

# 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                                                          |
| <b>3: Address(es) of manufacturing site(s)</b>                                                                                        | ALLERGY THERAPEUTICS 2, UNIT A/B, DOMINION WAY,<br>WORTHING, BN14 8NW, UNITED KINGDOM      |
| <b>4: Legally registered address of authorisation holder</b>                                                                          | ALLERGY THERAPEUTICS (UK) LIMITED, DOMINION WAY,<br>WORTHING, 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<br>2004 [SI 2004/1031] |
| <b>7: Name of responsible officer of the competent authority<br/>of the member state granting the manufacturing<br/>authorisation</b> | Confidential                                                                               |
| <b>8: Authorisation Date</b>                                                                                                          | 08/11/2024                                                                                 |
| <b>9: Annexes attached</b>                                                                                                            | Annex 1 and/or Annex 2                                                                     |

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

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

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

**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) |

**Part 1 - MANUFACTURING OPERATIONS**

**[ 1.1 ] Sterile Investigational Medicinal Products**

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

[ 1.1.1.2 ] Lyophilisates

[ 1.1.1.4 ] 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)

[ 1.2.1.6 ] Liquids for internal use

[ 1.2.1.15 ] Other non-sterile medicinal products

The solid dosage forms packed are solid dosage forms from sterile manufacture i.e. freeze dried dosage forms

[ 1.2.2 ] Batch certification

**[ 1.3 ] Biological investigational medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.1 ] Blood products

[ 1.3.1.2 ] Immunological products

[ 1.3.2 ] Batch certification

[ 1.3.2.1 ] Blood products

[ 1.3.2.2 ] 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

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