

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 17/02/2026

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)
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

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