

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 51718

2: Name of authorisation holder CLYDESDALE PHARMA LTD

3: Address(es) of manufacturing site(s) CLYDESDALE PHARMA LTD, UNIT 3-5 CAMPBELL COURT, BRAMLEY, TADLEY, RG26 5EG, UNITED KINGDOM

4: Legally registered address of authorisation holder CLYDESDALE PHARMA LTD, UNIT 3-5 CAMPBELL COURT, BRAMLEY, TADLEY, RG26 5EG, 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 22/01/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

CLYDESDALE PHARMA LTD, UNIT 3-5 CAMPBELL COURT, BRAMLEY, TADLEY, RG26 5EG, 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 [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.1] Capsules, hard shell [1.2.1.2] Capsules, soft shell [1.2.1.3] Chewing gums [1.2.1.5] Liquids for external use [1.2.1.6] Liquids for internal use

[1.2.1.8] Other solid dosage forms

[1.2.1.9] Pressurised preparations

[1.2.1.11] Semi-solids

[1.2.1.12] Suppositories

[1.2.1.13] Tablets

[1.2.1.14] Transdermal patches

[1.2.2] Batch certification

[1.6] Quality control testing

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.3] Chemical/Physical

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation