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	≤ 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	≤ 0.10%	< 0.10 %
6. Heavy Metals	≤ 10 ppm	< 10 ppm
7. Molybdenum	≤ 25 ppm	< 1 ppm
8. HPLC chromatographic purity	I0373-01 ≤ 0.15 %	< 0.05 %
	I0373-02 ≤ 0.15 %	< 0.05 %
	I0373-03 ≤ 0.15 %	< 0.05 %
	I0373-04 ≤ 0.15 %	< 0.05 %
	I0373-05 ≤ 0.15 %	< 0.05 %
	Unknown ≤ 0.10 %	< 0.05 %
	Total ≤ 1.0 %	0.00 %
9. HPLC Assay (dried basis)	98.0 – 102.0 %	101.0%
10. Residual solvents	Methanol < 3000 ppm	44 ppm
	Ethyl Acetate < 5000 ppm	1242 ppm
	THF < 720 ppm	< LOD*
	Methyl-THF < 5000 ppm	< LOD*

*LOD: limit of detection

Corresponde al OST 16A25-BOL-313724 de Fapron Iberica.

31.3.16

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20/01/16

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