



Certificate of Analysis

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

Product Code 2610460
Batch Number 1910002550
Batch Size 22.055 KG

Manufacturing date 20/12/2019
Re-test date 19/12/2021
Certificate Nr. 890000003356

Test	References	Specification	MLU	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	%	0.0
Heavy metals	USP<231> Meth II	<= 20 ppm		< 20 ppm
Assay (TBAH)	EP / USP	98.0 - 102.0	% d.b.	99.0
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	%	0.06
Total impurities (except Isotretinoin)	Int Val Meth (HPLC)	<= 0.50	%	0.12
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	< LOQ (26)
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	414
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	0.5
Clarity of solution in THF (10%)	Internal Method	Clear		Clear
Particle size distribution d(10)	Internal Method	>= 15	µm	27
Particle size distribution d(50)	Internal Method	<= 150	µm	120
Particle size distribution d(90)	Internal Method	>= 300	µm	317

Alessandro Paganelli
Resp. Laboratorio QM
Approved February 13, 2020

Cosimo Chirivì
Qualified Person
Approved February 14, 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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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.

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

Alessandro Paganelli
Resp. Laboratorio QM
Approved February 13, 2020

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Qualified Person
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