

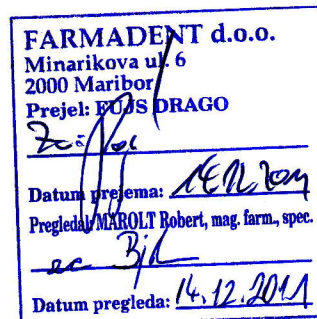
# Analizni izvid / Certificate of analysis

## Progesteronum

Serijska številka / Batch n<sup>o</sup>: LX0776-100001  
 Deklaracija / Corresponds Ph.Eur.  
 Proizvajalec / Manufacturer: Changzhou Jiaerke pharmaceuticals Group Corp. Ltd

Datum analize / Date of analysis: 15/06/2010  
 Datum proizvodnje / Manufacturing date: 05/2010  
 Uporabno do / Expiry date: 05/2013

	Specifikacija / Specification Values	Rezultati / Batch Values
Lastnosti / Properties:	Bel ali skoraj bel prašek ali brezbarvni kristali, skoraj netopen v vodi, lahko topen v alkoholu, zmerno topen v acetonu in mašč. oljih. Izkazuje polimorfnost. / <i>White or almost white, crystalline powder or colourless crystals. Practically insoluble in water, freely soluble in ethanol, sparingly soluble in acetone and in fatty oils. It shows polymorphism.</i>	Ustreza / Conforms
Istovetnost / Identification:	according to test	Ustreza / Conforms
Vsebnost / Assay:	97,0 – 103,0 %	99,3
Specifična optična sučnost / Specific optical rotation:	+186 to +194	+189
Sorodne substance / Related substances:	according to test	Ustreza / Conforms
Izguba pri sušenju / Loss on drying:	≤ 0,5 %	0,33
Zaostala topila / Residual solvents:		
. methanol	≤ 500 ppm	< 6,5
. ethanol	≤ 2000 ppm	777
. toluene	≤ 300 ppm	<4,0
. cyclohexane	≤ 50 ppm	<13



Opombe / Notes:	
Mnenje / Opinion:	Po navedbah proizvajalca substanca ustreza zgoraj navedenim parametrom Ph.Eur.6. <i>According to the manufacturers specifications, the product corresponds to the stated parameters Ph.Eur.6.</i>

Ines LOGAR mag.farm., spec.  
 Vodja službe za kontrolo kakovosti  
 Quality assurance manager

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