

# 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** 05/12/2025

**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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile products</b> [ 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