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46/1171.

CERTIFICATE OF ANALYSIS

Product ISOTRETINOIN USP35/EP7 **Code N°** 2611200 **Batch N°** 1240376

Manufacturing date May 2012 **Retesting date (where applicable)** Apr 2014 **Expiration date (where applicable)**

Analysis Number		M4PF051702		
Test	**References**	**Results**	**M.U.**	**Limits**
Appearance	EP - USP	Yellow crystalline powder	---	Yellow 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>	0,02	%	≤ 0,1
Heavy metals	USP <231> Method II; EP 2.4.8	< 20	ppm	≤ 20
Assay (TBAH)	EP	100,9	% dried	98,0 ÷ 102,0
Related substances (HPLC)	EP			
- Tretinoin		< 0,05	%	≤ 0,50
- 13-cis-5,6-epoxy-5,6-dihydroretinoic acid		0,05	%	≤ 0,15
- Specified unidentified impurity RRT = 0,95		0,09	%	≤ 0,15
- Any other impurity		< 0,05	%	≤ 0,10
- Total impurities		0,26	%	≤ 0,50
Residual solvents (GC)	Internal method			
- OVI (USP)		Not used	--	Not used
- ICH Class 1 solvents		Not used	--	Not used
- ICH Class 2 solvents			--	
- Ciclohexane		335	ppm	≤ 1500
- Hexane		< 10	ppm	≤ 100
- Methanol		< 50	ppm	≤ 500
- ICH Class 3 solvents			--	
- Ethanol		< 50	ppm	≤ 500
- Ethyl Acetate		1130	ppm	≤ 2400
Particle size (Malvern)	Internal method			
- d(0,9)		269	µm	150÷550
- d(0,5)		145	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 : SOLMAG S.P.A. - Stabilimento di Garbagnate

Date

29/05/2012

CQ Manager (Roberto Quaglia)