GALDERMA
EST. 1981

CERTIFICATE OF COMPLIANCE

PRODUCT DESCRIPTION : **DIFFERIN® 0.1 % GEL 30 G**

BATCH NUMBER : **6051300**

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 : **0051**

MANUFACTURING DATE (MM/DD/YYYY) : **06/26/2026**

PRODUCT CODE : **021678**

SHELF LIFE : **36 MONTHS**

PRODUCT REGISTRATION NUMBER : **ND LP-n° (010910)-(RG-RU)**

EXPIRY DATE (MM/YYYY) : **06/2029**

REFERENCE SPECIFICATION : **F0051.CTD32P51.V00.RU**

ANALYSIS NUMBER : **B-20260715-00030**

ANALYSIS TYPE : **Full**

RELEASED UNITS QUANTITY : **56520 Units**

MEAN FILL (>= Nominal value of label claim AC.02.SOP.5005) : **30.5 g**

TESTS	METHODS	SPECIFICATIONS	RESULTS
Macroscopic appearance	Visual examination (AL.74.ATP.3001)	Smooth white homogeneous gel	Complies
pH *(25°C, on the gel)*	Ph.Eur. 2.2.3* (AL.74.ATP.3000)	4.75 - 5.25	5.03
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, 5 MIN, BROOKFIELD RVDVII+, HELIPATH, SPINDLE F, 12 RPM)*	Ph.Eur. 2.2.10* (AL.74.ATP.3003)	50 000 - 100 000 mPa.s	80815 mPa.s
Adapalene (Assay and Identification) (LC)	AC.02.ATP.3528		
Identification		Positive	Positive
Phenoxyethanol (Assay and Identification) (LC)	AC.02.ATP.3529		
Identification		Positive	Positive
Methyl parahydroxybenzoate (Assay and Identification) (LC)	AC.02.ATP.3529		
Identification		Positive	Positive
Adapalene (Assay and Identification) (LC)	AC.02.ATP.3528		
Content		0.095 - 0.105 % w/w	0.100 % w/w
% LC content		95 - 105 % LC	100 % LC
Phenoxyethanol (Assay and Identification) (LC)	AC.02.ATP.3529		
Content		0.225 - 0.275 % w/w	0.252 % w/w

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% LC content		90 - 110 % LC	101 % LC
Methyl parahydroxybenzoate (Assay and Identification) (LC)	AC.02.ATP.3529		
Content		0.090 - 0.110 % w/w	0.100 % w/w
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 per gram	< 100 CFU/g
Methyl parahydroxybenzoate (Assay and Identification) (LC)	AC.02.ATP.3529		
% LC content		90 - 110 % LC	100 % LC
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° (010910)-(RG-RU) dated 11.07.2025**
Storage Conditions : No higher than 25. Do not freeze

API manufacturer :
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.

This document has been manually signed by a qualified person : Blandine GIRY

Date : 03 SEPT. 2026

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