Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 25044
2: Name of authorisation holder	BDD PHARMA LIMITED
3: Address(es) of manufacturing site(s)	BDD PHARMA LIMITED, BIOCITY SCOTLAND, BO'NESS ROAD, MOTHERWELL, ML1 5UH, UNITED KINGDOM BDD PHARMA LIMITED, BIO-IMAGING CENTRE, BASEMENT MEDICAL BLOCK WITHIN GLASGOW ROYAL INFIRMARY, 84 CASTLE STREET, GLASGOW, G4 0SF, UNITED KINGDOM
4: Legally registered address of authorisation holder	BDD PHARMA LIMITED, BIO-IMAGING CENTRE, BASEMENT MEDICAL BLOCK WITHIN GLASGOW ROYAL INFIRMARY, 84 CASTLE STREET, GLASGOW, G4 0SF, 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	01/07/2025
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

BDD PHARMA LIMITED, BIOCITY SCOTLAND, BO'NESS ROAD, MOTHERWELL, ML1 5UH, 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

[1.2] 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

[1.2.1.2] Capsules, soft shell

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.8] Other solid dosage forms

[1.2.1.9] Pressurised preparations

[1.2.1.11] Semi-solids

[1.2.1.13] Tablets

Special Requirements

Melatonin

[1.2.1.15] Other non-sterile medicinal products

Manufacture of intermediates, Overencapsulation,Buccal film, Any authorised products listed above may incorporate radiolabel and may contain biotechnology

[1.2.2] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.5] Biotechnology products

Special Requirements

Use of Biotechnology drug substance, blend or intermediate in manufacture of non-sterile finished dosage form

[1.3.1.8] Other biological medicinal products

Any authorised products listed above may incorporate radiolabel. Radiolabelling of pre-formulated biological medicinal products.

[1.3.2] Batch certification

[1.3.2.5] Biotechnology products

Special Requirements

Use of Biotechnology drug substance, blend or intermediate in manufacture of non-sterile finished dosage form

[1.3.2.8] Other biological medicinal products

Any authorised products listed above may incorporate radiolabel. Radiolabelling of pre-formulated biological medicinal products.

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.2] Capsules, soft shell

[1.5.1.5] Liquids for external use

[1.5.1.6] Liquids for internal use

[1.5.1.8] Other solid dosage forms

[1.5.1.9] Pressurised preparations

[1.5.1.11] Semi-solids

[1.5.1.13] Tablets

[1.5.1.15] Other non-sterile medicinal products

Buccal films, ntermediates, Overencapsulated products, Radio-labelled products

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

Importation of QP certified IMPs from the "approved countries for import" list

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

BDD PHARMA LIMITED, BIO-IMAGING CENTRE, BASEMENT MEDICAL BLOCK WITHIN GLASGOW ROYAL INFIRMARY, 84 CASTLE STREET, GLASGOW, G4 0SF, 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

[1.2] 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

[1.2.1.2] Capsules, soft shell

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.8] Other solid dosage forms

[1.2.1.9] Pressurised preparations

[1.2.1.11] Semi-solids

[1.2.1.13] Tablets

Special Requirements

Melatonin

[1.2.1.15] Other non-sterile medicinal products

Buccal film/ Any Authorised products listed above may be radiolabelled and contain biotechnology

[1.2.2] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.5] Biotechnology products

Special Requirements

Radiopharmaceuticals

[1.3.2] Batch certification

[1.3.2.5] Biotechnology products

Special Requirements

Radiopharmaceuticals

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.2] Capsules, soft shell

[1.5.1.5] Liquids for external use

[1.5.1.6] Liquids for internal use

[1.5.1.8] Other solid dosage forms

[1.5.1.9] Pressurised preparations

[1.5.1.11] Semi-solids

[1.5.1.13] Tablets

[1.5.1.15] Other non-sterile medicinal products

radio-labelled products/ Buccal Film

[1.5.2] Secondary packaging

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.3] Biological medicinal products

[2.2.3.5] Biotechnology products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

mportation of QP certified IMPs from the "approved countries for import"