

## PREGNENOLONA BASE

PRODUCT CODE: 002349	CAS Nº: 145-13-1	ANALYSIS Nº: 034/25
MANUFACTURER BATCH: C07-231003(M)	CERTIFICATE ID: 45.125	
SUPPLIER BATCH: 24G08-APR24127	MANUFACTURING DATE: 02/10/2023	
METAPH BATCH: 0080225	EXPIRY DATE: 01/09/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white crystalline powder	White crystalline powder (*)
Melting point	188 - 193 °C	192.1 °C
Identification	Complies	Complies (*)
Specific optical rotation	+27.5 / +31.5	+30.2
Loss on drying	=< 0.50 %	0.13 %
Related substances		
Any impurity	=< 0.5 %	< 0.5 % (#)
Total impurities	=< 1.0 %	0.2 %
Assay	98.5 - 101.5 %	99.4 %
Residual solvents [In-house]		
Methanol	=< 3000 ppm	244 ppm
Ethanol	=< 5000 ppm	Not Detected

### COMPLIES WITH

Manufacturer Specifications

### REMARKS

(#) Impurities detailed underneath:

Impurity 1 = 0.01 %  
 Impurity 2 = 0.01 %  
 Impurity 3 = 0.01 %  
 Impurity 4 = 0.14 %

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

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

(\*) Data controlled by Metapharmaceutical Industrial SL.

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

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

Analysis date: 19/02/2025  
 Signature: Albert Sanchez Lopez (QP)  
 Conclusion: Complies

Manufacturer: 40000657

