

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 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	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	07/05/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

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

Human Investigational 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 Investigational Medicinal Products [1.1.3] Batch certification [1.2] Non-sterile investigational medicinal 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

[1.2.1.15] Other non-sterile medicinal products

Capsules Hard Shell - encapsulation of cytotoxic tablets, Filling of Powders.

[1.2.2] Batch certification

[1.4] Other investigational medicinal products or manufacturing activities

[1.4.1] Manufacture of:

[1.4.1.1] Herbal 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

[1.5.1.15] Other non-sterile medicinal products

Filling of powders. Capsule hard shells encapsulation of cytotoxic tablets

[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

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

[2.2.3] Biological medicinal products

[2.2.3.1] Blood products

[2.2.3.2] Immunological products

[2.2.3.5] Biotechnology products

[2.2.3.6] Human or animal extracted products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing