

Analizni izvid / Certificate of analysis

Oxytetracyclini hydrochloridum

Serijska številka / Batch n°: LX0475-110003 ✓ Datum analize / Date of analysis: 23/01/2013
 Deklaracija / Corresponds to: Ph.Eur. Datum proizvodnje / Manufacturing date: 12/2011
 Proizvajalec / Manufacturer: Shandong Jinyang Pharmaceutical CO. Uporabno do / Expiry date: 12/2015 ✓

| | Specifikacija / Specification Values | Rezultati / Batch Values |
|--|--|--------------------------|
| Lastnosti / Properties: | Rumen kristaliničen prašek, higroskopen, lahko topen v vodi, zmerno topen v etanolu (96 odstotnem). Vodne raztopine sčasoma postanejo motne zaradi obarjanja oksitetraciklina. / Yellow, crystalline hygroscopic powder, freely soluble in water, sparingly soluble in ethanol (96 per cent). Solutions in water become turbid on standing, owing to the precipitation of oxytetracycline. | Ustreza / Conforms |
| Istovetnost / Identification: | v skladu s preskusom / it complies with the test | Ustreza / Conforms |
| Vsebnost / Assay: | 95,0 – 102,0 % * | 95,1 |
| pH / pH: | 2,3 – 2,9 | 2,55 |
| Specifični optični zasuk / Specific optical rotation: | -188 / -200° * | -195,0 |
| Specifična absorbanca / Specific absorbance (353 nm): | 270 – 290 * | 281 |
| Svetlobo absorbirajoče nečistote / Light-absorbing impurities: | v skladu s preskusom / it complies with the test | Ustreza / Conforms |
| Sorodne snovi / Related substances: | v skladu s preskusom / it complies with the test | Ustreza / Conforms |
| Težke kovine / Heavy metals: | ≤ 50 ppm | 0,10 |
| Voda / Water: | ≤ 2,0 % | 1,128 |
| Sulfatni pepel / Sulphated ash: | ≤ 0,5 % | 0,16 |

FARMADENT d.o.o.
 Minarikova ul. 6
 2000 Maribor
 Prejel: FUJS DRAGO
 Datum prejema: 5.3.2013
 Pregledal: MARIJAN Robert, mag. farm., spec.
 Datum pregleda: 6.3.2013

| | |
|-------------------|--|
| Opombe / Notes: | * brezvodna substanca / anhydrous substance |
| Mnenje / Opinion: | Po preskušeni parametri vzorec ustreza Ph.Eur.7. According to the tested parameters the sample corresponds to Ph.Eur.7. |

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

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