

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 17087
<b>2: Name of authorisation holder</b>	ALLERGY THERAPEUTICS (UK) LIMITED ALLERGY THERAPEUTICS 2, UNIT A/B, DOMINION WAY, WORTHING, BN14 8NW, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	ALLERGY THERAPEUTICS (UK) LIMITED, DOMINION WAY, WORTHING, BN14 8SA, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	ALLERGY THERAPEUTICS (UK) LIMITED, DOMINION WAY, 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>	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
<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 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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Products</b> [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms) [ 1.1.1.4 ] Small volume liquids <b>[ 1.3 ] Biological medicinal products</b> [ 1.3.1 ] Biological medicinal products [ 1.3.1.2 ] Immunological products <b>[ 1.5 ] Packaging</b> [ 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 (UK) LIMITED, DOMINION WAY, WORTHING, BN14 8SA, 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)
  - [ 1.1.1.2 ] Lyophilisates
  - [ 1.1.1.4 ] Small volume liquids
- [ 1.1.3 ] Batch certification

**[ 1.2 ] Non-sterile products**

- [ 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