National Institute of Pharmacy and Nutrition

CERTIFICATE NUMBER: ***OGYÉI/41297-4/2018***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER *(1), (2)*

Part 1

Issued following an inspection in accordance with :

The competent authority of Hungary confirms the following:

The manufacturer: **Naprod Life Sciences Pvt. Ltd.**

Site address: **G17/1 Tarapur Industrial Area (M.I.D.C.), Boisar, Maharashtra, 401506, 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.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2018-08-28***, 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.

Part 2

1 MANUFACTURING OPERATIONS
1.1 Sterile products
1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates Special Requirements : 7 Other: Oncology products(en) 1.1.1.4 Small volume liquids Special Requirements : 7 Other: Oncology products(en) *1.1.2 Terminally Sterilised (processing operations for the following dosage forms)* 1.1.2.3 Small volume liquids Special Requirements : 7 Other: Oncology products(en)
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 Special Requirements : 7 Other: Oncology products(en) 1.2.1.13 Tablets Special Requirements : 7 Other: Oncology products(en)
1.5 Packaging
1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell Special Requirements : 7 Other: Oncology products(en) 1.5.1.13 Tablets Special Requirements : 7 Other: Oncology products(en) *1.5.2 Secondary packaging*
1.6 Quality control testing
1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

Clarifying remarks (for public users):

The certificate includes oncology and non-oncology products (lyophilisates, injectables, tablets and capsules)

2019-01-29

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

Confidential

National Institute of Pharmacy and Nutrition

Tel:***Confidential***

Digitally signed by Chirtoacă Iurie
Date: 2022.12.14 17:50:01 EET
Reason: MoldSign Signature
Location: Moldova

Fax:***Confidential***
