Olon Spa Stab. Garbagnate M.
Via Milano, 186
20024 Garbagnate Milanese (MI)

PEC: olon@pec.olonspa.it
Tel. HQ: +39 02 9523.1
Tel. Plant: +39 02 994421

Olon S.p.A. - Sede Legale
Strada Rivoltana Km 6/7
20053 Rodano (MI)

Certificate of Analysis

Product name	**TRETINOIN - USP/EP Current Edition**		
		Manufacturing date	22/02/2022
Product Code	2610460	Re-test date	21/02/2025
Batch Number	2210000408	Certificate Nr.	100000022387
Order	1221091	Batch Size	24,965 KG
Quantity	3,000 KG	Ref. Order	2022-3224

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	%	0,1
Residue on ignition	EP / USP	<= 0,1	%	0,1
Assay (TBAH)	EP / USP	98,0 - 102,0	% d.b.	99,2
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	%	0,05
Any unspecified impurity	Int Val Meth (HPLC)	<= 0,10	%	0,02
Total impurities (except Isotretinoin)	Int Val Meth (HPLC)	<= 0,50	%	0,11
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	115
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	%	0,05
Any unspecified impurity (EP)	EP (HPLC)	<= 0,10	%	< LOQ (<0,05)
Total impurities (EP)	EP (HPLC)	<= 0,50	%	0,05
Clarity of solution in chloroform	Internal Method	<= 3,0	NTU	0,5
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

Alessandro Paganelli Resp. Laboratorio QM Approved March 04, 2022	Cosimo Chirivì Qualified Person Released March 23, 2022		
'Emission'	Ambra Tesei	Qualified Person	May 25, 2022

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Test	References	Specification	M.U.	Result

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

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'Emission'	Ambra Tesei	Qualified Person	May 25, 2022