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CERTIFICATE OF ANALYSIS

Product **ISOTRETINOIN USP35/EP7** Code N° **2611200** Batch N° **1240551**

Manufacturing date **Jul 2012** Retesting date (where applicable) **Jun 2014** Expiration date (where applicable)

Analysis Number		M4PF071202		Limits	
Test	References	Results	M.U.	Min	Max
Description	EP-USP	Yellow crystalline powder		Yellow crystalline powder	orange crystalline powder
Identification					
- IR	EP 2.2.24; USP <197M>	Conforms to Standard		Conforms to Standard	
- UV	USP <197U>	Conforms to Standard		Conforms to Standard	
Loss on drying	EP 2.2.32; USP <731>	0,2	%		0,5
Residue on ignition	EP 2.4.14; USP <281>	0,05	%		0,1
Heavy metals	USP <231> Method II; EP 2.4.8	< 20	ppm		20
Assay (TBAH)	EP	100,3	% dried	98,0	102,0
Related Substances HPLC (EP) :	EP				
- Tretinoin		< 0,05	%		NMT 0,50
- Specified unidentified impurity RRT = 0,95		0,06	%		NMT 0,15
- 13-cis-5,6-epoxy-5,6-dihydroretinoic acid		0,05	%		NMT 0,15
- Any other impurity		< 0,05	%		NMT 0,10
- Total Impurities		0,21	%		NMT 0,50
OVI (USP)					
Residual Solvents (GC) :	Internal method			Not used	
- ICH Class 1 solvents :				Not used	
- ICH Class 2 solvents :					
Cyclohexane		614	ppm	< 150 (LOQ)	1500
Hexane		<10	ppm	< 10 (LOQ)	100
Methanol		<50	ppm	< 50 (LOQ)	500
- ICH Class 3 solvents :					
Ethanol		<50	ppm	< 50 (LOQ)	500
Ethyl Acetate		1786	ppm	< 500 (LOQ)	2400
Particle size (laser) :	Internal method				
- d(0,9)		247	µm	150	550
- d(0,5)		80	µm	50	300
Packaging and Storage	Store in an airtight container, protected from oxygen and from light, at a temperature not exceeding 25°C. It is recommended that the contents of an opened container be used as soon as possible and any unused part be protected by an atmosphere of an inert gas.				

This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline Volume 4 Part II (ICH Q7A) .
Manufacturing site of the Active Pharmaceutical Ingredient : GARBAGNATE MIL.se

Date

July 30 ,2012

Q.C. Manager (Roberto Quaglia)

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