



6710056-5043

CERTIFICATE OF COMPLIANCE

PRODUCT DESCRIPTION : AKLIEF Trifarotene 50 microgram/g – Cream - 30GBATCH NUMBER : 6710056MANUFACTURING SITE : LABORATOIRES GALDERMA, ZI MONTDESIR, ALBY SUR CHERAN, 74540, FRANCEAUTHORIZATION NUMBER : 2024_052_1_2 - February 15, 2024IMPORTING COUNTRY (DESTINATION) : RUSSIAN FEDERATIONFORMULA NUMBER : 0710MANUFACTURING DATE (MM/DD/YYYY) : 09/05/2026PRODUCT CODE : 025043SHELF LIFE : 24 MONTHSPRODUCT REGISTRATION NUMBER : LP-N°(001233)-(RG-RU)EXPIRY DATE (MM/YYYY) : 09/2028REFERENCE SPECIFICATION : GD.03.DEU.01780.R01.01.EU.32P51ANALYSIS NUMBER : B-20260914-00018ANALYSIS TYPE : FullRELEASED UNITS QUANTITY : 30336 UnitsMEAN FILL ($\geq$ Nominal value of label claim AC.02.SOP.5005) : 30.5 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	5.6
Viscosity	Ph.Eur. 2.2.10* (AL.74.ATP.3003)	60 000 - 100 000 mPa.s	71000 mPa.s
(Brookfield RVDVII+, SSA, mobile 29, 10 rpm, 25,0 +/- 0,5 °C ; 2 min)			
Assay of Impurities (HPLC)	AL.74.ATP.0437		
Any unspecified		$\leq$ 1.0 % LC	0.1 % LC
Sum of impurities		$\leq$ 1.0 % LC	0.1 % LC
Trifarotene (Identification and assay)	AL.74.ATP.0437		
Trifarotene (Assay) (HPLC)		95.0 - 105.0 % LC	101.0 % LC
Phenoxyethanol (Identification and assay) (HPLC)	AL.74.ATP.0438		
Phenoxyethanol (Assay) (HPLC) (%LC)		90.0 - 110.0 % LC	99.6 % 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		



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BATCH NUMBER : 6710056

TESTS	METHODS	SPECIFICATIONS	RESULTS
	1111,62/JP G4,4.05*		
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 : Normative Document : LP-n° (001233) - (RG-RU) dated 19.09.2022

Storage Conditions : No higher than 25.

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 :

ARNOULD Amandine

Date : 12-Oct-2026 02:16:28 UTC