

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA 17087

**2: Name of authorisation holder** ALLERGY THERAPEUTICS (UK) LIMITED

**3: Address(es) of manufacturing site(s)** ALLERGY THERAPEUTICS (UK) LIMITED, DOMINION WAY, WORTHING, BN14 8SA, UNITED KINGDOM

**4: Legally registered address of authorisation holder** ALLERGY THERAPEUTICS 2, UNIT A/B, DOMINION WAY, WORTHING, BN14 8NW, UNITED KINGDOM

**5: Scope of authorisation and dosage forms** ALLERGY THERAPEUTICS (UK) LIMITED, DOMINION WAY, WORTHING, BN14 8SA, UNITED KINGDOM

**6: Legal Basis of authorisation** ANNEX 1 and/ or ANNEX 2

**7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation** Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

**8: Authorisation Date** Confidential

**9: Annexes attached** 10/02/2025

Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

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

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile 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 products</b> [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)

- [ 1.2.1.5 ] Liquids for external use
- [ 1.2.1.6 ] Liquids for internal use
- [ 1.2.1.8 ] Other solid dosage forms
- [ 1.2.1.17 ] 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 medicinal products

- [ 1.3.1 ] Biological medicinal products
  - [ 1.3.1.2 ] Immunological products
- [ 1.3.2 ] Batch certification
  - [ 1.3.2.2 ] Immunological products

### [ 1.4 ] Other 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
  - [ 1.5.1.6 ] Liquids for internal use
  - [ 1.5.1.8 ] Other solid dosage forms
  - [ 1.5.1.17 ] Other non-sterile medicinal products

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

- [ 1.5.2 ] Secondary packaging

### [ 1.6 ] Quality control testing

- [ 1.6.1 ] Microbiological: sterility
- [ 1.6.3 ] Chemical/Physical
- [ 1.6.4 ] Biological

## SCOPE OF AUTHORISATION

### Annex 1

Name and address of the site:

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

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

### Part 1 - MANUFACTURING OPERATIONS

#### [ 1.1 ] Sterile Products

- [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)
  - [ 1.1.1.4 ] Small volume liquids

**[ 1.3 ] Biological medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.2 ] Immunological products

**[ 1.5 ] Packaging**

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.1 ] Microbiological: sterility

[ 1.6.3 ] Chemical/Physical

[ 1.6.4 ] Biological