Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 41013

2: Name of authorisation holder SEACROSS PHARMACEUTICALS LIMITED

SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT

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

BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY,

UNITED KINGDOM

SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT

BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY,

UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI equal Basis of authorisation

2012/1916)

Confidential

7: Name of responsible officer of the competent authority of

the member state granting the manufacturing authorisation

4: Legally registered address of authorisation holder

8: Authorisation Date 13/06/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY, 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

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

Issue Date: 13 Jun 2025