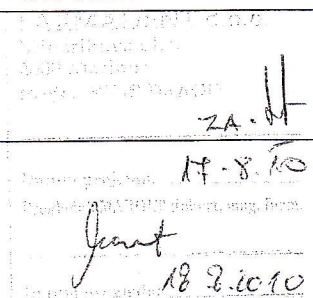


Tretinoinum

Serijska številka / Batch n°: **1040112**
 Deklaracija / Corresponds to: **Ph.Eur., USP**
 Proizvajalec / Manufacturer: **Fidia**



	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 %	101,1
Sorodne substance / Related substances:	according to test	Ustreza / Conforms
• isotretinoin	≤ 0,5 %	0,01
• 4-methoxyretinoic acid (impurity A)	≤ 0,15 %	0,03
• (all-trans)-5,6-epoxy-5,6-dihydroretinoic acid	≤ 0,15 %	0,01
• largest unknown impurity	≤ 0,10 %	0,03
• total impurities (apart from isotretinoin)	≤ 0,5 %	0,11
Težke kovine / Heavy metals:	≤ 20 ppm	Ustreza / Conforms
Izguba pri sušenju / Loss on drying:	≤ 0,5 %	< 0,10
Sulfatni pepel / Sulphated ash:	≤ 0,1 %	< 0,10
Zaostala topila/Residual solvents:		
• Chloroform	≤ 50 ppm	< 25
• Methanol	≤ 1000 ppm	< 26
• Ethyl acetate	≤ 2000 ppm	252
• Isopropanol	≤ 2000 ppm	266
Bistrost raztopine/Clarity of solution 2%:		
• in chloroform	3,0 NTU	< 3
• in THF	clear	Ustreza / Conforms
Velikost delcev/Particle size:		
• d (10)	≥ 5 µm	24
• d (50)	≤ 250 µm	117
• d (90)	≤ 700 µm	691
Shranjevanje/Packaging and storage:	Shranjevanje v trdno zaprli ovojlini, zaščiteno pred svetlobo/Preserve in airtight containers, protected from light.	
Datum analize / Date of analysis:	25/04/2010	
Uporabno do / Expiry date:	02/2012	
Datum proizvod / Manufacturing date:	02/2010	

Mnenje/Opinion: Po navedbah proizvajalca substanca ustreza monografiji v Ph.Eur. 6th. /
 According to the manufacturers specifications the substance corresponds to the Ph.Eur. 6th monography.

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Odgovorna oseba za sprostitve serije/
 Responsible Laboratory Manager Quality Control