Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 20416

2: Name of authorisation holder CRESCENT PHARMA LIMITED

CRESCENT PHARMA LIMITED, KEY HOUSE, SARUM HILL,

BASINGSTOKE, RG21 8SR, UNITED KINGDOM

3: Address(es) of manufacturing site(s) CRESCENT PHARMA LIMITED, UNITS 3 AND 4, QUIDHAMPTON

BUSINESS UNITS, POLHAMPTON LANE OVERTON, HAMPTON,

BASINGSTOKE, RG25 3ED, UNITED KINGDOM

4: Legally registered address of authorisation holder

BASINGSTOKE, RG21 8SR, 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 Confidential

manufacturing authorisation

8: Authorisation Date 19/08/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

CRESCENT PHARMA LIMITED, KEY HOUSE, SARUM HILL, BASINGSTOKE, RG21 8SR, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile products

[1.2.2] Batch certification

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

Issue Date: 19 Aug 2024

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

CRESCENT PHARMA LIMITED, UNITS 3 AND 4, QUIDHAMPTON BUSINESS UNITS, POLHAMPTON LANE OVERTON, HAMPTON, BASINGSTOKE, RG25 3ED, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

Manufacturer's Authorisation: UK MIA 20416

Page 2 of 2

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