

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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| 1: Authorisation Number | UK MIA(IMP) 52842 |
| 2: Name of authorisation holder | CAMBRIDGE ALLERGY LTD |
| 3: Address(es) of manufacturing site(s) | CAMBRIDGE ALLERGY LTD, CENTRAL BUILDING, HOEFORD POINT, BARWELL LANE, GOSPORT, PO13 0AU, UNITED KINGDOM |
| 4: Legally registered address of authorisation holder | CAMBRIDGE ALLERGY LTD, BEECH HOUSE, 4A NEWMARKET ROAD, CAMBRIDGE, CB5 8DT, UNITED KINGDOM |
| 5: Scope of authorisation and dosage forms | ANNEX 1 and/ or ANNEX 2 |
| 6: Legal Basis of authorisation | Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031] |
| 7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation | Confidential |
| 8: Authorisation Date | 05/04/2024 |
| 9: Annexes attached | Annex 1 and/or Annex 2 |

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

CAMBRIDGE ALLERGY LTD, CENTRAL BUILDING, HOEFORD POINT, BARWELL LANE, GOSPORT, PO13 0AU, UNITED KINGDOM

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| Human Investigational Medicinal Products |
| Authorised Operations |
| MANUFACTURING OPERATIONS (according to part 1) |
| Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.1] Capsules, hard shell [1.2.1.15] Other non-sterile medicinal products Multi-dose container [1.2.2] Batch certification [1.5] Packaging [1.5.1] Primary packaging [1.5.1.1] Capsules, hard shell |

[1.5.1.15] Other non-sterile medicinal products

Powder for oral use (Blend of peanut powder in excipients filled into either pull-apart hard HMPC capsules or multi-dose container)

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

[1.6.4] Biological