



Head Office: Viale Milano, 26 - 36075 Montecchio Maggiore - Vicenza (Italy)

FAX +39-0444-698094 PHONE +39-0444-708011

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CERTIFICATE OF ANALYSIS

CoA # 24975

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:** 201701230286**Code:** 1188

Manufacturing date: 18-May-2016

Retest Date : 17-May-2021

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)	128deg_C	126deg_C - 131deg_C
MELTING RANGE (end) (USP)	129deg_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)	181deg_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	0.0%	NMT 0.10%
HEAVY METALS (USP <231> Meth. II)	less than 10 ppm	NMT 10 ppm
PALLADIUM (ICP-MS)	<1.0ppm	NMT 10ppm
ASSAY BY HPLC (calc. on dried subst.) (USP)	100.0%	97.0% - 103.0%
ASSAY BY HPLC (calc. on dried substance) (EP)	100.0%	97.0% - 102.0%
EP IMP. B (HPLC)	0.08%	NMT 0.15%
EP IMP. J (HPLC)	<0.05%	NMT 0.15%
EP IMP. H (HPLC)	0.08%	NMT 0.15%



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Test Item:**Test Results:****Specifications:**

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)	0.2%	NMT 0.5%
RESIDUAL METHANOL	<40ppm	NMT 1000ppm
RESIDUAL ETHANOL	423ppm	NMT 2000ppm
RESIDUAL TOLUENE	<40ppm	NMT 890ppm
RESIDUAL ISOPROPYL ALCOHOL	<40ppm	NMT 1000ppm
RESIDUAL TERT-BUTHYL METHYL ETHER	<40ppm	NMT 500ppm



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,2,6,7,8,9,11,12,14,15,16,17-dodecahydrocyclopenta
[a]phenanthren-3-one**CAS NBR: 57-83-0****Lot Number: 201701230286****Code: 1188**

Manufacturing date: 18-May-2016

Retest Date : 17-May-2021

Test Item:**Test Results:****Specifications:****RESIDUAL HEPTANE**

<40ppm

NMT 800ppm

The product complies with specifications of USP 38 and EP 8.5.

Lot Approval Date: 28-February-2017

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, in connection with marketing authorization.QA release date: 31-March-2017

Certificate of Analysis was e-signed on 12-Jun-2017 by Federica Panarotto, Quality Control Manager

Certificate of Analysis was e-signed on 12-Jun-2017 by Assunta Bortoli Qualified Person

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