

CERTIFICATE OF ANALYSIS

Material No: 704146
Name: Isotretinoine M 0.5kg

Lot No: 17452088

Manufacturing date: 19-Nov-2017
Retest date: 18-Nov-2022
Actual specification: 989-17

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	3
<u>Residual solvents (GC)</u>			
Acetone	max. 100	ppm	4
Ethanol	max. 100	ppm	5
Ethyl acetate	max. 100	ppm	2
Methanol	max. 100	ppm	25
Heptane	max. 1000	ppm	309
Isopropyl alcohol	max. 2000	ppm	592
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	99.8
<u>Particle size (laser diffraction)</u>			
D (10%)	max. 40	µm	16

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D (50%)	75 - 150	µm	106
D (90%)	max. 450	µm	422

Release comment: Identification may also be guaranteed by other means / methods (General Notices of Ph.Eur., USP).

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: 18-Dec-2017
Manufacturer: Siegfried PharmaChemikalien Minden GmbH
Karlstr. 15
32423 Minden
Germany

Site Quality Assurance: Dr. Wienken

This certificate of analysis has been signed electronically.

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