Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

2: Name of authorisation holder

3: Address(es) of manufacturing site(s)

4: Legally registered address of authorisation holder

5: Scope of authorisation and dosage forms

6: Legal Basis of authorisation

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

8: Authorisation Date

9: Annexes attached

UK MIA 46446

CRESCENT MANUFACTURING LIMITED

CRESCENT MANUFACTURING LIMITED, 2 CUNARD ROAD, PARK ROYAL, LONDON, NW10 6PN, UNITED KINGDOM

CRESCENT MANUFACTURING LIMITED, 2 CUNARD ROAD,

LONDON, NW10 6PN, UNITED KINGDOM

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI

2012/1916)

Confidential

23/04/2024

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

CRESCENT MANUFACTURING LIMITED, 2 CUNARD ROAD, PARK ROYAL, LONDON, NW10 6PN, 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)

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.8] Other solid dosage forms

Special Requirements

B-lactam Antibiotics

[1.2.1.11] Semi-solids

[1.5] Packaging

[1.5.1] Primary packaging

Issue Date: 23 Apr 2024

[1.5.1.5] Liquids for external use [1.5.1.6] Liquids for internal use [1.5.1.11] Semi-solids

[1.5.1.17] Other non-sterile medicinal products

Special Requirements

Special Requirements

B-lactam Antibiotics

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

