODE: 1065A
MOL. WEIGHT: 194,15	MOL. FORMULA: C ₆ H ₆ N ₆ O ₂	ARTICLE CODE: 151415

ATTRIBUTES	SHOULD BE
Appearance	White or slightly brown or slightly pink powder
Solubility	Sparingly soluble in water, soluble in dimethyl sulfoxide, very slightly soluble in ethanol (96 %), practically insoluble in toluene
Identification A	Complies
Identification B	Complies
Related substances	
Impurity D	=< 0.5 %
Impurity A (sum of the peaks)	=< 0.15 %
Impurity B	=< 0.15 %
Impurity E	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.8 %
Water	=< 0.4 %
Sulfated ash	=< 0.1 %
Assay	98.0 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Store at 2 - 8°C. Protect from light and moisture.

REMARKS

Temozolomide 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.