

## Analizni izvid / Certificate of analysis

FARMADENT d.o.o.

Minarikova ul. 6  
2000 Maribor  
Prejel: FUJS DRAGODatum prejema: 29-3-13  
Pregledal: MAROLT Robert, mag. farm. spec.

Datum pregleda: 24-10-13

## Oxytetracyclini hydrochloridum

Serijska številka / Batch n°: LX0475-120004  
 Deklaracija / Corresponds to: Ph.Eur.  
 Proizvajalec / Manufacturer: Norbrook Laboratories

Datum analize / Date of analysis: 28/03/2013  
 Datum proizvodnje / Manufacturing date: 05/2012  
 Uporabno do / Expiry date: 03/2014

	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:	according to test	Ustreza / Conforms
Vsebnost / Assay:	95,0 – 102,0 % *	99,8
pH / pH:	2,3 – 2,9	2,6
Specifični optični zasak / Specific optical rotation:	-188 / -200° *	-194,6
Specifična absorbanca / Specific absorbance (353 nm):	270 – 290 *	281,2
Svetlobo absorbirajoče nečistote / Light-absorbing impurities:	according to test	Ustreza / Conforms
Sorodne snovi / Related substances:	according to test	Ustreza / Conforms
Težke kovine / Heavy metals:	≤ 50 ppm	< 50
Voda / Water:	≤ 2,0 %	0,85
Sulfatni pepel / Sulphated ash:	≤ 0,5 %	0,1

Opombe / Notes: \* brezvodna substanca / anhydrous substance

Mnenje / Opinion: Po preskušanih parametrih vzorec ustreza Ph.Eur.7.  
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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Stran/Page 1/1

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