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

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

METAPHARMACEUTICAL

N DE LOTE: 02204124

Certificate of ~~Analysis~~

18/04/2024

Product name	**TRETINOIN - USP/EP Current Edition**		
		Manufacturing date	04/07/2023
Product Code	2610460	Re-test date	03/07/2026
Batch Number	2310001248	Certificate Nr.	100000032589
Order	1240426	Batch Size	24,475 KG
Quantity	3,000 KG	Ref. Order	836

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	%	0,0
Assay (TBAH)	EP / USP	98,0 - 102,0	% d.b.	101,8
Isotretinoin	Int Val Meth (HPLC)	<= 0,50	%	< LOQ (<0,01)
Epoxy derivative	Int Val Meth (HPLC)	< 0,15	%	< LOQ (<0,02)
Impurity a (4-methoxy retinoic acid)	Int Val Meth (HPLC)	< 0,15	%	< LOQ (<0,02)
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	366
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)
Any unspecified impurity (EP)	EP (HPLC)	<= 0,10	%	0,07
Total impurities (EP)	EP (HPLC)	<= 0,50	%	0,07
Clarity of solution in chloroform	Internal Method	<= 3,0	NTU	0,3
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 August 01, 2023	Laila Farahat Qualified Person Released August 30, 2023		
'Emission'	Beatrice Parma	QA Specialist	March 14, 2024

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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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