



TECHNICAL DATA SHEET

002684-TDS-ENG-2021

PRIMIDONA - EP		
DESCRIPTION DCI: PRIMIDONE		DESCRIPTION DOE: PRIMIDONA
CAS N°: 125-33-7	EC N°: 204-737-0	AEMPS CODE: ---
MOL. WEIGHT: 218.30	MOL. FORMULA: C ₁₂ H ₁₄ N ₂ O ₂	ARTICLE CODE: 002684

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Very slightly soluble in water, slightly soluble in ethanol (96 %). It dissolves in alkaline solutions
Identification	Complies
Related substances	
Unspecified impurities	= < 0.10 %
Total impurities	= < 0.3 %
Loss on drying	= < 0.5 %
Sulfated ash	= < 0.1 %
Assay	98.0 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 10.3

STORAGE

Store in well closed container. Protected from light.

REMARKS

Primidone 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.