Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 4351
2: Name of authorisation holder	PENN PHARMACEUTICAL SERVICES LIMITED
3: Address(es) of manufacturing site(s)	PENN PHARMACEUTICAL SERVICES LIMITED, UNITS 23-24, TAFARNAUBACH INDUSTRIAL ESTATE, TAFARNAUBACH, TREDEGAR, NP22 3AA, UNITED KINGDOM
4: Legally registered address of authorisation holder	PENN PHARMACEUTICAL SERVICES LIMITED, UNITS 23-24, TAFARNAUBACH INDUSTRIAL ESTATE, TAFARNAUBACH, TREDEGAR, NP22 3AA, UNITED KINGDOM
5: Scope of authorisation and dosage forms	ANNEX 1 and/ or ANNEX 2
6: Legal Basis of authorisation	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	23/09/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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

Human Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 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)

[1.2.1.1] Capsules, hard shell

Special Requirements

Inclusion of Potent, Toxic Compounds

[1.2.1.5] Liquids for external use

Special Requirements

Inclusion of Potent, Toxic Compounds

[1.2.1.6] Liquids for internal use

Special Requirements

Inclusion of Potent, Toxic Compounds

[1.2.1.11] Semi-solids

Special Requirements

Inclusion of Potent, Toxic Compounds

[1.2.1.12] Suppositories

Special Requirements

Inclusion of Potent, Toxic Compounds

[1.2.1.13] Tablets

Special Requirements

Inclusion of Potent, Toxic Compounds

[1.2.1.17] Other non-sterile medicinal products

Filling of Powders

[1.2.2] Batch certification

[1.3] Biological medicinal products

[1.3.2] Batch certification

[1.3.2.2] Immunological products

[1.3.2.5] Biotechnology products

[1.3.2.6] Human or animal extracted products

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

Special Requirements

Inclusion of Potent, Toxic Compounds

[1.5.1.5] Liquids for external use

Special Requirements

Inclusion of Potent, Toxic Compounds

[1.5.1.6] Liquids for internal use

Special Requirements

Inclusion of Potent, Toxic Compounds

[1.5.1.11] Semi-solids

Special Requirements

Inclusion of Potent, Toxic Compounds

[1.5.1.12] Suppositories

Special Requirements

Inclusion of Potent, Toxic Compounds

[1.5.1.13] Tablets

Special Requirements

Inclusion of Potent, Toxic Compounds

[1.5.1.17] Other non-sterile medicinal products

Filling of powders

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

Part 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

[2.2.2] 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