



## Health and Youth Care Inspectorate – Pharmaceutical Products

CERTIFICATE NUMBER: NL/H 20/2013841A

### CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER<sup>1, 2</sup>

#### Part 1

Issued following an inspection in accordance with :

Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Netherlands confirms the following:

The manufacturer: **Aspen Oss B.V.**

Site address: **Kloosterstraat 6, 5349AB Oss, Veersemeer 4, 5347JN Oss, Boseind 17, 5281RM Boxtel, Oss, 5349AB, Netherlands**

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

**Art. 100 of the Medicines Act**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2020-01-16**, it is considered that it complies with :

- The principles of GMP for active substances<sup>3</sup> 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.

<sup>1</sup> 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.

<sup>2</sup> Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

<sup>3</sup> These requirements fulfil the GMP recommendations of WHO.

Issued as a true copy by me, Mr. A.G.M. Grundeken,  
civil law notary in Oss, the Netherlands.  
of the original document, shown and rendered on this,  
February 3rd 2020.



# APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: THE NETHERLANDS  
This public document
2. has been signed by **mr. A.G.M. Grundeken**
3. acting in the capacity of notary at Oss
4. bears the seal/stamp of aforesaid notary

## Certified

5. in 's-Hertogenbosch
6. on 05-02-2020
7. by the registrar of the district court of Oost-Brabant
8. no. 20/338

9. Seal/stamp:

10. Signature:

C.P.J. van Wijgerden





## Part 2

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

**ASENAPINE( en)** - confidential  
**ALTRENOGEST( en)** - confidential  
**BEPRIDIL HYDROCHLORIDE( en)** - confidential  
**BUDESONIDE( en)** - confidential  
**DANAPAROID SODIUM( en)** - confidential  
**DESMOPRESSIN( en)** - confidential  
**DESOGESTREL( en)** - confidential  
**ESTRADIOL( en)** - confidential  
**ESTRADIOL VALERATE( en)** - confidential  
**ESTRIOL( en)** - confidential  
**ETHINYL ESTRADIOL( en)** - confidential  
**ETHYNODIOL DIACETATE( en)** - confidential  
**ETONOGESTREL( en)** - confidential  
**GANIRELIX( en)** - confidential  
**GONADORELIN ACETATE( en)** - confidential  
**GONADORELIN DIACETATE TETRAHYDRATE( en)** - confidential  
**HUMAN CHORIONIC GONADOTROPHIN( en)** - confidential  
**HEPARIN SODIUM( en)** - confidential  
**HYDROXYPROGESTERONE CAPROATE( en)** - confidential  
**LEUPRORELIN( en)** - confidential  
**LYNESTRENOL( en)** - confidential  
**MIRTAZAPINE( en)** - confidential  
**NALOXONE HYDROCHLORIDE( en)** - confidential  
**NALTREXONE HYDROCHLORIDE( en)** - confidential  
**NANDROLONE DECANOATE( en)** - confidential  
**NORETHINDRONE( en)** - confidential  
**NORETHINDRONE ACETATE( en)** - confidential  
**OXYTOCIN( en)** - confidential  
**PROGESTERONE( en)** - confidential  
**ROCURONIUM BROMIDE( en)** - confidential  
**SUGAMMADEX( en)** - confidential  
**TESTOSTERONE( en)** - confidential  
**TESTOSTERONE CYPIONATE( en)** - confidential  
**TESTOSTERONE DECANOATE( en)** - confidential  
**TESTOSTERONE ISOCAPROATE( en)** - confidential  
**TESTOSTERONE PHENYLPROPIONATE( en)** - confidential  
**TESTOSTERONE PROPIONATE( en)** - confidential  
**TESTOSTERONE UNDECANOATE( en)** - confidential  
**TIBOLONE( en)** - confidential  
**ESTERIFIED ESTROGENS( en)** - confidential  
**ESTROGENS CONJUGATED( en)** - confidential  
**FONDAPARINUX( en)** - confidential  
**ESTRADIOL-3-ACETATE( en)** - confidential



2020-01-23

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

***Dr. Roelof Mol***  
***Health and Youth Care Inspectorate -- Pharmaceutical***  
***Products***  
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