



Farmila-Thea Farmaceutici SpA  
Via E. Fermi, 50 20019 Settimo Milanese (Mi)

Product Name: Theagel®

Code/ Код: 6000863

Batch n°/Серія: 106397

Expiry date/ Термін придатності: 04.2026

Manufacturing date/ Дата виробництва:

Batch quantity / Розмір серії: 14010

29.04.2024

Date of analysis/ Дата аналізу:

Certificate of Analysis N°/ Сертифікат аналізу №.: 040000031610

24.05.2024

TESTS/ АНАЛІЗ	SPECIFICATIONS/ СПЕЦИФІКАЦІЇ	RESULTS/ РЕЗУЛЬТАТИ
Appearance (visual inspection) Зовнішній вигляд (візуальний огляд)	Clear colourless to yellow-brownish gel  Прозорий гель від безбарвного до жовто-коричневого	Complies Відповідає
pH (Current Eur.Ph 2.2.3.) рН (Діюча Євр. Фарм 2.2.3.)	6.8 – 7.8 6,8 – 7,8	7.4 7.4
Viscosity (Current Eur.Ph 2.2.10) В'язкість (Діюча Євр. Фарм 2.2.10)	15000 -25000 mPa.s 15000 -25000 мПа.с	17750 mPa.s 17750 мПа.с
Stability to centrifugation Стійкість до центрифугування	No separation of phase Немає поділу фази	Complies Відповідає
Loss on drying (Current Eur.Ph 2.2.32) Витрати при висиханні (Діюча Євр. Фарм 2.2.32)	89.5 – 94.5 % 89,5 – 94,5 %	92.0% 92.0%
Average content Середній вміст	≥ 30 g ≥ 30 г	31 g 31 г
Sterility (Current Eur.Ph 2.6.1.) Стерильність (Діюча Євр. Фарм 2.6.1.)	Sterile Стерильний	Sterile Стерильний
Packaging control Контроль пакування	Complies Відповідає	Complies Відповідає
State Стан	APPROVED СХВАЛЕНО	

I hereby certify that the above information is authentic and accurate This batch of finished product has been controlled at the above mentioned site in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country. The Analytical Batch Record and analysis records were reviewed and found to be in compliance.

Quality Control Manager/ Margherita Valente

Date: 24.05.24

Менеджер з контролю якості

Qualified Person/ Laura Iannotti

Date: 24.05.24

Уповноважена особа

Dr. ... 52342

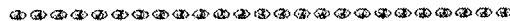
05.09.2024



Certificate No. BC604/2024

Batch Certificate for Cosmetic Product

Product Name	Theagel
Product Code	687G30L10
Dosage Form	ophthalmic gel
Strength/Potency	Carbopol
Batch Number	106397
Expiry Date	04/2026
Package Size	30 g
Manufacturing Date	29/04/2024
Analytical Certificate No.	040000031610
Number of Released Units	14010
Country	UKRAINE
Manufacturer	Farmila-Thea Farmaceutici S.p.A.
Authorization No. Manufacturing Site	aM - 47/2023
Reference No. Cosmetic Products Notification Portal	12.2-18-3/17544
Remarks	-----



I hereby certify that the above information is authentic and accurate and that all the manufacturing stages of this batch of finished product have been carried out including quality control in full compliance with the GMP at the above mentioned site and in full compliance with requirements of the EU and of the Marketing Authorisation(s) of the destination country/countries.

That Farmila-Thea Farmaceutici S.p.A. complies with the ISO 22716:2007 for the manufacturing of cosmetics for ophthalmology, also for third parties (Certificate No. 19602)


The documentation pertinent to the lot described above was reviewed and all the aspects of manufacturing and packaging were judged acceptable and consistent with the requirements outlined in the Master Manufacturing documents. All the components were analysed and released in compliance with Specifications and any deviation was thoroughly reviewed and solved before the release. This batch meets acceptance requirements and it is released according to current rules governing cosmetic product in the European Community.

Qualified Person

Dr.ssa Laura Iannotti

Authorization No. aIDT-34/2013

Release date: 24/06/24



**LABORATOIRES Théa**

Autorisation pour expédition par  
l'Assurance Qualité  
**Authorization for shipment by  
Quality Assurance**

Date : 27-Jun-2024  
By : Andréa LEVADOUX