

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 49934

**2: Name of authorisation holder** UPPERTON LIMITED

**3: Address(es) of manufacturing site(s)** UPPERTON LIMITED, ALBERT EINSTEIN CENTRE, NOTTINGHAM SCIENCE AND TECHNOLOGY PARK, NOTTINGHAM, NG7 2TN, UNITED KINGDOM

**4: Legally registered address of authorisation holder** UPPERTON LIMITED, UNIT 3, 5 & 11 BEESTON BUSINESS PARK, TRENT GATEWAY, TECHNOLOGY DRIVE, BEESTON, NOTTINGHAM, NG9 1LA, 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** 15/04/2025

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**UPPERTON LIMITED**, ALBERT EINSTEIN CENTRE, NOTTINGHAM SCIENCE AND TECHNOLOGY PARK, NOTTINGHAM, NG7 2TN, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <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

[ 1.2.1.6 ] Liquids for internal use

**Special Requirements**

Substance with hormonal activity

[ 1.2.1.8 ] Other solid dosage forms

[ 1.2.1.11 ] Semi-solids

[ 1.2.1.13 ] Tablets

[ 1.2.1.15 ] Other non-sterile medicinal products

Spray dried bulk intermediate pharmaceutical products for Oral, nasal and pulmonary administration.

[ 1.2.2 ] Batch certification

**[ 1.3 ] Biological investigational medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.8 ] Other biological medicinal products

Spray dried bulk intermediate and finished products from recombinant sources.

[ 1.3.2 ] Batch certification

[ 1.3.2.8 ] Other biological medicinal products

Spray dried bulk intermediate and finished products from recombinant sources.

**[ 1.4 ] Other investigational medicinal products or manufacturing activity**

[ 1.4.1 ] Manufacture of:

[ 1.4.1.1 ] Herbal products

**Special Requirements**

GWP4202541 (API) in Acetone Solution

**[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.1 ] Capsules, hard shell

[ 1.5.1.6 ] Liquids for internal use

[ 1.5.1.8 ] Other solid dosage forms

[ 1.5.1.11 ] Semi-solids

[ 1.5.1.13 ] Tablets

[ 1.5.1.15 ] Other non-sterile medicinal products

Herbal

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.3 ] Chemical/Physical

[ 1.6.4 ] Biological

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

**UPPERTON LIMITED**, UNIT 3, 5 & 11 BEESTON BUSINESS PARK, TRENT GATEWAY, TECHNOLOGY DRIVE, BEESTON,  
NOTTINGHAM, NG9 1LA, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<p><b>Part 1 - MANUFACTURING OPERATIONS</b></p> <p><b>[ 1.2 ] Non-sterile investigational medicinal products</b></p> <p>[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)</p> <p>[ 1.2.1.1 ] Capsules, hard shell</p> <p>[ 1.2.1.6 ] Liquids for internal use</p> <p><b>Special Requirements</b></p> <p>Substance with hormonal activity</p> <p>[ 1.2.1.8 ] Other solid dosage forms</p> <p>[ 1.2.1.11 ] Semi-solids</p> <p>[ 1.2.1.13 ] Tablets</p> <p>[ 1.2.1.15 ] Other non-sterile medicinal products</p> <p>Spray dried bulk intermediate pharmaceutical products for oral, nasal and pulmonary administration</p> <p>[ 1.2.2 ] Batch certification</p> <p><b>[ 1.3 ] Biological investigational medicinal products</b></p> <p>[ 1.3.1 ] Biological medicinal products</p> <p>[ 1.3.1.8 ] Other biological medicinal products</p> <p>Spray dried bulk intermediate and finished products from recombinant sources</p> <p>[ 1.3.2 ] Batch certification</p> <p>[ 1.3.2.8 ] Other biological medicinal products</p> <p>Spray dried bulk intermediate and finished products from recombinant sources</p> <p><b>[ 1.4 ] Other investigational medicinal products or manufacturing activity</b></p> <p>[ 1.4.1 ] Manufacture of:</p> <p>[ 1.4.1.1 ] Herbal products</p> <p><b>Special Requirements</b></p> <p>GWP4202541 (API) in Acetone solution</p> <p><b>[ 1.5 ] Packaging</b></p> <p>[ 1.5.1 ] Primary packaging</p> <p>[ 1.5.1.1 ] Capsules, hard shell</p> <p>[ 1.5.1.6 ] Liquids for internal use</p> <p>[ 1.5.1.8 ] Other solid dosage forms</p> <p>[ 1.5.1.11 ] Semi-solids</p> <p>[ 1.5.1.13 ] Tablets</p> <p>[ 1.5.1.15 ] Other non-sterile medicinal products</p> <p>Herbal</p> <p>[ 1.5.2 ] Secondary packaging</p> <p><b>[ 1.6 ] Quality control testing</b></p> <p>[ 1.6.3 ] Chemical/Physical</p> <p>[ 1.6.4 ] Biological</p>