

TECHNICAL DATA SHEET

002349-TDS-ENG-2026

PREGNENOLONA BASE		
DESCRIPTION DCI: PREGNENOLONE		DESCRIPTION DOE: PREGNENOLONA
CAS Nº: 145-13-1	EC Nº: 205-647-4	AEMPS CODE: ---
MOL. WEIGHT: 316,47	MOL. FORMULA: C21H32O2	ARTICLE CODE: 002349

ATTRIBUTES	SHOULD BE
Appearance	White or almost white crystalline powder
Melting point	185 - 194 °C
Identification	Complies
Specific optical rotation	+27 / +31
Loss on drying	=< 0.5 %
Related substances	
Any impurity	=< 0.5 %
Total impurities	=< 1.0 %
Assay	98.0 - 102.0 %
Residual solvents [In-house]	
Methanol	=< 3000 ppm
Ethanol	=< 5000 ppm
Methylene Chloride	=< 600 ppm
Microbiological control	
TAMC	=< 1000 CFU/g
TYMC	=< 100 CFU/g

COMPLIES WITH

Manufacturer Specifications

STORAGE

Keep tightly closed, in a dry and cool place and protected from the light.

REMARKS

Pregnenolone 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.