

Analizni izvid / Certificate of analysis

FARMADENT d.o.o.

Minarikova ul. 6
2000 Maribor
Prejel: FUJS DRAGOZA: 

Datum prejema: 8.5.12

Pregledal: MAHOLT Robert, mag. farm., spec.

Datum pregleda: 10.5.2012

Chloramphenicolum

Serijska številka / Batch n°: LX0211-110002
 Deklaracija / Corresponds to: Ph.Eur., BP
 Proizvajalec / Manufacturer: Notheast General Pharmaceutical Factory

Datum analize / Date of analysis: 21/12/2011
 Datum proizvodnje / Manufacturing date: 01/2011
 Uporabno do / Expiry date: 01/2016

	Specifikacija / Specification Values	Rezultati / Batch Values
Lastnosti / Properties:	Bel, sivo bel ali rumenkast, fin ali kristaliničen prašek ali drobni kristali, iglice ali podolgovate ploščice, težko topne v vodi, lahko topne v alkoholu in v propilen glikolu. Etanolna raztopina je desnosučna, medtem ko je etilacetatna levosučna. / A white, greyish-white or yellowish-white, fine, crystalline powder or fine crystals, needles or elongated plates, slightly soluble in water, freely soluble in alcohol and in propylene glycol. A solution in ethanol is dextrorotatory and a solution in ethyl acetate is laevorotatory.	Ustreza / Conforms
Istovetnost / Identification:	According to test	Ustreza / Conforms
Vsebnost / Assay:	98,0 – 102,0 % (dried substance)	98,90
Kislost ali alkalnost / Acidity or alkalinity:	According to test	Ustreza / Conforms
Specifična optična sučnost / Specific optical rotation:	+18,5 to +20,5	+19,4
Sorodne snovi / Related substances:	According to test	Ustreza / Conforms
Kloridi / Chlorides:	≤ 100 ppm	Ustreza / Conforms
Izguba pri sušenju / Loss on drying:	≤ 0,5 %	0,27
Sulfatni pepel / Sulphated ash:	≤ 0,1 %	<0,01
Zaostala topila / Residual solvents:		
. isopropyl alcohol	≤ 3000 ppm	Not detected
. methanol	≤ 3000 ppm	Not detected
. chlorobenzene	≤ 360 ppm	Not detected
. benzene	≤ 2ppm	Not detected

Opombe / Notes:

Mnenje / Opinion:

Po navedbah proizvajalca substanca ustreza zgoraj navedenim parametrom Ph.Eur 7.
 According to the manufacturers specifications the substance corresponds to the stated parameters Ph.Eur 7.

Ines LOGAR mag.farm., spec.

Vodja službe za kontrolo kakovosti
Quality assurance manager

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