

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 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 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 06/02/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

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 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 [1.2.1.5] Liquids for external use [1.2.1.6] Liquids for internal use

- [1.2.1.8] Other solid dosage forms
- [1.2.1.12] Suppositories
- [1.2.1.17] Other non-sterile medicinal products
 - Creams and ointments

[1.5] Packaging

- [1.5.1] Primary packaging
 - [1.5.1.1] Capsules, hard shell
 - [1.5.1.5] Liquids for external use
 - [1.5.1.6] Liquids for internal use
 - [1.5.1.8] Other solid dosage forms
 - [1.5.1.12] Suppositories
 - [1.5.1.17] Other non-sterile medicinal products
 - Creams and ointments
- [1.5.2] Secondary packaging

[1.6] Quality control testing

- [1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[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