

# Analizni izvid / Certificate of analysis

## Clindamycini hydrochloridum

Serijska številka / Batch n<sup>o</sup>: LX0222-120001 ✓  
 Deklaracija / Corresponds to: Ph.Eur.  
 Proizvajalec / Manufacturer: Zhejiang Tiantai Pharmaceutical Co., Ltd.

Datum analize / Date of analysis: 24/09/2012  
 Datum proizvodnje / Manufacturing date: 04/2012  
 Uporabno do / Expiry date: 04/2015 ✓

|   | Specifikacija / Specification Values  | Rezultati / Batch Values |
|---|---|--------------------------|
| Lastnosti / Properties:                                   | Bel ali skoraj bel kristaliničen prašek, zelo lahko topen v vodi, težko topen v etanolu (96 odstotnem). / White or almost white crystalline powder, very soluble in water, slightly soluble in ethanol (96 per cent). | Ustreza / Conforms       |
| Istovetnost / Identification:                             | v skladu s preskusom / it complies with the test  | Ustreza / Conforms       |
| Vsebnost* / Assay*:                                       | 91,0 – 102,0 %  | 99,3                     |
| pH / pH:  | 3,0 – 5,0   | 4,3                      |
| Specifična optična sučnost* / Specific optical rotation*: | +135 ° / +150 °   | + 145                    |
| Sorodne substance / Related substances:                   | according to test   | Ustreza / Conforms       |
| Voda / Water:   | 3,0 - 6,0 %   | 4,33                     |
| Sulfatni pepel / Sulphated ash:                           | ≤ 0,5 %   | < 0,01                   |

**FARMADENT d.o.o.**  
 Minarikova ul. 9  
 2000 Maribor  
 Prejel: EUJS DRAGO  
*[Signature]*  
 Datum prejema: 10.10.2012  
 Pregledal: MAROLT Robert, mag. farm., spec.  
*[Signature]*  
 Datum pregleda: 11.10.2012

|                   |   |
|-------------------|---|
| Opombe / Notes:   | * brezvodna substanca / anhydrous substance   |
| Mnenje / Opinion: | Po preskušanih parametrih vzorec ustreza Ph.Eur.7.<br>According to the tested parameters the sample corresponds to Ph.Eur.7 <sup>th</sup> . |

Ines LOGAR mag.farm., spec.

Vodja službe za zagotavljanje kakovosti  
 Quality assurance manager

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Obr.: 7512

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