

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 4351
<b>2: Name of authorisation holder</b>	PENN PHARMACEUTICAL SERVICES LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	PENN PHARMACEUTICAL SERVICES LIMITED, UNITS 23-24, TAFARNAUBACH INDUSTRIAL ESTATE, TAFARNAUBACH, TREDEGAR, NP22 3AA, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	PENN PHARMACEUTICAL SERVICES LIMITED, UNITS 23-24, TAFARNAUBACH INDUSTRIAL ESTATE, TAFARNAUBACH, TREDEGAR, NP22 3AA, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	07/05/2024
<b>9: Annexes attached</b>	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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.3 ] Batch certification <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 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