Lot: 009/112

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CERTIFICATE OF ANALYSIS

Product ISOTRETINOIN USP35/EP7 **Code N°** 2611200 **Batch N°** 1240701

Manufacturing date Sep 2012 **Retesting date (where applicable)** Aug 2014 **Expiration date (where applicable)**

Analysis Number		M4PF090702		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>	0,1	%		0,5
Residue on ignition	EP 2.4.14; USP <281>	0,04	%		0,1
Heavy metals	USP <231> Method II; EP 2.4.8	< 20	ppm		20
Assay (TBAH)	EP	98,6	% dried	98,0	102,0
Related Substances HPLC (EP) :	EP				
- Tretinoin		< 0,05	%		NMT 0,50
- Specified unidendified impurity RRT = 0,95		0,08	%		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		0,23	%		NMT 0,50
OVI (USP)				Not used	
Residual Solvents (GC) :	Internal method				
- ICH Class 1 solvents :				Not used	
- ICH Class 2 solvents :					
Cyclohexane		250	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		903	ppm	< 500 (LOQ)	2400
Particle size (laser) :	Internal method				
- d(0,9)		286	µm	150	550
- d(0,5)		118	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
September 19 ,2012

Q.C. Manager (Roberto Quaglia)