

Analizni izvid / Certificate of analysis

Tretinoinum

Serijska številka / Batch n°: LX0610-110003
 Deklaracija / Corresponds to: Ph.Eur., USP
 Proizvajalec / Manufacturer: Fidia

Datum analize / Date of analysis: 04/07/2011
 Datum proizvod / Manufacturing date: 04/2011
 Uporabno do / Expiry date: 04/2013

	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 alkoholu. Občutljiv je na zrak, toploto in svetlobo, predvsem v raztopini. / A yellow or light orange, crystalline powder, practically insoluble in water, soluble in methylene chloride, slightly soluble in alcohol. 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 %	100,0
Sorodne substance / Related substances:	according to test	Ustreza / Conforms
. isotretinoin	≤ 0,5 %	< 0,05
. 4-methoxyretinoic acid (impurity A)	≤ 0,15 %	< 0,05
. epoxy derivate	≤ 0,15 %	< 0,05
. largest unknown impurity	≤ 0,20 %	< 0,05
. total impurities (apart from isotretinoin)	≤ 1,0 %	0,12
Težke kovine / Heavy metals:	≤ 20 ppm	Ustreza / Conforms
Izguba pri sušenju / Loss on drying:	≤ 0,5 %	0,03
Sulfatni pepel / Sulphated ash:	≤ 0,1 %	0,02
Zaostala topila / Residual solvents:		
. Chloroform	≤ 50 ppm	< 25
. Methanol	≤ 100 ppm	< 26
. Ethyl acetate	≤ 100 ppm	68
. Isopropanol	≤ 2000 ppm	355
Bistrost raztopine / Clarity of solution 2%:		
. in chloroform	≤ 3,0 NTU	< 3,0
. in THF	clear	Ustreza / Conforms
Shranjevanje / Packaging and storage:	Shranjevanje v trdno zaprti obojnini, zaščiteno pred svetlobo. / Preserve in airtight containers, protected from light.	

ARMADENT d.o.o.
 Inarikova ul. 6
 8000 Maribor
 Prejel: FUJS DRAGO
 Datum prejema: 14.2.12
 Pregledal: MABOLT Robert, mag. farm., spec.
 Datum pregleda: 14.2.2012

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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