

Stabilimento di Carbagnate
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Olon S.p.A.
Sede Legale
Strada Rivoltana km 8/7
Rodano (MI)



olon s.p.a.

Certificate of analysis

Product **TRETINOIN-USP/EP current edition** Code N° **2810460** Batch N° **1510002566**

Manufacturing date **DEC 2015** Retest date (where applicable) **NOV 2017**

Analysis Number **P1PF120501** Bulletin **4P1593481**

Test	References	Result	M.U.	Limits
Description		Yellow, crystalline powder	--	Yellow or light orange, crystalline powder
IR		Conforms to Standard	--	Conforms to Standard
UV		Conforms to Standard	--	Conforms to Standard
Loss on drying		0,1	%	≤ 0,5
Sulphated Ash		0,1	%	≤ 0,1
Heavy metals		< 20	ppm	≤ 20
Assay (TBAH)		100,1	%	98,0 + 102,0
Isotretinoin		< 0,01	%	≤ 0,50
Epoxy derivative		0,04	%	< 0,15
Impurity A (4-methoxy retinoic acid)		0,04	%	< 0,15
Highest impurity unknown		0,02	%	≤ 0,10
Total impurities (except Isotretinoin)		0,20	%	≤ 0,50
ICH Class 1 solvents : Not used		Not tested	--	Not tested
ICH Class 2 solvents :		In specifica	--	Conforms
Chloroform		< 25	ppm	≤ 50
Methyl alcohol		< 26	ppm	≤ 100
ICH Class 3 solvents		In specifica	--	Conforms
Ethyl acetate		< 20	ppm	≤ 100
Isopropanol		363	ppm	≤ 2000
Isotretinoin		< 0,05	%	≤ 0,50
Epoxy derivative		< 0,05	%	< 0,15
4-methoxy retinoic acid (imp a)		< 0,05	%	< 0,15
Largest unknown impurity		< 0,05	%	≤ 0,10
Total impurities		< 0,05	%	≤ 0,50
In chloroform		0,4	NTU	≤ 3,0
In THF (10%)		Clear	--	Clear
Packaging and storage		Preserve in airtight containers, protected from light	--	Preserve in airtight containers, protected from light

Capitale Sociale € 40.000.000 I.V. - R.I. Milano, Cod. Fisc. e P. IVA n. 05101100157 - R.E.A. Milano n. 1201640
Società del Gruppo P. & R. S.p.A. soggetta all'attività di direzione e coordinamento della Società Capogruppo P. & R. S.p.A.
Strada Rivoltana km 8/7 - 20080 Rodano (MI) - ITALY capitale sociale € 12.000.000,00 I.V. - C.F.e P.I. 00951030181

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Analysis Date

01/20/2016

QC Manager

20 GEN. 2016

Reviewed by Qualified Person

Notes:

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: Stabilimento di Garbagnate