

Stabilimento di Garbagnate
Via Milano, 186
20024 Garbagnate Milanese (MI)

PEC: olon@pec.olonspa.it
Tel. 02 9944221
Fax 0382.812006

Olon S.p.A.
Sede Legale
Strada Rivoltana km 6/7
Rodano (MI)



Certificate of analysis

Product **TRETINOIN-USP/EP current edition** Code N° **2610460** Batch N° **1410001586**

Manufacturing date **10/2014** Retest date (where applicable) **SEP 2016**

Analysis Number **04PF100902** Bulletin **4P1492277**

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)		101,4	%	98,0 + 102,0
Isotretinoin		< 0,01	%	≤ 0,50
Epoxy derivative		0,07	%	< 0,15
Impurity A (4-methoxy retinoic acid)		0,02	%	< 0,15
Highest impurity unknown		0,02	%	≤ 0,10
Total impurities (except Isotretinoin)		0,15	%	≤ 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		39	ppm	≤ 100
ICH Class 3 solvents		In specifica	--	Conforms
Ethyl acetate		< 20	ppm	≤ 100
Isopropanol		638	ppm	≤ 2000
Isotretinoin		< 0,05	%	≤ 0,50
Epoxy derivative		0,06	%	< 0,15
4-methoxy retinoic acid (imp a)		< 0,05	%	< 0,15
Largest unknown impurity		< 0,05	%	≤ 0,10
Total impurities		0,06	%	≤ 0,50
In chloroform		0,3	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. 06101100157 - 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 6/7 - 20060 Rodano (MI) - ITALY capitale sociale € 12.000.000,00 i.v. - C.F. e P.I. 00651030101

Certificate of analysis

Product **TRETINOIN-USP/EP current edition** Code N° **2610460** Batch N° **1410001586**

Manufacturing date **10/2014** Retest date (where applicable) **SEP 2016**

Analysis Number **04PF100902** Bulletin **4P1492277**

Test	References	Result	M.U.	Limits
------	------------	--------	------	--------

Analysis Date

12/03/2014

QC Manager

- 3 DIC. 2014

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