METAPHARMACEUTICAL IND SL
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PREGNENOLONA BASE

PRODUCT CODE: 002349	CAS Nº: 145-13-1	ANALYSIS Nº: 211/25	
MANUFACTURER BATCH:	YXCTA250101	CERTIFICATE ID:	47.315
SUPPLIER BATCH:	----	MANUFACTURING DATE:	02/01/2025
METAPH BATCH:	0070725	RETEST DATE:	01/01/2028

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white crystalline powder	White crystalline powder
Melting point	188 - 193 ºC	188 ºC
Identification	Complies	Complies
Specific optical rotation	+27.5 / +31.5	+30º
Loss on drying	=< 0.50 %	0.04 %
Related substances		
Any impurity	=< 0.5 %	0.02 %
Total impurities	=< 1.0 %	0.02 %
Assay	98.5 - 101.5 %	98.7 %
Residual solvents [In-house]		
Methanol	=< 3000 ppm	< 50 ppm
Ethanol	=< 5000 ppm	< 50 ppm
Methylene Chloride	=< 600 ppm	< 50 ppm
Microbiological control		
TAMC	=< 1000 CFU/g	< 10 CFU/g
TYMC	=< 100 CFU/g	< 10 CFU/g

COMPLIES WITH

Manufacturer Specifications

REMARKS

Product fully analyzed within the EU, in compliance with the currents 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.

All 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: 05/09/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies

Manufacturer: 40001090