



Crystal pharma

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° to +182.0° (c=1; CHCl ₃ ; 25 °C)	+176.2°
5. Residue on ignition	$\leq 0.10\%$	< 0.10 %
6. Heavy Metals	≤ 10 ppm	< 10 ppm
7. Molybdenum	≤ 25 ppm	< 1 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 ppm Ethyl Acetate < 5000 ppm THF < 720 ppm Methyl-THF < 5000 ppm	44 ppm 1242 ppm < LOD* < LOD*

*LOD: limit of detection

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

16A25 B02

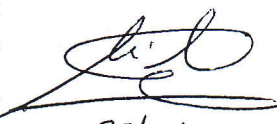
Director Técnico

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Quality Assurance Department