

Stabilimento di Gargagnate Milanese
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Olón S.p.A.
Sede Legale 20024/20024
Strada Rivoltana km. 6/7
Rodano (MI)



CERTIFICATE OF ANALYSIS

Product **TRETINOIN-USP35/EP7** Code N° **2610460** Batch N° **1240867**

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

Analysis Number	M4PF101004	Limits		
Test	Results	M.U.	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	0.08	%		0.5
Residue on Ignition	0.04	%		0.1
Heavy metals	< 20	ppm		20
Assay (TBAH)	99.0	%dried	98.0	102.0
Related Substances HPLC :				
- Isotretinoin	< 0.05	%		0.50
- Epoxy derivative	0.05	%		Less than 0.15
- Impurity a (4-methoxy retinoic acid)	< 0.02	%		Less than 0.15
- Largest unknown impurity	< 0.05	%		0.10
- Total impurities (apart from Isotretinoin)	0.20	%		0.50
Residual Solvents (GC)				
- ICH Class 1 solvents : Not used			Not tested	
- ICH Class 2 solvents :				
Chloroform	< 25	ppm		50
Methanol	< 26	ppm		100
- ICH Class 3 solvents :				
Ethyl Acetate	< 20	ppm		100
Isopropanol	508	ppm		2000
Related Substances (HPLC) EP :				
- Isotretinoin	< 0.05	%		0.80
- 4-Methoxyretinoic acid (impurity a)	< 0.05	%		Less than 0.15
- (all-trans)-5,6-epoxy-5,6-dihydroretinoic acid	0.05	%		Less than 0.15
- Largest unknown impurity	0.05	%		0.10
- Total impurities (apart from isotretinoin)	0.20	%		0.50
Clarity of solution 2%				
- in chloroform (NTU)	2.2	NTU		3.0
- in THF	Clear		Clear	
Packaging and Storage		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: OLÓN S.p.A. - GARGAGNATE MIL. ss

Date

October 24, 2012

Reissued on

March 22, 2013

Q.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. 1201640
Società del Gruppo P&R S.p.A. soggetta all'attivazione di direzione e coordinamento della Società Capogruppo Gruppo P&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. 02651130151