

Stabilimento di Garbagnate Milanese
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Strada Rivoltana km. 6/7
Rodano (MI)



CERTIFICATE OF ANALYSIS

Product **ISOTRETINOIN USP35/EP7** Code N° **2611200** Batch N° **1240862**

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

Analysis Number		M4PF101702		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 <1974>	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>	0.08	%		0.1
Heavy metals	USP <231> Method II EP 2.4.8	< 20	ppm		20
Assay (TBAH)	EP	100.8	% dried	99.0	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-ox-5,6-epoxy-5,6-dihydroretinoic acid		0.02	%		NMT 0.15
- Any other impurity		0.04	%		NMT 0.10
- Total Impurities		0.19	%		NMT 0.50
OVi (USP)				Not used	
Residual Solvents (GC)	Internal method				
- ICH Class 1 solvents				Not used	
- ICH Class 2 solvents					
Cyclohexane		234	ppm	< 150 (LOQ)	1500
Hexane		<10	ppm	< 10 (LOQ)	150
Methanol		<50	ppm	< 50 (LOQ)	500
- ICH Class 3 solvents					
Ethanol		<50	ppm	< 50 (LOQ)	500
Ethyl Acetate		1084	ppm	< 500 (LOQ)	2400
Particle size (laser)	Internal method				
- d(0.9)		301	µm	150	550
- d(0.5)		123	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
October 30, 2012

Reissued on
December 05, 2012

G.C. Manager (Roberto Quaglia)

Capitale Sociale € 40.000.000 i.v. - R.I. Milano, Cod. Fisc. E.P. IVA n. 08101100157 - R.E.A. Milano n. 1201840
Società del Gruppo P.A.R. S.p.A. soggetta all'attivazione di direzione e coordinamento della Società Capogruppo Gruppo P.A.R. S.p.A.
Strada Rivoltana km 6/7 - 20090 Rodano (MI) - ITALY capitale sociale € 12.000.000,00 i.v. - C.F. e P.I. 00851010151