



Certificate of Analysis

Product name **TRETINOIN - USP/EP Current Edition**

Product Code	2610460	Manufacturing date	10/12/2019
Batch Number	1910002477	Re-test date	09/12/2021
Order	1200168	Certificate Nr.	100000007715
Quantity	3,000 KG	Batch Size	20,505 KG
		Ref. Order	2020 453

Test	References	Specification	M.U.	Result
Appearance	EP / USP	Crystalline powder		Crystalline powder
Colour	EP / USP	Yellow or light orange		Yellow
IR identification	EP2.2.24/USP<197M>	Conforms to standard		Conforms to standard
UV identification	USP <197U>	Conforms to standard		Conforms to standard
Loss on drying	EP2.2.32/USP<731>	<= 0,5	%	0,0
Residue on ignition	EP / USP	<= 0,1	%	0,1
Heavy metals	USP<231> Meth II	<= 20 ppm		< 20 ppm
Assay (TBAH)	EP / USP	98,0 - 102,0	% d.b.	99,3
Isotretinoin	Int Val Meth (HPLC)	<= 0,50	%	< LOQ (0,01)
Epoxy derivative	Int Val Meth (HPLC)	< 0,15	%	0,02
Impurity a (4-methoxy retinoic acid)	Int Val Meth (HPLC)	< 0,15	%	< LOQ (0,02)
Highest impurity unknown	Int Val Meth (HPLC)	<= 0,10	%	0,03
Total impurities (except Isotretinoin)	Int Val Meth (HPLC)	<= 0,50	%	0,07
ICH Class 1 solvents : not used	Int Val Meth (GC)	Not tested		Not tested
ICH Class 2 solvents	Int Val Meth (GC)	In specific		In specific
Chloroform	Int Val Meth (GC)	<= 50	ppm	< LOQ (25)
Methyl alcohol	Int Val Meth (GC)	<= 100	ppm	45
ICH Class 3 solvents	Int Val Meth (GC)	In specific		In specific
Ethyl acetate	Int Val Meth (GC)	<= 100	ppm	< LOQ (20)
Isopropyl alcohol	Int Val Meth (GC)	<= 2000	ppm	571
Isotretinoin (EP)	EP (HPLC)	<= 0,50	%	< LOQ (0,05)
Epoxy derivative (EP)	EP (HPLC)	< 0,15	%	< LOQ (0,05)
Impurity a (EP) (4-methoxy retinoic acid)	EP (HPLC)	< 0,15	%	< LOQ (0,05)
Largest unknown impurity (EP)	EP (HPLC)	<= 0,10	%	< LOQ (0,05)
Total impurities (EP)	EP (HPLC)	<= 0,50	%	< LOQ (0,05)
Clarity of solution in chloroform	Internal Method	<= 3,0	NTU	0,4
Clarity of solution in THF (10%)	Internal Method	Clear		Clear

Packaging and storage: store in airtight containers, in a dry place, protected from light, heat and moisture, at a mean temperature of 25°C (allowed excursions 15-30°C). It is recommended that the contents of an opened container be used as soon as possible and any unused part be protected under vacuum or under atmosphere of an inert gas.

Alessandro Paganelli
Resp. Laboratorio QM
Approved December 19, 2019

Cosimo Chirivi
Qualified Person
Released December 24, 2019

Emission February 10, 2020

Capitale Sociale € 40.000.000 I.v. - R.I. Milano Cod. Fisc. e P.IVA n. 08101100167 - 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 - 20090 Rodano (MI) - ITALY capitale sociale € 12.000.000,00 I.v. - C.F. e P.I. 00651030181

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



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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 Milanese

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