Logistic batch number

6074316-1826

GALDERMA
EST. 1981

CERTIFICATE OF COMPLIANCE

PRODUCT DESCRIPTION : DIFFERIN® - ADAPALEN 0.1 % - CREAM 30 g

BATCH NUMBER : 6074316

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 : 0074

MANUFACTURING DATE (MM/DD/YYYY) : 07/21/2026

PRODUCT CODE : 021826

SHELF LIFE : 36 MONTHS

PRODUCT REGISTRATION NUMBER : LP-N°(010937)-(RG-RU)

EXPIRY DATE (MM/YYYY) : 07/2029

REFERENCE SPECIFICATION : GD.02.DEU.01862.R00.01.RU.32P51

ANALYSIS NUMBER : B-20260727-00048

ANALYSIS TYPE : Full

RELEASED UNITS QUANTITY : 30780 Units

MEAN FILL (>= Nominal value of label claim AC.02.SOP.5005) : 30.2 g

TESTS	METHODS	SPECIFICATIONS	RESULTS
Macroscopic appearance	Visual examination (AL.74.ATP.3001)	White, shiny cream	Complies
pH *(25°C)*	Ph.Eur. 2.2.3* (AL.74.ATP.3000)	6.0 - 7.0	6.4
Particles size	Ph.Eur. 2.9.37* (AL.74.ATP.3007)		
<= 20 µm		>= 90.0 %	100.0 %
<= 50 µm		>= 99.0 %	100.0 %
Viscosity *(25 ºC/5min - Rheometer with cone & plate)*	Ph.Eur. 2.2.10* (AL.74.ATP.3003)	700 - 7 000 mPa.s	1534 mPa.s
Adapalene (Assay and Identification) (LC)	AC.02.ATP.3528		
Identification		Positive	Positive
Phenoxyethanol (Assay and Identification) (LC)	AC.02.ATP.3542		
Identification		Positive	Positive
Methyl parahydroxybenzoate (Assay and Identification) (LC)	AC.02.ATP.3542		
Identification		Positive	Positive
Propyl parahydroxybenzoate (Assay and Identification) (LC)	AC.02.ATP.3542		
Identification		Positive	Positive
Adapalene (Assay and Identification) (LC)	AC.02.ATP.3528		
Content		0.095 - 0.105 % w/w	0.099 % w/w

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TESTS	METHODS	SPECIFICATIONS	RESULTS
% LC content		95 - 105 % LC	100 % LC
Phenoxyethanol (Assay and Identification) (LC)	AC.02.ATP.3542		
Content		0.450 - 0.550 % w/w	0.497 % w/w
% LC content		90 - 110 % LC	99 % LC
Methyl parahydroxybenzoate (Assay and Identification) (LC)	AC.02.ATP.3542		
Content		0.180 - 0.220 % w/w	0.199 % w/w
% LC content		90 - 110 % LC	100 % LC
Propyl parahydroxybenzoate (Assay and Identification) (LC)	AC.02.ATP.3542		
Content		0.090 - 0.110 % w/w	0.099 % w/w
% LC content		90 - 110 % LC	99 % LC
Total aerobic microbial count (TAMC) + Total combined yeasts/moulds count (TYMC)	Ph. Eur 2.6.12/USP 1111,61/JP G4,4.05*	NMT 100 CFU/g	< 100 CFU/g
Specific microorganisms	Ph. Eur 2.6.13/USP 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 : ND LP-n° (010937)-(RG-RU) dated 15.07.2025**
Storage Conditions : No higher than 25. Do not freeze
API manufacture:
FINORGA
497, route de Givors – BP 9
38670 CHASSE SUR RHONE

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.

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TESTS	METHODS	SPECIFICATIONS	RESULTS

This document has been electronically signed by a qualified person :

BLANCO Dorota

Date : August 25, 2026

LABORATOIRES GALDERMA
ZI MONTDESIR, ALBY SUR CHERAN, 74540, FRANCE