Siegfried

Siegfried PharmaChemikalien Minden GmbH
Karlstr. 15
32423 Minden
Germany

+49 571 391 2684
+49 571 391 2138 Fax

CERTIFICATE OF ANALYSIS

Material No: 704146
Name: Isotretinoine M 0.5kg

Lot No: 19112137
Master Lot: 19112133

Manufacturing date: 15-Mar-2019
Retest date: 13-Mar-2024
Actual specification: 989-20

Test Parameter	Method	Specification	Dimension	Result
Characters	Visual			
Appearance		Yellow-orange crystalline powder		complies
Identity UV	USP			
Identity UV		Absorptivities at 354nm do not differ by more than 3.0% from the reference standard		complies
Identity (Raman)	Inhouse			
Identity (Raman)		In accordance with the reference spectrum		complies
Heavy metals	Ph. Eur.			
Heavy metals		max. 10	ppm	< 10
Loss on drying	Ph. Eur.			
Loss on drying		max. 0.5	%	< 0.1
Residue on ignition	Ph. Eur., USP			
Residue on ignition		max. 0.1	%	< 0.1
Residual solvents (GC)	Ph. Eur., USP			
Acetone		max. 100	ppm	3
Ethanol		max. 100	ppm	< 5
Ethyl acetate		max. 100	ppm	< 2
Methanol		max. 100	ppm	23
Heptane		max. 1000	ppm	283
Isopropyl alcohol		max. 2000	ppm	912
Dioxane		max. 50	ppm	< 5
Related substances (HPLC)	Inhouse			
Tretinoin		max. 0.2	%	< 0.1
Unspecified Impurities		Max. 0.10% each		complies
Total impurities		max. 0.5	%	< 0.1
Triphenylphosphinoxide in Isotretinoin	Inhouse			
Triphenylphosphinoxide		max. 90	ppm	< 45
Content (potentiometric)	Ph. Eur.			
Content		98.0 - 102.0	% in dry sub	100.1

Siegfried

Siegfried PharmaChemikalien Minden GmbH
Karlstr. 15
32423 Minden
Germany

+49 571 391 2684
+49 571 391 2138 Fax

CERTIFICATE OF ANALYSIS

Material No: 704146
Name: Isotretinoine M 0.5kg

Lot No: 19112137
Master Lot: 19112133

Manufacturing date: 15-Mar-2019
Retest date: 13-Mar-2024
Actual specification: 989-20

Test Parameter	Method	Specification	Dimension	Result
Particle size (laser diffraction)	Inhouse			
D (10%)		max. 40	µm	19
D (50%)		75 - 150	µm	125
D (90%)		max. 450	µm	389

Release comment:

Siegfrieds identification tests replace the Ph. Eur./USP tests based on general notice of Ph. Eur./USP.
Related substances (HPLC): Any impurity at a level greater than (>0.05) the reporting threshold is reported with RRT and corresponding quantitative result. If no impurities with relative retention time (RRT) are listed, then no impurities are present above the reporting threshold.

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: **26-Apr-2019**
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).