



Health and Youth Care Inspectorate – Pharmaceutical Products

CERTIFICATE NUMBER: NL/H 20/2013841A

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 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 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.

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
Tel: +31 881205 000
Fax: +31 881205 001