

PROGESTERONA MICRONIZADA (EUR. PH.) VEGETAL ORIGIN

PRODUCT CODE: 46433149	CAS Nº: 57-83-0	ANALYSIS Nº: 165/25
MANUFACTURER BATCH: C01-250409	CERTIFICATE ID: 46.815	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 16/04/2025	
METAPH BATCH: 0520525	RETEST DATE: 15/04/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder or colourless crystals	White crystalline powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Specific optical rotation	+186 / +194	+190.6
Related substances		
Impurity I (sum of the 2 epimers)	<= 0.6 %	Not Detected
Impurity C	<= 0.3 %	0.14 %
Impurity B	<= 0.2 %	0.05 %
Sum of impurities D and E	<= 0.15 %	Not Detected
Impurity G	<= 0.15 %	Not Detected
Impurity J	<= 0.15 %	Not Detected
Impurity K	<= 0.15 %	< 0.05 %
Impurity L	<= 0.15 %	Not Detected
Impurity M	<= 0.15 %	< 0.05 %
Impurity H at 286 nm	<= 0.15 %	Not Detected
Unspecified impurities	<= 0.10 %	< 0.05 %
Sum of impurities other than H	<= 1.0 %	0.2 %
Loss on drying	<= 0.5 %	0.08 %
Assay	97.0 - 102.0 %	98.9 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

It shows polymorphism.

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

VEGETAL ORIGIN Progesterone 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 locked up in cool place. Keep container tightly closed in a dry and well-ventilated place.

Analysis date: 11/06/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000657
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