

Batch N° / T88
№ Серії: T88

Manufacturing date/
Дата виробництва: 27/03/2024

Control N°/
№ Контролю : NA

Country of manufacturer/
Країна виробника: France
Франція

Expiry/
Термін придатності: 03/2026

Date of analysis/
Дата аналізу: 14/05/2024

ANALYSIS/АНАЛІЗ	SPECIFICATIONS/СПЕЦИФІКАЦІЇ	RESULTS/ РЕЗУЛЬТАТИ
General Characters/ Загальні властивості		
Appearance (Visual inspection) Зовнішній вигляд (Візуальний огляд)	White to slightly yellow pad impregnated with the hygiene lotion Серветка, зволожена очищувальним лосьйоном, кольором біла до злегка жовтої	Complies Відповідає
Leak test (Internal method (IPC)) Тест на герметичність (Вн. метод (ІПК))	No leakage Відсутність витoku	Complies Відповідає
Identification/ Ідентифікація		
Capryloyl glycine (Internal method (HPLC)) Каприлоїл гліцин (Вн. метод (ВЕРХ))	Chromatogram is identical to that of standard Хроматограма ідентична хроматограмі стандарту	Complies Відповідає
Assay/ Аналіз		
Capryloyl glycine (Internal method (HPLC)) Каприлоїл гліцин (Вн. метод (ВЕРХ))	1.80 - 2.20 g/100 g 1.80 - 2.20 г/100 г	2.05 g/100 g 2.05 г/100 г
Sterility Eur. Ph. 2.6.1 Стерильність Євр.Фарм. 2.6.1	Sterile Стерильно	Complies Відповідає

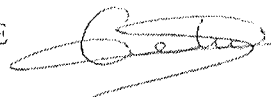
PRODUCT COMPLIES/ ПРОДУКЦІЯ ВІДПОВІДАЄ

We hereby certify that the above information is authentic and accurate. This certificate is the copy of the manufacturer certificate of analysis; this batch has been manufactured, packed and analysed in full compliance with the specifications described in the dossier of the country. This batch is released for sale.


Цим підтверджую, що вищевказана інформація є справжньою і точною. Цей сертифікат є копія сертифікату якості виробника; ця партія була виготовлена, упакована і проаналізована в повній відповідності зі специфікаціями, описаними в досьє країни. Ця партія випущена у продаж.

Clermont-Ferrand, 15 July 2024
Клермон-Ферран,

JULIE GENDRE



PRODUCT QUALITY MANAGER

BULLETIN D'ANALYSES CERTIFICATE OF ANALYSIS - Sachet Bag	 eurowipes ANJAC	N° : PRO-E-117
		Page : 1 / 1
		Date : 20/09/2022
		Edition : 8

Version électronique du document original rédigé, vérifié et validé en interne
 Electronic version of the original document written, checked and validated internally.

Produit fini : *Finish Product* : Blephaclean

Référence : *Reference* : CMC-DP-2305 V03 T1177, Wipes

N° de Lot : Batch N° : T88	Date de fabrication : Manufacturing date : 27/03/2024	Site de fabrication : Manufacturing site : EURO WIPES 2, rue du Grand Champ Parc d'Activités de l'Aunay 28400 NOGENT LE ROTROU
Code Article : Article number : 1176LG20L13	Péremption : Validity : 03/2026	Date d'analyse : Analysis date : 14/05/2024

ANALYSES ANALYSIS	RESULTATS RESULTS	SPECIFICATIONS SPECIFICATIONS
Caractères généraux <i>General Characters</i>		
Aspect <i>Appearance</i>	CONFORME	Lingette blanche ou sensiblement jaune imprégnée de solution d'hygiène. <i>White to slightly yellow pad impregnated with the hygiene lotion</i>
Test d'étanchéité <i>Leak test</i>	CONFORME	Absence de fuite <i>No leakage</i>
Identification <i>Identification</i>		
Capryloyl glycine <i>Capryloyl glycine</i>	CONFORME	Chromatogramme identique à celui du standard <i>Chromatogram is identical to that of standard</i>
Essais <i>Tests</i>		
Capryloyl glycine <i>Capryloyl glycine</i>	2.05	1,80 -2,20 g/100g 1.80 -2.20 g/100g
Stérilité <i>Sterility</i>	CONFORME	Conforme au test Ph. Eur. en vigueur <i>Complies with current Eur. Ph. test</i>


Je certifie par la présente que les informations ci-dessus sont authentiques et exactes. Ce lot de produit a été fabriqué, y compris le conditionnement et le contrôle qualité sur le site mentionné ci-dessus, en pleine conformité avec les exigences ISO applicables de l'autorité de réglementation locale et avec les spécifications de l'autorisation de mise sur le marché du pays importateur. Les dossiers de fabrication, de conditionnement et de contrôle qualité des lots ont été examinés et se sont révélés conformes aux ISO applicables.

