

# 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,<br>TAFARNAUBACH INDUSTRIAL ESTATE, TAFARNAUBACH,<br>TREDEGAR, NP22 3AA, UNITED KINGDOM |
| <b>4: Legally registered address of authorisation holder</b>                                                                          | PENN PHARMACEUTICAL SERVICES LIMITED, UNITS 23-24,<br>TAFARNAUBACH INDUSTRIAL ESTATE, TAFARNAUBACH,<br>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<br>2004 [SI 2004/1031]                                                |
| <b>7: Name of responsible officer of the competent authority<br/>of the member state granting the manufacturing<br/>authorisation</b> | Confidential                                                                                                                              |
| <b>8: Authorisation Date</b>                                                                                                          | 13/05/2026                                                                                                                                |
| <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)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)                                                                                                                                                                                        |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Investigational Medicinal Products</b><br>[ 1.1.3 ] Batch certification<br><b>[ 1.2 ] Non-sterile investigational medicinal products</b><br>[ 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