

## Analizni izvid / Certificate of analysis

## Tretinoinum

Serijska številka / Batch n°: LX0610-110005 ✓  
 Deklaracija / Corresponds to: Ph.Eur.  
 Proizvajalec / Manufacturer: FIDIA FARMACEUTICI S.p.a. divisione SOLMAG

Datum analize / Date of analysis: 24/09/2012  
 Datum proizvodnje / Manufacturing: 12/2011  
 Uporabno do / Expiry date: 12/2013 ✓

	Specifikacija / Specification Values	Rezultati / Batch Values
Lastnosti / Properties:	Rumen ali rahlo oranžen, kristaliničen prašek, skoraj netopen v vodi, topen v metilen kloridu, težko topen v etanolu (96 odstotnem). Tališče: okoli 182 °C, z razpadom. Občutljiv je na zrak, toploto in svetlobo, posebno v raztopini. / <i>Yellow or light orange, crystalline powder, practically insoluble in water, soluble in methylene chloride, slightly soluble in ethanol (96 per cent). mp: about 182 °C, with decomposition. It is sensitive to air, heat and light, especially in solution.</i>	Ustreza / Conforms
Istovetnost / Identification:	according to test	Ustreza / Conforms
Vsebnost / Assay:	98,0 – 102,0 % (dried substance)	99,7
Sorodne snovi / Related substances:	according to test	Ustreza / Conforms
Težke kovine / Heavy metals:	≤ 20 ppm	< 20
Izguba pri sušenju / Loss on drying:	≤ 0,5 %	0,40
Sulfatni pepel / Sulphated ash:	≤ 0,1 %	0,09
Zaostala topila / Residual solvents:		
. chloroform	≤ 50 ppm	< 25
. methanol	≤ 100 ppm	39
. ethyl acetate	≤ 100 ppm	49
. isopropanol	≤ 2000 ppm	239

## 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<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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