



PRASTERONA (DEHIDROEPIANDROSTERONA - DHEA) (FRENCH PH.)

PRODUCT CODE: 890	CAS Nº: 53-43-0	ANALYSIS Nº: 212/25
MANUFACTURER BATCH: C04-250601(M)	CERTIFICATE ID: 47.316	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 29/06/2024	
METAPH BATCH: 0080725	RETEST DATE: 28/06/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white crystalline powder	White crystalline powder
Identification B	Complies	Complies
Specific rotation power	+11.0 / +14.0	+12.3
Related substances		
Impurity A	=< 0.10 %	Not Detected
Impurity B	=< 0.10 %	Not Detected
Impurity D	=< 0.10 %	Not Detected
Impurity E	=< 0.10 %	< 0.025 %
Impurity F	=< 0.08 %	< 0.025 %
Impurity C	=< 0.02 %	Not Detected
Any other impurity	=< 0.10 %	Not Detected
Total impurities	=< 0.50 %	< 0.025 %
Hydroxylamine	=< 5 ppm	0.33 ppm
Water	=< 1.0 %	0.01 %
Sulfated ash	=< 0.1 %	0.08 %
Assay	97.5 - 102.0 %	97.7 %

COMPLIES WITH

French Pharmacopoeia 2025

REMARKS

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

Prasterone VEGETAL ORIGIN is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Analysis date: 02/10/2025

Signature: Albert Sánchez López (QP)

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000657

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