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	24/06/2024
Product Code	2610460	Re-test date	24/06/2027
Batch Number	0024101291	Certificate Nr.	100000035581
Order	1241511	Batch Size	24,525 KG
Quantity	8,000 KG	Ref. Order	4468

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.	100,9
Isotretinoin	Int Val Meth (HPLC)	<= 0,50	%	< LOQ (<0,01)
Epoxy derivative	Int Val Meth (HPLC)	< 0,15	%	0,03
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	%	0,10
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	157
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	%	< LOQ (<0,05)
Total impurities (EP)	EP (HPLC)	<= 0,50	%	< 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

Alessandro Paganelli Resp. Laboratorio QM Approved September 09, 2024	Laila Farahat Qualified Person Released September 09, 2024		
'Emission'	Giovanna Improta	QA SPECIALIST	September 13, 2024

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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

METAPHARMACEUTICAL

N DE LOTE:
0081124

07/11/2024

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