

National Institute of Pharmacy and Nutrition

CERTIFICATE NUMBER: OGYÉI/69174-5/2018

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: **Porton Pharma Solution Ltd.**

Site address: **1 Fine Chemical Zone, Chongqing Chemical Industry Park, Changshou, Chongqing, 401220, China**

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 **2019-06-28** , it is considered that it complies with :

- The principles of GMP for active substances³ 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 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

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

CANAGLIFLOZIN(en)

DARUNAVIR ETHANOLATE(en)

INTERMEDIATE 295729(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance : [REDACTED]

| | |
|------------|--|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1 Manufacture of active substance intermediates |
| 3.6 | Quality Control Testing |
| | 3.6.1 Physical / Chemical testing |
| | 3.6.2 Microbiological testing excluding sterility testing |

Active Substance : [REDACTED]

| | |
|------------|--|
| 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 |
| 3.5 | General Finishing Steps |
| | 3.5.1 Physical processing steps : Drying, packaging |
| 3.6 | Quality Control Testing |
| | 3.6.1 Physical / Chemical testing |
| | 3.6.2 Microbiological testing excluding sterility testing |

Active Substance : [REDACTED]

| | |
|------------|--|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.1 Manufacture of active substance intermediates |
| 3.6 | Quality Control Testing |
| | 3.6.1 Physical / Chemical testing |
| | 3.6.2 Microbiological testing excluding sterility testing |

Clarifying remarks (for public users)

Workshops 102, 103, 106, 108, 110

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