



fidia
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Divisione SOLMAG

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Lote: 1020612

CERTIFICATE OF ANALYSIS

Product **TRETINOIN-USP34/EP7** Code N° **2810460** Batch N° **1240039**

Manufacturing date **Jan 2012** Retesting date (where applicable) **Dec 2013** Expiration date (where applicable)

Analysis Number	M4PF012007		
Test	Results	M.U.	Limits
Appearance	Yellow, crystalline powder	---	Yellow to light orange crystalline powder
Identification			
- IR	Conforms to Standard	---	Conforms to Standard
- UV	Conforms to Standard	---	Conforms to Standard
Loss on drying	0,09	%	≤ 0,6
Sulphated ash			
- Sulphated Ash	0,06	%	≤ 0,1
Heavy metals	< 20	ppm	≤ 20
Assay			
- Assay (TBAH)	101,4	% dried	99,0 - 102,0
Related substances (HPLC)			
- Isotretinoin	< 0,06	%	≤ 0,50
- Epoxy derivative	0,03	%	≤ 0,15
- Impurity a (4-methoxy retinoic acid)	0,02	%	≤ 0,15
- Largest unknown impurity	0,06	%	≤ 0,10
- Total impurities (apart from Isotretinoin)	0,22	%	≤ 0,50
Residual solvents (GC)			
- ICH Class 1 solvents: Not used	Not tested	---	Not tested
- ICH Class 2 solvents:			
- Chloroform	< 25	ppm	≤ 50
- Methanol	53	ppm	≤ 100
- ICH Class 3 solvents:			
- Ethyl Acetate	< 20	ppm	≤ 100
- Isopropyl Alcohol	351	ppm	≤ 2000
Related substances (HPLC) EP			
- Isotretinoin	< 0,06	%	≤ 0,50
- 4-methoxy retinoic acid (impurity a)	< 0,06	%	≤ 0,15
- Epoxy derivative	< 0,06	%	≤ 0,15
- Largest unknown impurity	0,06	%	≤ 0,10
- Total impurities (apart from Isotretinoin)	0,22	%	≤ 0,50
Clarity of solution 2%			
- In THF	Clear	---	Clear
- In chloroform (NTU)	0,7	NTU	≤ 3,0
Packaging and storage			Preserve in airtight containers, protected from light

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: SOLMAG S.P.A. - Stabilimento di Garbagnate

Date

X CQ Manager (Roberto Quaglia)

24/05/2012

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