# Medicines and Healthcare products Regulatory Agency

# MANUFACTURER'S AUTHORISATION

- 1: Authorisation Number
- 2: Name of authorisation holder
- 3: Address(es) of manufacturing site(s)
- 4: Legally registered address of authorisation holder
- 5: Scope of authorisation and dosage forms
- 6: Legal Basis of authorisation

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

8: Authorisation Date

9: Annexes attached

UK MIA(IMP) 19055

CALDERDALE AND HUDDERSFIELD NHS FOUNDATION TRUST

CALDERDALE AND HUDDERSFIELD NHS FOUNDATION TRUST, GATE 2 ACRE MILL, SCHOOL STREET WEST, HUDDERSFIELD, HD3 3ET, UNITED KINGDOM

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ANNEX 1 and/ or ANNEX 2

Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]

Confidential

12/07/2024 Annex 1 and/or Annex 2

#### SCOPE OF AUTHORISATION

Annex 2 Name and address of the site:

#### CALDERDALE AND HUDDERSFIELD NHS FOUNDATION TRUST, GATE 2 ACRE MILL, SCHOOL STREET WEST,

HUDDERSFIELD, HD3 3ET, 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

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.1] Large volume liquids

[1.1.1.3] Semi-solids

[1.1.1.4] Small volume liquids

# [ 1.1.2 ] Terminally Sterilised (processing operations for the following dosage forms)

[1.1.2.1] Large volume liquids

[1.1.2.2] Semi-solids

[1.1.2.3] Small volume liquids

[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

[1.2.1.5] Liquids for external use

[ 1.2.1.6 ] Liquids for internal use

[ 1.2.1.8 ] Other solid dosage forms

#### **Special Requirements**

Over encapsulation

[ 1.2.1.11 ] Semi-solids

[1.2.1.12] Suppositories

[ 1.2.2 ] Batch certification

# [ 1.4 ] Other investigational medicinal products or manufacturing activitiy

[ 1.4.1 ] Manufacture of:

[ 1.4.1.3 ] Other

Heparin and insulin/Importation of QP certified IMPs from a country on the approved country for import list

[1.4.2] Sterilisation of active substances/excipients/finished products:

- [1.4.2.1] Filtration
- [ 1.4.2.2 ] Dry heat
- [ 1.4.2.3 ] Moist heat

# [ 1.5 ] Packaging

- [1.5.1] Primary packaging
  - [1.5.1.5] Liquids for external use

[1.5.1.6] Liquids for internal use

- [1.5.1.11] Semi-solids
- [1.5.1.12] Suppositories
- [ 1.5.1.13 ] Tablets
- [ 1.5.2 ] Secondary packaging

# [ 1.6 ] Quality control testing

- [ 1.6.1 ] Microbiological: sterility
- [ 1.6.2 ] Microbiological: non-sterility
- [1.6.3] Chemical/Physical

# Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

# [ 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

# [ 2.3 ] Other Importation Activities

[ 2.3.1 ] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing