

CERTIFICATE of ANALYSIS

11- α -HYDROXIPROGESTERONE

BATCH No.: U0373/0 10040

MAN DATE: Feb/11

RE-TEST DATE: Feb/16

TEST	SPECIFICATIONS	RESULTS
1. Description	White to almost white crystalline powder	Complies
2. Identification		
2.1. IR	According to reference standard	Complies
2.2. HPLC	According to reference standard	Complies
3. Loss on drying	$\leq 1.0 \%$	0.1 %
4. Specific optical rotation	$+175.0^{\circ}$ to $+182.0^{\circ}$	$+179.7^{\circ}$
5. Residue on ignition	$\leq 0.10\%$	$< 0.10 \%$
6. Heavy Metals	≤ 10 ppm	< 10 ppm
7. Molybdenum	≤ 25 ppm	< 25 ppm
8. HPLC chromatographic purity	I0373-01 $\leq 0.15 \%$ I0373-02 $\leq 0.15 \%$ I0373-03 $\leq 0.15 \%$ I0373-04 $\leq 0.15 \%$ I0373-05 $\leq 0.15 \%$ Unknown $\leq 0.10 \%$ Total $\leq 1.0 \%$	$< 0.05 \%$ $< 0.05 \%$ $< 0.05 \%$ $< 0.05 \%$ $< 0.05 \%$ 0.06 % 0.06 %
9. HPLC Assay (dried basis)	98.0 – 102.0 %	99.3%
10. Residual solvents	Ethyl Acetate < 5000 ppm Methanol < 3000 ppm THF < 720 ppm Methyl-THF < 5000 ppm	4936 ppm 102 ppm $< \text{LOD}^*$ $< \text{LOD}^*$

*LOD: limit of detection


 14/07/15
 Quality Assurance Department