

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 4102

2: Name of authorisation holder CUSTOM PHARMACEUTICALS LIMITED

3: Address(es) of manufacturing site(s) 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 Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Confidential

8: Authorisation Date 23/04/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.1] Capsules, hard shell [1.2.1.8] Other solid dosage forms [1.2.1.13] Tablets [1.2.1.17] Other non-sterile medicinal products Granules and Powders.

[1.2.2] Batch certification
[1.5] Packaging
[1.5.1] Primary packaging
[1.5.1.17] Other non-sterile medicinal products
Granules and powders
[1.6] Quality control testing
[1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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

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

Part 1 - MANUFACTURING OPERATIONS
[1.2] Non-sterile 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
[1.5.1.17] 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