

# Analizni izvid / Certificate of analysis

**FARMADENT d.o.o.**  
Minarikova ul. 6  
2000 Maribor  
Prejel: FUJIS DRAGO  
ZA: *Colore*  
Datum prejema: 9.8.11  
Pregledal: *MAROLT Robert mag. farm., spec.*  
*Jarab*  
Datum pregleda: 9.8.2011

<http://analyze.lex.si>

## Hydrocortisoni acetat

Serijska številka / Batch n°: LX0319-100002 ✓  
Deklaracija / Corresponds to: Ph.Eur.  
Proizvajalec / Manufacturer: Tianjin Tianyao Pharmaceuticals Co., Ltd

Datum analize / Date of analysis: 20/06/2011  
Datum proizvodnje / Manufacturing date: 11/2010  
Uporabno do / Expiry date: 11/2013 ✓

	Specifikacija / Specification Values	Rezultati / Batch Values
Lastnosti / Properties:	Bel ali skoraj bel, kristaliničen prašek, skoraj netopen v vodi, težko topen v brezvodnem etanolu in v metilen kloridu./ <i>White or almost white, crystalline powder, practically insoluble in water, slightly soluble in anhydrous ethanol and in methylene chloride.</i>	Ustreza / Conforms
Istovetnost / Identification:	v skladu s preskusom / <i>it complies with the test</i>	Ustreza / Conforms
Vsebnost / Assay:	97,0 – 103,0 % *	100,2
Specifična optična sučnost / Specific optical rotation:	+ 158° to + 167 ° *	+163
Sorodne substance / Related substances:	v skladu s preskusom / <i>it complies with the test</i>	Ustreza / Conforms
Izguba pri sušenju / Loss on drying:	≤ 0,5 %	<0,1
Velikost delcev / Particle size:	99 % < 25 µm / 90 % < 10 µm	Ustreza / Conforms
Zaostala topila / Residual solvents:	CPMP/ICH/283/95	Ustreza / Conforms
BSE/TSE:	No contamination with TSE/BSE-risk materials.	Ustreza / Conforms

Opombe / Notes: \* sušena substance / dried substance

Mnenje / Opinion: Po preskušanih parametrih vzorec ustreza Ph.Eur.7<sup>th</sup>.  
*According to the tested parameters the sample corresponds to Ph.Eur.7<sup>th</sup>.*

Ines LOGAR mag.farm., spec.

Vodja službe za kontrolo kakovosti  
*Quality assurance manager*

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Stran/Page 1/1