

CERTIFICATE of ANALYSIS

11- α -HYDROXIPROGESTERONE

BATCH No: U0373/0 15010

MAN DATE: Dec/15

RE-TEST DATE: Dec/20

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	$\leq 1.0 \%$	0.0 %
4. Specific optical rotation	$+175.0^\circ$ to $+182.0^\circ$ ($c=1$; CHCl_3 ; 25°C)	$+176.2^\circ$
5. Residue on ignition	$\leq 0.10\%$	$< 0.10 \%$
6. Heavy Metals	$\leq 10 \text{ ppm}$	$< 10 \text{ ppm}$
7. Molybdenum	$\leq 25 \text{ ppm}$	$< 1 \text{ ppm}$
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 $\leq 1.0 \%$	$< 0.05 \%$ $< 0.05 \%$ $< 0.05 \%$ $< 0.05 \%$ $< 0.05 \%$ $< 0.05 \%$ 0.00 %
9. HPLC Assay (dried basis)	98.0 – 102.0 %	101.0%
10. Residual solvents	Methanol $< 3000 \text{ ppm}$ Ethyl Acetate $< 5000 \text{ ppm}$ THF $< 720 \text{ ppm}$ Methyl-THF $< 5000 \text{ ppm}$	44 ppm 1242 ppm $< \text{LOD}^*$ $< \text{LOD}^*$

*LOD: limit of detection

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

16A25-B02

Director Técnico

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