

Stabilimento di Garbagnate
Via Milano, 186
20024 Garbagnate Milanese (MI)

PEC: olon@pec.olonspa.it
Tel. 02 9944221
Fax 0382.812006

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



late: 04/11/15

Certificate of analysis

Product **ISOTRETINOIN USP/EP current edition** Code N° **2611200** Batch N° **1510000329**

Manufacturing date **FEB 2015** Retest date (where applicable) **JAN 2017**

Analysis Number **P1PF021401** Bulletin **4P1512226**

Test	References	Result	M.U.	Limits
Description	EP - USP	Light orange crystalline powder	--	Yellow or light orange crystalline powder
IR	EP 2.2.24; USP <197M>	Conforms to Standard	--	Conforms to Standard
UV	USP <197U>	Conforms to Standard	--	Conforms to Standard
Loss on drying	EP 2.2.32; USP <731>	0,1	%	≤ 0,5
Sulphated Ash	EP 2.4.14; USP <281>	0,03	%	≤ 0,1
Heavy metals	USP <231> Method II; EP2.4.8	< 20	ppm	≤ 20
Assay (TBAH)		100,2	% db	98,0 + 102,0
Tretinoin	EP	< 0,05	%	≤ 0,50
13-cis-5,6-epoxy-5,6-dihydroretinoic acid	EP	0,03	%	≤ 0,15
Specified unidentified impurity RRT = 0,95	EP	0,03	%	≤ 0,15
Any other impurity	EP	< 0,05	%	≤ 0,10
Total impurities	EP	0,12	%	≤ 0,50
OVI (USP)		Not used	--	Not used
ICH Class 1 solvents	Internal method	Not used	--	Not used
ICH Class 2 solvents	Internal method	Conforms	--	Conforms
Cyclohexane	Internal method	212	ppm	≤ 1500
Hexane	Internal method	< 10	ppm	≤ 100
Methyl alcohol	Internal method	79	ppm	≤ 500
ICH Class 3 solvents	Internal method	Conforms	--	Conforms
Ethanol	Internal method	< 50	ppm	≤ 500
Ethyl acetate	Internal method	775	ppm	≤ 2400
d(0,9)	Internal method	292	µm	150+550
d(0,5)	Internal method	154	µm	50+300

Capitale Sociale € 40.000.000 i.v. - R.I. Milano, Cod. Fisc. e P. IVA n. 08101100157 - 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. 00551030181

Certificate of analysis

Product **ISOTRETINOIN USP/EP current edition** Code N° **2611200** Batch N° **1510000329**

Manufacturing date **FEB 2015** Retest date (where applicable) **JAN 2017**

Analysis Number **P1PF021401** Bulletin **4P1512226**

Test	References	Result	M.U.	Limits
Packaging and storage		Store in well closed containers, protected from oxygen and from light, at a mean temperature of 25°C		Store in well closed containers, protected from oxygen and from light, at a mean temperature of 25°C
Packaging 2		with allowed excursions at 15-30 °C.. It is recommended that the contents of an opened container be		with allowed excursions at 15-30 °C.. It is recommended that the contents of an opened container be
Packaging 3		used as soon as possible and any unused part be protected under vacuum or		used as soon as possible and any unused part be protected under vacuum or
Packaging 4		under atmosphere of an inert gas.		under atmosphere of an inert gas.

Analysis Date
03/20/2015

QC Manager

23 MAR. 2015

Reviewed by Qualified Person

Notes:
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: Stabilimento di Garbagnate