Logistic batch number

5710039-5043

GALDERMA
EST. 1981

CERTIFICATE OF COMPLIANCE

PRODUCT DESCRIPTION : **AKLIEF® Trifarotene 50 microgram/g – Cream - 30G**

BATCH NUMBER : **5710039**

MANUFACTURING SITE : **LABORATOIRES GALDERMA, ZI MONTDESIR, ALBY SUR CHERAN, 74540, FRANCE**

AUTHORIZATION NUMBER : **2024_052_1_2 - February 15, 2024**

IMPORTING COUNTRY (DESTINATION) : **RUSSIAN FEDERATION**

FORMULA NUMBER : **0710**

MANUFACTURING DATE (MM/DD/YYYY) : **08/22/2025**

PRODUCT CODE : **025043**

SHELF LIFE : **24 MONTHS**

PRODUCT REGISTRATION NUMBER : **LP-N°(001233)-(RG-RU)**

EXPIRY DATE (MM/YYYY) : **07/2027**

REFERENCE SPECIFICATION : **GD.03.DEU.01780.R01.01.EU.32P51**

ANALYSIS NUMBER : **B-20250901-00002**

ANALYSIS TYPE : **Full**

RELEASED UNITS QUANTITY : **7632 Units**

MEAN FILL (>= Nominal value of label claim AC.02.SOP.5005) : **30.4 g**

TESTS	METHODS	SPECIFICATIONS	RESULTS
Macroscopic appearance	Visual examination (AL.74.ATP.3001)	White and homogeneous preparation	Complies
Trifarotene (Identification and assay)	AL.74.ATP.0437		
Identification CD5789 (HPLC)		Retention time identical to that of the reference	Complies
Trifarotene (Identification) by UV spectrum		UV spectrum identical that of the reference	Complies
Phenoxyethanol (Identification and assay) (HPLC)	AL.74.ATP.0438		
Identification of phenoxyethanol (HPLC)		Retention time identical to that of the reference	Complies
pH	Ph.Eur. 2.2.3* (AL.74.ATP.3000)	4.5 - 6.5	5.7
Viscosity *(Brookfield RVDVII+, SSA, mobile 29, 10 rpm, 25,0 +/- 0,5 °C ; 2 min)*	Ph.Eur. 2.2.10* (AL.74.ATP.3003)	60 000 - 100 000 mPa.s	74000 mPa.s
Assay of Impurities (HPLC)	AL.74.ATP.0437		
Any unspecified		<= 1.0 % LC	0.3 % LC
Sum of impurities		<= 1.0 % LC	0.4 % LC
Trifarotene (Identification and assay)	AL.74.ATP.0437		
Trifarotene (Assay) (HPLC)		95.0 - 105.0 % LC	99.0 % LC
Phenoxyethanol (Identification and assay) (HPLC)	AL.74.ATP.0438		
Phenoxyethanol (Assay) (HPLC) (%LC)		90.0 - 110.0 % LC	100.6 % LC
Total aerobic microbial count (TAMC)	Ph. Eur 2.6.12/USP 1111,61/JP G4,4.05*	NMT 100 CFU per gram	< 100 CFU/g
Total combined yeasts / moulds count (TYMC)	Ph. Eur 2.6.12/USP 1111,61/JP G4,4.05*	NMT 10 CFU per gram	< 10 CFU/g
Specified micro-organisms	Ph. Eur 2.6.13/USP 1111,62/JP G4,4.05*		

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TESTS	METHODS	SPECIFICATIONS	RESULTS
Pseudomonas aeruginosa		Absence per gram	Absence per gram
Staphylococcus aureus		Absence per gram	Absence per gram

**All pharmacopoeia methods are carried out according to the current edition.*

NOTES : **PA : C28520**
API manufacturer :
HAS HEALTHCARE ADVANCED SYNTHESIS
Via Industria 24
6710 BIASCA
SWITZERLAND

Certification :

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 or product specification file for Investigational Medicinal Products.

The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

This document has been electronically signed by a qualified person :

LESPINASSE Ségolène

Date : **September 25, 2025**