

Batch Certificate

Product name	Linola Fett krema/ krema za dermalno uporabo
Importing Country	Slovenia
Marketing Authorisation Number	HN/01/01766/001 ; HN/01/01766/002
Strength / Potency	815 mg/ 100 g
Dosage form	cream
Package Size and type	240 pieces à 700 g
Lot/batch number	203180
MFD (finished product):	06.2022
EXP (finished product):	06.2025
Manufacturing / Packaging site(s): Name and Address	Dr. August Wolff GmbH & Co KG Sudbrackstrasse 56 D – 33611 Bielefeld Manufacturing's Authorisation Issued by: Regional Council Detmold No.: DE_NW_02_MIA_2021_0006/24.05.01-005 Dated: 11.02.2021
Certificate of Analysis (CoA): Date	07. 07. 2022
Comments/remarks:	

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP

Qualified Person: *A. Wolf*

Date: 01-Jul-2022

Name of Product: Linola Fett**700 g**

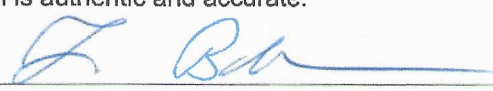
Batch: 203180 Material-No.: 00063685

Date of manufacture: Jun 9, 2022 Date of release: Jul 1, 2022 Expiration date: Jun 30, 2025

Test	Release Specifications	Results
Appearance	smooth	smooth
Colour	slightly yellowish	slightly yellowish
Odour	typical like wool fat	typical like wool fat
Microscopy	evenly distributed	evenly distributed
Centrifuge resistance I (water)	no water separation	no water separation
Centrifuge resistance II (fat)	<= 1mm fat separation	<= 1mm fat separation
Ident. unsaturated fatty acids (TLC)	complies with reference	complies with reference
Assay unsaturated fatty acids E3MB (LC)	95.0 - 105.0 %	101.0 %
Assay unsaturated fatty acids E3MB (LC)	774.3 - 855.7 mg/100g	823.5 mg/100g
Peroxide value	<= 5	2
Dosage form	cream	cream
Consistency by penetrometry (microcone)	4.0 - 17.0 mm	13.0 mm
Packaging size	700g	700g
Fill mass (mean)	>= 700.00 g	702.00 g
TAMC	<= 200 CFU/g	< 10 CFU/g
TYMC	<= 20 CFU/g	< 10 CFU/g
Pseudomonas aeruginosa	absent/g	absent/g
Staphylococcus aureus	absent/g	absent/g

I hereby certify that the above information is authentic and accurate.

Bielefeld, Jul 7, 2022


Dr. Ballwanz (Head of Quality Control)