



# F.I.S. — Fabbrica Italiana Sintetici S.p.A.

Headquarters — Viale Milano, 26 — 36075 Montecchio Maggiore (VI) — Italy  
Montecchio site — Viale Milano, 26 — 36075 Montecchio Maggiore (VI) — Italy — Ph. +39 0444 708011 — Fax +39 0444 698094

## CERTIFICATE OF ANALYSIS

CoA # 34478

**Product:** PROGESTERONE

**Chemical Name (IUPAC):** (8S,9S,10R,13S,14S,17S)-17-Acetyl-10,13-dimethyl-1,2,6,7,8,9,11,12,14,15,16,17-dodecahydrocyclopenta[a]phenanthren-3-one

**CAS NBR:** 57-83-0

**Lot Number:** 201906270148

**Code:** 1188

Manufacturing date: 02-April-2019

Retest Date : 31-March-2024

### Test Item:

### Test Results:

### Specifications:

APPEARANCE (EP)	almost white crystalline powder	white or almost white crystalline powder
IDENTIFICATION BY IR SPECTROPHOTOMETRY	positive	Must exhibit maxima at same wavelenghts as EP-CRS and USP RS
IDENTIFICATION BY TLC	positive	Must be positive (EP)
IDENTIFICATION BY UV SPECTROPHOTOMETRY	positive	According to USP-RS
MELTING RANGE (start) (USP)	130deg_C	126deg_C - 131deg_C
MELTING RANGE (end) (USP)	131deg_C	126deg_C - 131deg_C
SPEC. ROTATION - 20^C (on dried subst.) (EP)	190deg_angle	186deg_angle - 194deg_angle
SPEC. ROTATION - 25^C (on dried subst.) (USP)	177deg_angle	175deg_angle - 183deg_angle
LOSS ON DRYING (2 hours at 105^C) (EP 2.2.32)	0.1%	NMT 0.5%
LOSS ON DRYING (4 hours under vacuum) (USP <731>)	0.1%	NMT 0.5%
RESIDUE ON IGNITION	0.03%	NMT 0.10%
PALLADIUM (ICP-MS)	<1ppm	NMT 10ppm
ASSAY BY HPLC (calc. on dried subst.) (USP)	99.9%	97.0% - 103.0%



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**Test Item:**

**Test Results:**

**Specifications:**

ASSAY BY HPLC (calc. on dried substance) (EP)	99.9%	97.0% - 102.0%
EP IMP. B (HPLC)	<0.05%	NMT 0.15%
EP IMP. J (HPLC)	<0.05%	NMT 0.15%
EP IMP. H (HPLC)	<0.05%	NMT 0.15%
EP IMP. K (HPLC)	<0.05%	NMT 0.15%
EP IMP. C (HPLC)	<0.05%	NMT 0.15%
EP IMP. M (HPLC)	<0.05%	NMT 0.15%
EP IMP. L (HPLC)	<0.05%	NMT 0.15%
EP IMP. I (SUM OF 2 EPIMERS) (HPLC)	<0.05%	NMT 0.15%
SUM EP IMP. D AND EP IMP. E (HPLC)	<0.05%	NMT 0.15%
EP IMP. G (HPLC)	<0.05%	NMT 0.15%
EACH UNSPECIFIED IMPURITIES (HPLC)	<0.05%	NMT 0.10%
SUM OF IMPURITIES OTHER THAN H (HPLC)	0.0%	NMT 0.5%
RESIDUAL METHANOL	<40ppm	NMT 1000ppm



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**Test Item:**

**Test Results:**

**Specifications:**

RESIDUAL ETHANOL

590ppm

NMT 2000ppm

RESIDUAL TOLUENE

<40ppm

NMT 890ppm

RESIDUAL ISOPROPYL ALCOHOL

<40ppm

NMT 1000ppm

RESIDUAL TERT-BUTHYL METHYL ETHER

<40ppm

NMT 500ppm

RESIDUAL HEPTANE

<40ppm

NMT 800ppm

The product complies with specifications of USP 42 and EP 9.0.

Lot Approval Date: 11-July-2019

Control and manufacturing records have been reviewed according to FIS internal SOP and found to be in accordance with cGMPs, applicable laws and with all current documentation submitted by FIS to regulatory authorities or to the customer.

QA release date: 12-July-2019

Certificate of Analysis was e-signed on 16-Jul-2019 by Paola Berin Quality Control Manager

Certificate of Analysis was e-signed on 17-Jul-2019 by Tommaso Messeri Qualified Person

*The information hereto reported is Confidential. Any disclosure to third parties should be approved by FIS.*