

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 17661

2: Name of authorisation holder PCCA LIMITED

3: Address(es) of manufacturing site(s) PCCA LIMITED, UNITS 1, 2 AND 3 REGENTS DRIVE, LOW PRUDHOE INDUSTRIAL ESTATE, PRUDHOE, NE42 6PX, UNITED KINGDOM

4: Legally registered address of authorisation holder PCCA LIMITED, UNITS 1, 2 AND 3 REGENTS DRIVE, LOW PRUDHOE INDUSTRIAL ESTATE, PRUDHOE, NE42 6PX, UNITED KINGDOM

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

6: Legal Basis of authorisation Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]

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

8: Authorisation Date 19/05/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

PCCA LIMITED, UNITS 1, 2 AND 3 REGENTS DRIVE, LOW PRUDHOE INDUSTRIAL ESTATE, PRUDHOE, NE42 6PX, UNITED KINGDOM

Human Investigational 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 investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.1] Capsules, hard shell [1.2.1.5] Liquids for external use [1.2.1.6] Liquids for internal use [1.2.1.8] Other solid dosage forms

[1.2.1.11] Semi-solids

[1.2.1.12] Suppositories

[1.2.1.15] Other non-sterile medicinal products

Ointments, Creams, Emulsions, Ear Drops, Lotions, Paints, Applications Medicinal Shampoos, Nasal Drops, Suspensions, Mouthwashes/Gargles, Disinfectants, Reefers

[1.4] Other investigational medicinal products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.3] Other

Hormones, Cytostatics / Cytotoxics, Dithranol, Coal tar, Penicillins, Cephalosporins. Radiopharmaceuticals/radionuclide generators.

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[1.2] Non-sterile investigational medicinal products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.1] Capsules, hard shell

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.8] Other solid dosage forms

[1.2.1.11] Semi-solids

[1.2.1.12] Suppositories

[1.2.1.15] Other non-sterile medicinal products

Ointments, Creams, Emulsions, Ear Drops, Lotions, Paints, Applications Medicinal Shampoos, Nasal Drops, Suspensions, Mouthwashes/Gargles, Disinfectants, Reefers

[1.4] Other investigational medicinal products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.3] Other

Hormones, Cytostatics / Cytotoxics, Dithranol, Coal tar, Penicillins, Cephalosporins. Radiopharmaceuticals/radionuclide generators.

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

[2.3] Other Importation Activities

[2.3.4] Other

Hormones, Cytostatics / Cytotoxics, Dithranol, Coal tar, Penicillins, Cephalosporins. Radiopharmaceuticals/radionuclide generators.