

Stabilimento di Garbagnate Milanese
Via Milano, 186
20024 Garbagnate Milanese (MI)

PEC: signal@pec.olonspa.it
Telefono 02 89442.1
Fax 02 89442.220

Olon S.p.A.
Sede Legale
Strada Rivoltana km. 67
Rivolta (MI)



CERTIFICATE OF ANALYSIS

Product **TRETINOIN-USP34/EP7** Code N° **2610460** Batch N° **1240647**

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

Analysis Number		M4PF073103		
Test	Results	M.U.	Limits	
			Min	Max
Description	Yellow, crystalline powder		Yellow, crystalline powder	Light orange
Identification				
- IR	Conforms to Standard		Conforms to Standard	
- UV	Conforms to Standard		Conforms to Standard	
Loss on drying	0.03	%		
Residue on ignition	0.04	%		0.5
Heavy metals	< 20	ppm		0.1
Assay (TBAH)	100.4	%	98.0	102.0
Related Substances HPLC				
- Isotretinoin	< 0.05	%		
- Epoxy derivative	0.10	%		0.50
- Impurity a (4-methoxy retinoic acid)	< 0.02	%		Less than 0.15
- Largest unknown impurity	< 0.05	%		Less than 0.15
- Total impurities (apart from Isotretinoin)	0.10	%		0.10
Residual Solvents (GC):				0.50
- ICH Class 1 solvents: Not used				
- ICH Class 2 solvents:			Not tested	
Chloroform	< 25	ppm		
Methanol	44	ppm		50
- ICH Class 3 solvents:				100
Ethyl Acetate	< 20	ppm		
Isopropanol	154	ppm		100
Related Substances (HPLC) I.P.				2000
- Isotretinoin	< 0.05	%		
- 4-Methoxyretinoic acid (Impurity a)	< 0.05	%		0.50
- (all-trans)-5-E-epoxy-5,6-dihydroretinoic acid	0.10	%		Less than 0.15
- Largest unknown impurity	< 0.05	%		Less than 0.15
- Total impurities (apart from isotretinoin)	0.18	%		0.10
Clarity of solution 2%				0.50
- in chloroform (NTU)	1.1	NTU		
- in THF	Clear			5.0
Packaging and Storage			Clear	
			Preserve in airtight containers, protected from light.	

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: OLON S.P.A. - GARBAGNATE MI, sc

Date
September 11, 2012

Reissued on
January 03, 2013

Q.C. Manager (Roberto Caviglia)

Capitale Sociale € 40.000.000 i.v. - R.I. Milano, Cod. Fisc. E.P. IVA n. 09101100157 - R.E.A. Milano n. 1201640
Società del Gruppo P&A S.p.A. soggetta all'attività di direzione e coordinamento della Società Capogruppo Gruppo P&A S.p.A.
Strada Rivoltana km 67 - 20090 Rivolta (MI) - ITALY capitale sociale € 12.000.000,00 i.v. - C.F. e P.I. 09051900157