

CERTIFICATE OF ANALYSIS

Material No: 704146
Name: Isotretinoine M 0.5kg

Lot No: 17062154

Manufacturing date: 17-Feb-2017
Retest date: 16-Feb-2022
Actual specification: 989-16

Test Parameter	Specification	Dimension	Result
<u>Characters</u>			
Appearance	Yellow-orange crystalline powder		complies
<u>Identity</u>			
Identification	Must comply		complies
<u>Identity (Raman)</u>			
Identity (Raman)	Must comply		complies
<u>Heavy metals</u>			
Heavy metals	max. 10	ppm	< 10
<u>Loss on drying</u>			
Loss on drying	max. 0.5	%	< 0.1
<u>Residue on ignition</u>			
Residue on ignition	max. 0.1	%	< 0.1
<u>Phosphorus</u>			
Phosphorus	Max.10 ppm		complies
<u>Residual solvents (GC)</u>			
Acetone	max. 100	ppm	5
Ethanol	max. 100	ppm	< 5
Ethyl acetate	max. 100	ppm	< 2
Methanol	max. 100	ppm	19
Heptane	max. 1000	ppm	320
Isopropyl alcohol	max. 2000	ppm	647
Dioxane	max. 50	ppm	< 5
<u>Related substances (HPLC)</u>			
Tretinoin	max. 0.2	%	< 0.1
Unspecified Impurities	Max. 0.10% each		complies
Total unspecified impurities (excluding Tretinoin)	max. 0.5	%	< 0.1
<u>Content (potentiometric)</u>			
Content	98.0 - 102.0	% in dry sub	98.9
<u>Particle size (laser diffraction)</u>			
D (10%)	max. 40	µm	14

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Test Parameter	Specification	Dimension	Result
D (50%)	75 - 150	µm	96
D (90%)	max. 450	µm	437

Release comment: Identification may also be guaranteed by other means / methods (General Notices of Ph.Eur., USP).
Phosphorus is tested on every 10th batch.

Isotretinoin meets the requirements of the current monographs of Ph.Eur., USP, IP and the Certificate of Suitability R1-CEP 1999-068.

Isotretinoin is manufactured according to current GMP requirements.

Released on: **31-Mar-2017**
Manufacturer: Siegfried PharmaChemikalien Minden GmbH
Karlstr. 15
32423 Minden
Germany

Site Quality Manager: Dr. Wenzel

This certificate of analysis has been signed electronically.

It has been created automatically by the validated Siegfried Laboratory Information Management System (LIMS).