Logistic batch number

6021375-1812

GALDERMA
EST. 1981

CERTIFICATE OF COMPLIANCE

PRODUCT DESCRIPTION : BASIRON ® AC - BENZOYL PEROXIDE 5 % GEL - 40 g

BATCH NUMBER : 6021375

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 : 0021

MANUFACTURING DATE (MM/DD/YYYY) : 06/22/2026

PRODUCT CODE : 021812

SHELF LIFE : 24 MONTHS

PRODUCT REGISTRATION NUMBER : P N014057/01

EXPIRY DATE (MM/YYYY) : 06/2028

REFERENCE SPECIFICATION : CD1579.F21.CTD32P51.V02.RU

ANALYSIS NUMBER : B-20260629-00031

ANALYSIS TYPE : Full

RELEASED UNITS QUANTITY : 77400 Units

MEAN FILL (>= Nominal value of label claim AC.02.SOP.5005) : 40.5 g

TESTS	METHODS	SPECIFICATIONS	RESULTS
Macroscopic appearance	Visual examination (AL.74.ATP.3001)	White to off-white smooth and homogeneous gel without foreign particles	Complies
Odour	Ph.Eur. 2.3.4* (AL.74.ATP.3002)	Characteristic odour	Complies
pH *(25°C)*	Ph.Eur. 2.2.3* (AL.74.ATP.3000)	4.8 - 5.8	5.5
Viscosity *(25 ºC, 5 MIN, BROOKFIELD RVDVII+, SSA, SPINDLE 29, 3 RPM)*	Ph.Eur. 2.2.10* (AL.74.ATP.3003)	75 000 - 200 000 mPa.s	153000 mPa.s
Particles size	Ph.Eur. 2.9.37* (AL.74.ATP.3007)		
<= 25 µm		>= 95.0 %	100.0 %
<= 100 µm		>= 99.0 %	100.0 %
Benzoyl Peroxyde (Assay and Identification) (LC)	AL.74.ATP.3512		
Identification		Positive	Positive
Disodium edetate (Identification) *(Identification)*	AL.74.ATP.3517	Positive	Positive
Benzoyl Peroxyde (Assay and Identification) (LC)	AL.74.ATP.3512		
Content		4.75 - 5.25 % w/w	4.97 % w/w
% LC content		95 - 105 % LC	99 % 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
Specific microorganisms	Ph. Eur 2.6.13/USP		

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	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 P N014057/01 dated 15.08.2025**
Storage Conditions : No higher than 25. Do not freeze

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 :

BESSAA Jade

Date : July 27, 2026