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control at the above mentioned site in full compliance with the applicable ISO requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with applicable ISO.

Date de signature :

04 JUIN 2024

A.Joffroy – Responsable Contrôle Qualité


EUROWIPES
 TAKE CARE ON LINE
 SERVICE QUALITÉ
 Parc d'Activités de l'Aunay
 2, rue du Grand Champ
 28400 NOGENT-LE-ROTROU - FRANCE
 Tél. 02 37 54 50 70 - Fax 02 37 54 57 74
 www.eurowipes-anjac.com

Euro Wipes

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www.eurowipes-anjac.com

Electronic version of the original document written, checked and validated internally.

Sterile pads BLEPHACLEAN

Product presentation : wipes

Batch Number :	Validity :	Product category :	Client article :	EW article :	Country of destination and registration N°:	Quantity certified :
T88	03/2026	Cosmetic	1176LG20L13	5400765	Ukraine	30 720 étuis

Production date (bulk) :	27/03/2024	Production Line (packaging) :	DSP3	Production date (packaging) :	02-03-04-05/04/2024
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- Registration document:
- ⇒ *Technical dossier for medical devices*
 - ⇒ *General technical and quality agreement EUROWIPES/THEA in effect*
 - ⇒ *Specification sheet*

ESTABLISHMENT AND VALIDATION RECORD BATCH

To be sent to the Resp. Quality Control Laboratoires THEA: 9 representative boxes of the batch distributed over the various conditioned articles (of which minimum 3 boxes per article)

Validation of sterilization: controlled doses : - on P between 27,8 kGy and 36,8 kGy ⇒ **Compliant** - Non-Compliant
- on G ≥ 23,3 kGy

Timeliness :

- number of days between the start of the preparation of the lot and the end of the filling (target ≤ 10 days) Nb of days = 9 Jours C NC
- number of days between filling and sterilization (target ≤ 10 days) Nb of days = 4-4 Jours C NC

Documents to be sent:

- Analysis report (PRO-E-117)
- Text report(s): sterility test
- Modus operandi of lotion manufacturing (R°1403717C)
- Microbiological Analysis of bulk B1 and B2 (MES-E-157)
- A complete clean up of the factory line (PRO-E-109)
- Cleaning & Disinfection registration (PRO-E-114 ou PRO-E-105)
- Packinglist points Sending IONISOS (ACH-E-10)
- Certificate of ionization
- Microbiological Analysis Finished Product (MES-E-178)
- Certificate of analysis of Capryloyl glycine : bulk and finished product (MES-E-165)
- Analysis certificat : Aspect Test (MES-E-164 ou MES-E-208)

Compliance of the expiry entered in the ERP : C NC

DECISION FINALE / FINAL DECISION

I hereby certify that the above information is authentic and accurate. I verify that the products and manufacturing steps of this batch are in compliance with the requirements in force:

- GMP,
- Regulation CE1223/2009 for cosmetic products,
- Current Medical Device Regulation in EU and in the destinations country/countries
- General technical and quality agreement EUROWIPES/THEA,
- Technical dossier for medical devices.

COMPLIANT on **04 JUIN 2024**

NON-COMPLIANT on

VISA of authorized person:

IT acceptance / ERP:

Ref. if non-conformity(ies) during this batch

Comments:

LABORATOIRES
Théa

Autorisation pour expédition par
l'Assurance Qualité
Authorization for shipment by
Quality Assurance
Date : 15-Jul-2024
By : Severine BARBATE

Alexandre JOFFROY
 Responsable Contrôle Qualité

EUROWIPES
 TAKE CARE OF LIFE
 SERVICE QUALITÉ
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Customer authorization obtained for a delivery under "quarantine status"