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olon s.p.a.

Lote: 01/7/213

CERTIFICATE OF ANALYSIS

Product TRETINOIN-USP/EP current edition **Code N°** 2610460 **Batch N°** 1340323

Manufacturing date Apr 2013 **Retesting date (where applicable)** Mar 2015 **Expiration date (where applicable)**

Analysis Number	N4PF041502		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	0,0	%		0,1
Heavy metals	< 20	ppm		20
Assay (TBAH)	100,7	%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	0,01	%		0,10
- Total Impurities(apart from Isotretinoin)	0,08	%		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	333	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	< 0,05	%		0,10
- Total impurities (apart from isotretinoin)	0,10	%		0,50
Clarity of solution 2%				
- in chloroform (NTU)	0,4	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

September 23, 2013

Q.C. Manager (Roberto Quaglia)

23/9/13

Reviewed by Qualified Person

23/09/13