

Certificate No.: OGYÉI/.....28087-5...../2018

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 : **CHINOIN Zrt / CHINOIN Pharmaceutical and Chemical Works Private Co. Ltd.**

Site address : **Tó u.1-5., Budapest, H-1045, Hungary**

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2018-04-20**, it is considered that it complies with :

- The principles of GMP for active substances (3) referred to in Article 47 of Directive 2001/83/EC

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. 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 EudraGMP. If it does not appear, please contact the issuing authority.

(1) The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.

(2) Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

(3) These requirements fulfil the GMP recommendations of WHO.

Name and signature of the authorized person of the Competent Authority of **Hungary**:

Date:

2018 JÜN 01



Ipolya Tarnai
Head of Inspectorate



Part 2

Manufacture of active substance. Names of substances subject to inspection :

[130209-82-4] LATANOPROST (en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance : LATANOPROST	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : .
3.5	General Finishing Steps
	3.5.1 Physical processing steps : . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Name and signature of the authorized person of the Competent Authority of *Hungary*:

Date:

2018 JÜN 01


 Ibolya Tarján
 Head of Inspectorate

A P O S T I L L E
(Convention de la Haye du 5 octobre 1961)

1. ország: Magyarország
pays: Hongrie
country: Hungary

Ezt a közokiratot
Le présent acte public
This public document

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

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

4. az okirat pecsétjével
(bélyegző-lenyomatával) van
ellátva: ORSZÁGOS GYÓGYSZERÉSZETI ÉS ÉLELMEZÉS-
EGÉSZSÉGÜGYI INTÉZET 12.
est revêtu du (timbre de):
bears the seal/stamp of:

Tanúsítja
Attesté
Certified

5. helység Budapest
a
at

6. időpont: év 2018. hónap július nap 4.
le: an mois jour
date: year month day

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

8. ügyszám 1: DF010074/2018. ügyszám 2: HUNAF 2018CLA006294
sous No.: sous No.:
No.: No.:

illeték: 5.500,- Ft.
taxe:
fee:

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

10. aláírás
signature:
signature:




(dr. Németh Mónika)
vezető-tanácsos

*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.*