

Hydroxyprogesteronum
(11-alfa)

FAGRON IBERICA, S.A.
Josep Canals, 150
08226 Terrassa (Barcelona)
C.I.F. ES-A-08160499

常州佳尔科药业集团有限公司

Changzhou Jiaerke Pharmaceuticals Group Corp., Ltd.

Zhenglu Town, Changzhou City, Jiangsu province, China

Tel: 0086-519-88930795

Fax: 0086-519-88736500

Certificate of Analysis

Product name:	11 α -Hydroxy-progesterone	Batch No.:	C23-110801
Quantity:	9kg	Packaging:	9kg/carton
Manuf. date:	Aug. 15, 2011	Test date:	Aug. 25, 2011
Re-test date:	Aug. 14, 2013	Report date:	Feb. 10, 2012
Standard:	Export criterion		
Items	Specifications	Results	
1. Appearance:	White or almost white crystalline powder	Almost white crystalline powder	
2. Melting point:	163°C to 170°C	167°C to 169°C	
3. Specific rotation:	+ 165°to + 185°	+172°	
4. Loss on drying:	0.5% Max.	0.40%	
5. Related substances:	Any impurity: 0.5% max. Total impurities:1.5% max.	0.28% 0.71%	
6.Purity:	98.5% Min.	99.3%	
7.Residual solvents:	Acetone: 2000ppm Max. Petroleum ether : 2000ppm Max.	110ppm 43ppm	
Conclusion: The above product conforms to Export criterion.			

QA Manager:

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Reported by:

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FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:
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1807-13
Director Técnico