

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 17087
<b>2: Name of authorisation holder</b>	ALLERGY THERAPEUTICS (UK) LIMITED ALLERGY THERAPEUTICS (UK) LIMITED, DOMINION WAY, WORTHING, BN14 8SA, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	ALLERGY THERAPEUTICS 2, UNIT A/B, DOMINION WAY, WORTHING, BN14 8NW, UNITED KINGDOM  ALLERGY THERAPEUTICS (UK) LIMITED, DOMINION WAY, WORTHING, Data Not Available, WEST SUSSEX, BN14 8SA, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	ALLERGY THERAPEUTICS (UK) LIMITED, DOMINION WAY, WORTHING, Data Not Available, WEST SUSSEX, BN14 8SA, 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>	12/03/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**ALLERGY THERAPEUTICS (UK) LIMITED**, DOMINION WAY, WORTHING, BN14 8SA, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms) [ 1.1.1.2 ] Lyophilisates [ 1.1.1.4 ] Small volume liquids [ 1.1.3 ] Batch certification <b>[ 1.2 ] Non-sterile investigational medicinal products</b>

<ul style="list-style-type: none"> <li>[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms) <ul style="list-style-type: none"> <li>[ 1.2.1.6 ] Liquids for internal use</li> <li>[ 1.2.1.15 ] Other non-sterile medicinal products <ul style="list-style-type: none"> <li>The solid dosage forms packed are solid dosage forms from sterile manufacture i.e. freeze dried dosage forms</li> </ul> </li> </ul> </li> <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>[ 1.3.1 ] Biological medicinal products <ul style="list-style-type: none"> <li>[ 1.3.1.1 ] Blood products</li> <li>[ 1.3.1.2 ] Immunological products</li> </ul> </li> <li>[ 1.3.2 ] Batch certification <ul style="list-style-type: none"> <li>[ 1.3.2.1 ] Blood products</li> <li>[ 1.3.2.2 ] Immunological products</li> </ul> </li> </ul>
<p><b>[ 1.4 ] Other investigational medicinal products or manufacturing activity</b></p> <ul style="list-style-type: none"> <li>[ 1.4.2 ] Sterilisation of active substances/excipients/finished products: <ul style="list-style-type: none"> <li>[ 1.4.2.1 ] Filtration</li> <li>[ 1.4.2.2 ] Dry heat</li> <li>[ 1.4.2.3 ] Moist heat</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>[ 1.5.1.5 ] Liquids for external use</li> <li>[ 1.5.1.6 ] Liquids for internal use</li> <li>[ 1.5.1.8 ] Other solid dosage forms</li> <li>[ 1.5.1.13 ] Tablets</li> <li>[ 1.5.1.15 ] Other non-sterile medicinal products <ul style="list-style-type: none"> <li>The solid dosage forms packed are solid dosage forms from sterile manufacture i.e. freeze dried dosage forms</li> </ul> </li> </ul> </li> <li>[ 1.5.2 ] Secondary packaging</li> </ul>
<p><b>[ 1.6 ] Quality control testing</b></p> <ul style="list-style-type: none"> <li>[ 1.6.1 ] Microbiological: sterility</li> <li>[ 1.6.3 ] Chemical/Physical</li> <li>[ 1.6.4 ] Biological</li> </ul>

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

**ALLERGY THERAPEUTICS 2, UNIT A/B, DOMINION WAY, WORTHING, BN14 8NW, UNITED KINGDOM**

Human Investigational Medicinal Products
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Authorised Operations
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MANUFACTURING OPERATIONS (according to part 1)
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<p><b>Part 1 - MANUFACTURING OPERATIONS</b></p> <p><b>[ 1.1 ] Sterile Investigational Medicinal Products</b></p>
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[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)

[ 1.1.1.2 ] Lyophilisates

[ 1.1.1.4 ] Small volume liquids

**[ 1.2 ] Non-sterile investigational medicinal products**

[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)

[ 1.2.1.6 ] Liquids for internal use

**[ 1.3 ] Biological investigational medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.1 ] Blood products

[ 1.3.1.2 ] Immunological products

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

[ 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

[ 1.5.1.8 ] Other solid dosage forms

[ 1.5.1.13 ] Tablets

[ 1.5.1.15 ] Other non-sterile medicinal products

The solid dosage forms packed are solid dosage forms from sterile

[ 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

[ 1.6.4 ] Biological