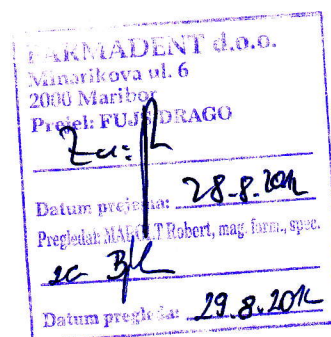


Analizni izvid / Certificate of analysis

Tretinoinum

Serijska številka / Batch n°: LX0610-110004 Datum analize / Date of analysis: 29/05/2012
 Deklaracija / Corresponds to: Ph.Eur. Datum proizvodnje / Manufacturing: 12/2011
 Proizvajalec / Manufacturer: FIDIA FARMACEUTICI S.p.a. divisione SOLMAG 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. / 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.	Ustreza / Conforms
Istovetnost / Identification:	according to test	Ustreza / Conforms
Vsebnost / Assay:	98,0 – 102,0 % (dried substance)	101,2
Sorodne snovi / Related substances:	according to test	Ustreza / Conforms
Težke kovine / Heavy metals:	≤ 20 ppm	< 20
Izguba pri sušenju / Loss on drying:	≤ 0,5 %	0,03
Sulfatni pepel / Sulphated ash:	≤ 0,1 %	0,05
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 7th.

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

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