

Analizni izvid / Certificate of analysis

LEX

Oxytetracyclini hydrochloridum

Serijska številka/Batch n°: **091618**
Deklaracija/Corresponds to: **Ph.Eur.**
Proizvajalec/Manufacturer: **Norbrook Laboratories**

FARMADENT d.o.o. http://analize.lex.si Minarikova ul. 6 2000 Maribor Prejel: FUJS DRAGO ZA: <i>[Signature]</i>
Datum prejema: <i>5.4.09</i> Pregledal: MAROLT Robert, mag. farm. <i>[Signature]</i>
Datum pregleda: <i>5.4.2009</i>

Specifikacija/Spec. Values

Rezultati/Batch Values

Lastnosti / Properties:	Rumen higroskopni kristaliničen prašek, lahko topen v vodi, zmerno topen v etanolu (96 odstotnem). Zaradi oboritve oksitetraciklina, se lahko v vodnih raztopinah pojavi oborina. / 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 % (anhydrous substance)	99,2
pH / pH:	2,3 – 2,9	2,59
Specifični optični zasuk / Specific optical rotation:	-188 to -200 (anhydrous substance)	-199,4
Specifična absorbanca / Specific Absorbance(353nm):	270 – 290 (anhydrous substance)	281,7
Svetlobo absorbirajoče nečistote / Light-absorbing impurities:	according to test	Ustreza/Conforms
Sorodne substance / Related substances:	according to test	Ustreza/Conforms
Težke kovine / Heavy metals:	≤ 50 ppm	Ustreza/Conforms
Voda / Water:	≤ 2,0 %	0,59
Sulfatni pepel / Sulphated ash:	≤ 0,5 %	Ustreza/Conforms

Opombe/ Notes:

Datum analize/Date of analysis: 10/08/2009
Datum reanalize/Retested date: 29/03/2011
Uporabno do/Expiry date: 03/2012
Datum proizvod/Manufacturing date: 06/2009

Mnenje/Opinion: Po preskušanih parametrih vzorec ustreza zahtevam Ph.Eur.6th. /
According to the tested parameters the sample corresponds to Ph.Eur. 6th.

Ines Logar mag.farm.,spec.

Odgovorna oseba za sprostitve serije/
Responsible Laboratory Manager Quality Control