



NATIONAL CENTER FOR PUBLIC HEALTH AND PHARMACY

Directorate for Drug Inspection

National Centre For Public Health And Pharmacy

CERTIFICATE NUMBER: *NNGYK/9422-4/2025*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER^{1,2}

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Hungary confirms the following:

The manufacturer: ***Base Medico Private Limited***

Site address: ***Survey No. 570, Near Essar Petrol Pump, Village Tundav, Taluka Savli, Vadodara, 391775, India***

OMS Organisation Id. / OMS Location Id.: ***ORG-100054290 / LOC-100096091***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-12-12***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572.³

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (<http://eudragmdp.ema.europa.eu/>).

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

¹The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC is also applicable to importers.

²Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

³These requirements fulfil the GMP recommendations of WHO.



Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.13 Tablets
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	1.6.2 <i>Microbiological: non-sterility</i> 1.6.3 <i>Chemical/Physical</i>

2025-05-09

Name and signature of the authorised person of the Competent Authority of Hungary

Zakariás El Koulali

Zakariás El Koulali
National Centre For Public Health And Pharmacy
 Tel:
 Fax:



APOSTILLE

(Convention de la Haye du 5 octobre 1961)

1. ország:
pays:
country:

Magyarország
Hongrie
Hungary

Ezt a közokiratot
Le présent acte public
This public document

2. írta alá:
a été signé par:
has been signed:

ZAKARIÁS EL KOULALI

3. minőségében eljárva:
agissant en qualité:
acting in capacity of

DIRECTOR

4. az okirat pecsétjével
(bélyegző-lenyomatával) van
ellátva:
est revêtu du (timbre de):
bears the seal/stamp of:

NEMZETI NÉPEGÉSZSÉGÜGYI ÉS GYÓGYSZERÉSZETI
KÖZPONT
11.

Tanúsítja
Atteste
Certified

5. helység
a
at

Budapest

6. időpont: év 2025. hónap június nap 18.
le: an mois jour
date: year month day

7. kiállító:
par:
by:

Magyarország Külgazdasági és Külügyminisztériuma
Ministère des Affaires étrangères et du Commerce extérieur de
Hongrie
Ministry of Foreign Affairs and Trade of Hungary

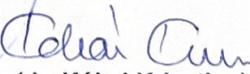
8. ügyszám: HUNFH 2025CLA002305/FH 001
sous No.:
No.:

illeték: 5.500,- Ft.
taxe:
fee:

9. pecsét (bélyegzőlenyomat)
sceau (timbre):
seal/stamp:

10. aláírás
signature:
signature:




(dr. Kókai Krisztina)
referatúra-vezető

*This Apostille only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears.
This Apostille does not certify the content of the document for which it was issued.*