

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 5866
<b>2: Name of authorisation holder</b>	GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED GLAXOSMITHKLINE RESEARCH & DEVELOPMENT, HARRIS'S LANE, WARE, SG12 0GX, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED, ADDENBROOKE'S HOSPITAL BOX 128, CLINICAL RESEARCH UNIT, HILLS ROAD, CAMBRIDGE, CB2 0GG, UNITED KINGDOM GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED, THIRD AVENUE, HARLOW, CM19 5AW, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED, GSK HOUSE, 980 GREAT WEST ROAD, BRENTFORD, TW8 9GS, 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>	10/10/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**GLAXOSMITHKLINE RESEARCH & DEVELOPMENT, HARRIS'S LANE, WARE, SG12 0GX, 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 [ 1.2.1.8 ] Other solid dosage forms

[ 1.2.1.13 ] Tablets

[ 1.2.1.15 ] Other non-sterile medicinal products

Solid non-sterile multi dose forms (including powders and granules), powder inhalation products and devices.

[ 1.2.2 ] Batch certification

**[ 1.6 ] Quality control testing**

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

**GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED**, ADDENBROOKE'S HOSPITAL BOX 128, CLINICAL RESEARCH UNIT, HILLS ROAD, CAMBRIDGE, CB2 0GG, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

**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

[ 1.2.1.5 ] Liquids for external use

[ 1.2.1.6 ] Liquids for internal use

[ 1.2.1.11 ] Semi-solids

[ 1.2.1.15 ] Other non-sterile medicinal products

Powder in bottle

**[ 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

[ 1.5.1.11 ] Semi-solids

[ 1.5.1.13 ] Tablets

[ 1.5.2 ] Secondary packaging

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<p><b>Part 1 - MANUFACTURING OPERATIONS</b></p> <p><b>[ 1.1 ] Sterile Investigational Medicinal Products</b></p> <ul style="list-style-type: none"><li>[ 1.1.3 ] Batch certification</li></ul> <p><b>[ 1.2 ] Non-sterile investigational medicinal products</b></p> <ul style="list-style-type: none"><li>[ 1.2.2 ] Batch certification</li></ul> <p><b>[ 1.3 ] Biological investigational medicinal products</b></p> <ul style="list-style-type: none"><li>[ 1.3.2 ] Batch certification<ul style="list-style-type: none"><li>[ 1.3.2.5 ] Biotechnology products</li></ul></li></ul> <p><b>[ 1.5 ] Packaging</b></p> <ul style="list-style-type: none"><li>[ 1.5.1 ] Primary packaging<ul style="list-style-type: none"><li>[ 1.5.1.1 ] Capsules, hard shell<ul style="list-style-type: none"><li>[ 1.5.1.13 ] Tablets</li></ul></li></ul></li><li>[ 1.5.2 ] Secondary packaging</li></ul> <p><b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b></p> <p><b>[ 2.2 ] Batch certification of imported medicinal products</b></p> <ul style="list-style-type: none"><li>[ 2.2.1 ] Sterile Products<ul style="list-style-type: none"><li>[ 2.2.1.1 ] Aseptically prepared</li><li>[ 2.2.1.2 ] Terminally sterilised</li></ul></li><li>[ 2.2.2 ] Non-sterile products</li><li>[ 2.2.3 ] Biological medicinal products<ul style="list-style-type: none"><li>[ 2.2.3.5 ] Biotechnology products</li><li>[ 2.2.3.8 ] Other biological medicinal products<ul style="list-style-type: none"><li>Synthetic Proteins</li></ul></li></ul></li></ul> <p><b>[ 2.3 ] Other Importation Activities</b></p> <ul style="list-style-type: none"><li>[ 2.3.1 ] Site of Physical Importation</li><li>[ 2.3.2 ] Importation of Intermediate which undergoes further processing</li><li>[ 2.3.4 ] Other<ul style="list-style-type: none"><li>Authorised for Importation of QP certified IMPs from a country on the approved country for import list.</li></ul></li></ul>