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Certificate of analysis

Product ISOTRETINOIN USP/EP current edition **Code N°** 2611200 **Batch N°** 1410001861

Manufacturing date 11/2014 **Retest date (where applicable)** OCT 2016

Analysis Number O4PF111202 **Bulletin** 4P1492367

Test	References	Result	M.U.	Limits
Description	EP - USP	Yellow 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>	0,0	%	≤ 0,1
Heavy metals	USP <231> Method II; EP2.4.8	< 20	ppm	≤ 20
Assay (TBAH)		99,7	% db	98,0 ÷ 102,0
Tretinoin	EP	< 0,05	%	≤ 0,50
13-cis-5,6-epoxy-5,6-dihydroretinoic acid	EP	0,04	%	≤ 0,15
Specified unidentified impurity RRT = 0,95	EP	0,06	%	≤ 0,15
Any other impurity	EP	0,06	%	≤ 0,10
Total impurities	EP	0,23	%	≤ 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	306	ppm	≤ 1500
Hexane	Internal method	< 10	ppm	≤ 100
Methyl alcohol	Internal method	< 50	ppm	≤ 500
ICH Class 3 solvents	Internal method	Conforms	--	Conforms
Ethanol	Internal method	< 50	ppm	≤ 500
Ethyl acetate	Internal method	895	ppm	≤ 2400
d(0,9)	Internal method	325	µm	150÷550
d(0,5)	Internal method	134	µm	50÷300

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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 under atmosphere of	--	used as soon as possible and any unused part be protected under vacuum or under atmosphere of
Packaging 4		an inert gas.	--	an inert gas.

Analysis Date
12/16/2014

QC Manager

16 DIC. 2014

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