Health Products Regulatory Authority

CERTIFICATE NUMBER: ***30759***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :

The competent authority of Ireland confirms the following:
The manufacturer: ***MYLAN LABORATORIES LIMITED***
Site address: ***F-4 and F-12, Malegaon MIDCSinnar Nashik District, 422113, Maharashtra State, India***

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.

Other
Distant Assessment

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-05-14***, it is considered that it complies with:

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 EudraGMDP. 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.*

Digitally signed by Chirtoacă Iurie
Date: 2022.09.29 14:55:07 EEST
Reason: MoldSign Signature
Location: Moldova

Part 2

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

Clarifying remarks (for public users)

Activities listed on the certificate were reviewed by distant assessment; an on-site inspection was not conducted. Live video footage was used to assess relevant manufacturing processes, facilities and equipment. The HPRA does not routinely issue hard copies of GMP certificates. Authenticity of GMP certification may be verified on the EudraGMDP database.

2021-07-19

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

---

Confidential
Health Products Regulatory Authority
Tel:***Confidential***
Fax:***Confidential***