Siegfried

METAPHARMACEUTICAL

N DE LOTE:
0010722

05/07/2022.

Siegfried PharmaChemikalien
Minden GmbH
Karlstrasse 15
32423 Minden
Germany
+49 571 391 0

Certificate of Analysis

Material No:	**704146**	Master Lot:	**22152170**
Name:	**Isotretinoin M 0.5kg**		
Lot No:	**22152187**	Manufacturing date:	13-Apr-2022
CAS No.	4759-48-2	Retest date:	13-Apr-2027
Formula:	-	Specification date:	16-Feb-2022
Molecular Weight:	-		

Test	Method	Specification	Result
Characters	Visual	Appearance: Yellow-orange crystalline powder	Complies
Identity UV	USP	Identification 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 reference spectrum	Complies
Heavy metals	Ph.Eur.	Max 10 ppm Heavy metals	<10 ppm
Loss on drying	Ph.Eur.	Max 0.5 % Loss on drying	<0.1 %
Residue on ignition	Ph. Eur., USP	Max 0.1 % Residue on ignition	<0.1 %
Residual solvents (GC)	Ph. Eur., USP	Max 100 ppm Acetone	7 ppm
	Ph. Eur., USP	Max 100 ppm Ethanol	<5 ppm
	Ph. Eur., USP	Max 100 ppm Ethyl acetate	<2 ppm
	Ph. Eur., USP	Max 100 ppm Methanol	<3 ppm
	Ph. Eur., USP	Max 1000 ppm Heptane	219 ppm
	Ph. Eur., USP	Max 2000 ppm Isopropyl alcohol	854 ppm
	Ph. Eur., USP	Max 50 ppm Dioxane	<5 ppm
Related substances (HPLC)	Inhouse	Max 0.2 % Tretinoin	<0.05 %
	Inhouse	Max 0.5 % Total impurities	<0.05 %
	Inhouse	Unspecified impurities: Max. 0.10% each	Complies %
Triphenylphosphinoxide in Isotretinoin	Inhouse	Max 90 ppm Triphenylphosphinoxide	<45 ppm
Content (potentiometric)	Ph. Eur./ USP	98.0 - 102.0 % in dry sub. Content	100.1 % in dry sub.
Particle size (laser diffraction)	Inhouse	Max 40 µm D (10%)	23 µm
	Inhouse	75 - 150 µm D (50%)	110 µm
	Inhouse	Max 450 µm D (90%)	389 µm

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Release comment: **meets specification**

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.
This batch was manufactured in accordance to the current applicable regulatory dossiers.
Isotretinoin is manufactured according to current GMP requirements.

Released On:	27-May-2022 10:57 (UTC+02:00)
	on behalf of Siegfried PharmaChemikalien
Released By:	Stefan Wienken
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This certificate of analysis is signed electronically.
It has been created automatically by the validated Siegfried Laboratory Information Management System (LIMS)