Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK ManA 4351 Insp GMP/GDP/IMP 4351/15302-0031[V]

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

Part 1

Issued following an inspection in accordance with :
Regulation 5 of the current Veterinary Medicines Regulations

The competent authority of United Kingdom confirms the following :

The Manufacturer : PENN PHARMACEUTICAL SERVICES LIMITED

Site address : PENN PHARMACEUTICAL SERVICES LIMITED, UNITS 23-24, TAFARNAUBACH INDUSTRIAL ESTATE, TAFARNAUBACH, TREDEGAR, NP22 3AA, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK ManA 4351 in accordance with Regulation 5 of The current Veterinary Medicines Regulations

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 28/03/2022 , it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation 5 of the current Veterinary Medicines Regulations

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 MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) These requirements fulfil the GMP recommendations of WHO.*

Part 2

Veterinary Medicinal Products

1. MANUFACTURING OPERATIONS

[1.1] Sterile Products

[1.1.3] Batch certification

[1.2] Non-sterile products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

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[1.2.1.1] Capsules, hard shell
Inclusion of Potent, Toxic Compounds

[1.2.1.5] Liquids for external use
Inclusion of Potent, Toxic Compounds

[1.2.1.6] Liquids for internal use
Inclusion of Potent, Toxic Compounds

[1.2.1.11] Semi-solids
Inclusion of Potent, Toxic Compounds

[1.2.1.13] Tablets
Inclusion of Potent, Toxic Compounds

[1.2.2] Batch certification

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell
Inclusion of Potent, Toxic Compounds

[1.5.1.5] Liquids for external use
Inclusion of Potent, Toxic Compounds

[1.5.1.6] Liquids for internal use
Inclusion of Potent, Toxic Compounds

[1.5.1.11] Semi-solids
Inclusion of Potent, Toxic Compounds

[1.5.1.13] Tablets
Inclusion of Potent, Toxic Compounds

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

2. IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.2] Microbiological: non-sterility

[2.1.3] Chemical/Physical

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

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[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing

Restrictions or Remarks

The scope of inspection included sampling activities at the site's satellite storage facility (site 451197).

17/05/2022	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential

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