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Strada Rivoltana km. 6/7
Rodano (MI)

olon s.p.a.

Lote: 01301/4.

CERTIFICATE OF ANALYSIS

Product	TRETINOIN-USP/EP current edition	Code N°	2610460	Batch N°	1340559

Manufacturing date	Jul 2013	Retesting date (where applicable)	Jun 2015	Expiration date (where applicable)	

Analysis Number	N4PF072502		Limits	
Test	Results	M.U.	Min	Max
Description	Yellow, crystalliine powder		Yellow, crystalliine powder	Light orange
Identification				
- IR	Conforms to Standard		Conforms to Standard	
- UV	Conforms to Standard		Conforms to Standard	
Loss on drying	0,1	%		0,5
Residue on ignition	0,1	%		0,1
Heavy metals	< 20	ppm		20
Assay (TBAH)	101,2	%dried	98,0	102,0
Related Substances HPLC :				
- Isotretinoin	< 0,01	%		0,50
- Epoxy derivative	< 0,02	%		Less than 0,15
- Impurity a (4-metoxy retinoic acid)	< 0,02	%		Less than 0,15
- Largest unknown impurity	0,02	%		0,10
- Total Impurities(apart from Isotretinoin)	0,09	%		0,50
Residual Solvents (GC) :				
- ICH Class 1 solvents : Not used			Not tested	
- ICH Class 2 solvents :				
Chloroform	< 25	ppm		50
Methanol	34	ppm		100
- ICH Class 3 solvents :				
Ethyl Acetate	< 20	ppm		100
Isopropanol	338	ppm		2000
Related Substances (HPLC) EP :				
- Isotretinoin	< 0,05	%		0,50
- 4-Methoxyretinoic acid (Impurity a)	< 0,05	%		Less than 0,15
- (all-trans)-5,6-epoxy-5,6dihydroretinoic acid	< 0,05	%		Less than 0,15
- Largest unknown impurity	0,06	%		0,10
- Total impurities (apart from isotretinoin)	0,13	%		0,50
Clarity of solution 2%				
- in chloroform (NTU)	0,7	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 : OLON S.P.A. - GARBAGNATE MIL.se

Date

August 29, 2013

Q.C. Manager (Roberto Quaglia)

29/8/13

Reviewed by Qualified Person

29/08/13