

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 4102

2: Name of authorisation holder CUSTOM PHARMACEUTICALS LIMITED

3: Address(es) of manufacturing site(s) CUSTOM PHARMACEUTICALS LIMITED, UNIT 2, FAIRWAY TRADING ESTATE, MOULSECOOMB WAY, BRIGHTON, BN2 4QL, UNITED KINGDOM

CUSTOM PHARMACEUTICALS LIMITED, CONWAY STREET, HOVE, BN3 3LW, UNITED KINGDOM

4: Legally registered address of authorisation holder CUSTOM PHARMACEUTICALS LIMITED, CONWAY STREET, HOVE, BN3 3LW, 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 04/11/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

CUSTOM PHARMACEUTICALS LIMITED, UNIT 2, FAIRWAY TRADING ESTATE, MOULSECOOMB WAY, BRIGHTON, BN2 4QL, UNITED KINGDOM

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) [1.2.1.13] Tablets Special Requirements Hormone Products

- [1.2.2] Batch certification
- [1.5] Packaging**
 - [1.5.1] Primary packaging
 - [1.5.1.1] Capsules, hard shell
 - [1.5.1.8] Other solid dosage forms
 - [1.5.1.13] Tablets
 - [1.5.1.15] Other non-sterile medicinal products
 - Granules and Powders
 - [1.5.2] Secondary packaging
- [1.6] Quality control testing**
 - [1.6.2] Microbiological: non-sterility
 - [1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

CUSTOM PHARMACEUTICALS LIMITED, CONWAY STREET, HOVE, BN3 3LW, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile investigational medicinal products <ul style="list-style-type: none"> [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) <ul style="list-style-type: none"> [1.2.1.1] Capsules, hard shell [1.2.1.8] Other solid dosage forms [1.2.1.13] Tablets <ul style="list-style-type: none"> Special Requirements Hormone Products [1.2.1.15] Other non-sterile medicinal products <ul style="list-style-type: none"> Granules and Powders [1.2.2] Batch certification [1.6] Quality control testing <ul style="list-style-type: none"> [1.6.3] Chemical/Physical