Medicines and Healthcare products Regulatory Agency

REGISTRATION OF MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ACTIVE SUBSTANCES TO BE USED AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

Registrant Details

1. Registration Number	UK API 22857
2. Name or corporate name of registrant	PHARMARON MANUFACTURING SERVICES (UK) LTD
3. Permanent or legal address of registrant	PHARMARON MANUFACTURING SERVICES (UK) LTD, WINDMILL INDUSTRIAL ESTATE, SHOTTON LANE, CRAMLINGTON, NE23 3JL, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	PHARMARON MANUFACTURING SERVICES (UK) LTD, WINDMILL INDUSTRIAL ESTATE, SHOTTON LANE, CRAMLINGTON, NE23 3JL, UNITED KINGDOM
5. National legal basis of registration	Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916)
6. Name of responsible officer of the competent authority of the member state validating the registration	Confidential
7. Date	25/04/2023

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in MHRA-GMDP.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

SCOPE OF REGISTRATION

Name and address of the site

PHARMARON MANUFACTURING SERVICES (UK) LTD, WINDMILL INDUSTRIAL ESTATE, SHOTTON LANE, CRAMLINGTON, NE23 3JL, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance
FLURBIPROFEN SODIUM DIHYDRATE
4000007377

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates

	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Salt formation
E	General Finishing Steps
	E.1 Physical Processing Steps Dried in Oven
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance
OPICAPONE
3000017734

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Dried to anhydrous
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance
DIPIPANONE HYDROCHLORIDE
2000007755

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps

	E.1 Physical Processing Steps Drying
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance
NITISINONE
1000000933

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance
CANNABIDIOL
1000000540

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
	B.6 Purification of Extracted Substance - PLANT
E	General Finishing Steps
	E.1 Physical Processing Steps Drying
	E.2 Primary Packaging
	E.3 Secondary Packaging

F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

NALOXONE HYDROCHLORIDE

2000008238

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Salt formation and crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

S-(+)-FLURBIPROFEN

3000017735

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Filtration, distillation, crystallisation and centrifugation
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

FLURBIPROFEN

1000002036

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Sodium salt neutralised and subsequent base crystallised from petrol
E	General Finishing Steps
	E.1 Physical Processing Steps Dried on filter drier and passed through a mill system
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

FLURBIPROFEN SODIUM DIHYDRATE (4000007377)

OPICAPONE (3000017734)

DIPIPANONE HYDROCHLORIDE (2000007755)

NITISINONE (1000000933)

CANNABIDIOL (1000000540)

NALOXONE HYDROCHLORIDE (2000008238)

S-(+)-FLURBIPROFEN (3000017735)

FLURBIPROFEN (1000002036)