

**MEDROXIPROGESTERONA ACETATO (EUR. PH.)**

PRODUCT CODE: 2240	CAS Nº: 71-58-9	ANALYSIS Nº: 315/24
MANUFACTURER BATCH: 2172AM0 0572424	CERTIFICATE ID: 44.409	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 08/07/2024	
METAPH BATCH: 0021224	EXPIRY DATE: 08/07/2029	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white crystalline powder	White crystalline powder
Solubility	Practically insoluble in water, freely soluble in methylene chloride, soluble in acetone, sparingly soluble in ethanol (96 %)	Complies (*)
Identification	Complies	Complies
Specific optical rotation	+47 / +53	+50
Impurity F	=< 0.5 %	0.3 %
Related substances		
Impurity D	=< 1.0 %	0.2 %
Impurity B	=< 0.7 %	0.1 %
Impurity A	=< 0.3 %	< 0.05 %
Impurity C	=< 0.2 %	< 0.05 %
Impurity E	=< 0.2 %	0.1 %
Impurity G	=< 0.2 %	Not Detected
Impurity I	=< 0.2 %	0.1 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 1.5 %	0.5 %
Loss on drying	=< 1.0 %	0.06 %
Assay	97.0 - 103.0 %	99.8 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

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

(*) Data adapted from the manufacturer's certificate of analysis.

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 the containers tightly closed and protected from sunlight.

Analysis date: 13/01/2025
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000236
FARMABIOS S.p.A. Active Pharmaceutical
Ingredients
Via Pavia, 1
(PV) ITALIA