CERTIFICATE of ANALYSIS

11-α-HYDROXIPROGESTERONE

BATCH No.: C0373/0 19010 **MAN DATE:** Sep/19 **RE-TEST DATE:** Sep/24

COUNTRY OF ORIGIN: SPAIN

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 %	0.1 %
4. Specific optical rotation	+175.0° to +182.0° (c=1; $CHCl_3$; 25 °C)	+180.6°
5. Residue on ignition	≤ 0.10%	< 0.10 %
6. Heavy Metals	≤ 10 ppm	< 10 ppm
7. Molybdenum	≤ 25 ppm	< 25 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 %	100.0 %
10. Residual solvents	Methanol < 3000 ppm	< LOQ*
	Ethyl Acetate < 5000 ppm	2555 ppm
	Tetrahydrofuran < 720 ppm	< LOD**
	Methyl-THF < 5000 ppm	< LOD**

GMP Compliance Declaration/Certificate of Compliance: Crystal Pharma, S.A.U. hereby certify that the information contained in this CoA/CoC is authentic and accurate. This batch has been manufactured and packaged at the above mentioned site in full compliance with GMP requirements of the local Regulatory Authority, applicable laws or regulations and tested according to the approved product specification. The Manufacturing Batch Records, packaging and analysis records have been reviewed, released and found to be in compliance with GMP requirements.

*LOQ: Limit of quantitation

**LOD:Limit of detection

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Quality Assurance Department

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