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Olon S.p.A.
Sede Legale
Strada Rivoltana km. 6/7
Rodano (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			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	0,03	%		
Residue on ignition	0,04	%		0,5
Heavy metals	< 20	ppm		0,1
Assay (TBAH)	100,4	%dried	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)	0,19	%		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) EP :				2000
- Isotretinoin	< 0,05	%		
- 4-Methoxyretinoic acid (Impurity a)	< 0,05	%		0,50
- (all-trans)-5,6-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			3,0
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 MIL.se.

Date
September 11, 2012

Reissued on
January 03, 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. 00951030181