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 2 AND 3 REGENTS DRIVE, LOW PRUDHOE INDUSTRIAL ESTATE, PRUDHOE, NE42 6PX, UNITED KINGDOM
4: Legally registered address of authorisation holder	PCCA LIMITED, UNITS 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	06/11/2025
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

PCCA LIMITED, UNITS 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

MHRA-GMDP MHRA-GMDP MHRA

[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 activitiy

[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 activitiy

[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.

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