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 50530
2. Name or corporate name of registrant	CELADON PHARMA LTD
3. Permanent or legal address of registrant	CELADON PHARMA LTD, 13 HOLFORD ESTATE, TAMESIDE DRIVE, BIRMINGHAM, B6 7AY, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	CELADON PHARMA LIMITED, 13 HOLFORD ESTATE, TAMESIDE DRIVE, BIRMINGHAM, B6 7AY, 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	25/07/2024

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

CELADON PHARMA LIMITED, 13 HOLFORD ESTATE, TAMESIDE DRIVE, BIRMINGHAM, B6 7AY, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance
CANNABIDIVARINIC ACID
1000020247

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps

	E.1 Physical Processing Steps Cannabis plant material will be dried, comminuted and extracted using a food-grade triglyceride oil. The resulting extract will be filtered and clarified, then adjusted with food-grade triglyceride oil or polyhydric alcohol to a standard THCA.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance
CANNABIGEROL
1000020244

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Cannabis plant material will be dried, comminuted and extracted using a food-grade triglyceride oil. The resulting extract will be filtered and clarified, then adjusted with food-grade triglyceride oil or polyhydric alcohol to a standard THCA.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance
CANNABICHROMENE
1000020246

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Cannabis plant material will be dried, comminuted and extracted using a food-grade triglyceride oil. The resulting extract will be filtered and clarified, then adjusted with food-grade triglyceride oil or polyhydric alcohol to a standard THCA.
	E.2 Primary Packaging
	E.3 Secondary Packaging

F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance
TETRAHYDROCANNABINOLIC ACID B
1000020241

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Cannabis plant material will be dried, comminuted and extracted using a food-grade triglyceride oil. The resulting extract will be filtered and clarified, then adjusted with food-grade triglyceride oil or polyhydric alcohol to a standard THCA.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance
CANNABIDIOLIC ACID
1000020242

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Cannabis plant material will be dried, comminuted and extracted using a food-grade triglyceride oil. The resulting extract will be filtered and clarified, then adjusted with food-grade triglyceride oil or polyhydric alcohol to a standard THCA.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance
TETRAHYDROCANNABIVARINIC ACID

1000020248

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Cannabis plant material will be dried, comminuted and extracted using a food-grade triglyceride oil. The resulting extract will be filtered and clarified, then adjusted with food-grade triglyceride oil or polyhydric alcohol to a standard THCA.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

CANNABINOL

1000020249

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Cannabis plant material will be dried, comminuted and extracted using a food-grade triglyceride oil. The resulting extract will be filtered and clarified, then adjusted with food-grade triglyceride oil or polyhydric alcohol to a standard THCA.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

CANNABICHROMENIC ACID

1000020245

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps

	E.1 Physical Processing Steps Cannabis plant material will be dried, comminuted and extracted using a food-grade triglyceride oil. The resulting extract will be filtered and clarified, then adjusted with food-grade triglyceride oil or polyhydric alcohol to a standard THCA.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

TETRAHYDROCANNABIVARIN

3000020337

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Cannabis plant material will be dried, comminuted and extracted using a food-grade triglyceride oil. The resulting extract will be filtered and clarified, then adjusted with food-grade triglyceride oil or polyhydric alcohol to a standard THCA.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

CANNABIGEROLIC ACID

1000020243

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Cannabis plant material will be dried, comminuted and extracted using a food-grade triglyceride oil. The resulting extract will be filtered and clarified, then adjusted with food-grade triglyceride oil or polyhydric alcohol to a standard THCA.
	E.2 Primary Packaging
	E.3 Secondary Packaging

F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance
TETRAHYDROCANNABINOLIC ACID A
2000019058

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Cannabis plant material will be dried, comminuted and extracted using a food-grade triglyceride oil. The resulting extract will be filtered and clarified, then adjusted with food-grade triglyceride oil or polyhydric alcohol to a standard THCA.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance
CANNABIDIOL
1000000540

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Cannabis plant material will be dried, comminuted and extracted using a food-grade triglyceride oil. The resulting extract will be filtered and clarified, then adjusted with food-grade triglyceride oil or polyhydric alcohol to a standard THCA.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance
CANNABIDIVARIN

1000017580

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Cannabis plant material will be dried, comminuted and extracted using a food-grade triglyceride oil. The resulting extract will be filtered and clarified, then adjusted with food-grade triglyceride oil or polyhydric alcohol to a standard THCA.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

CANNABIDIVARINIC ACID (1000020247)

CANNABIGEROL (1000020244)

CANNABICHROMENE (1000020246)

TETRAHYDROCANNABINOLIC ACID B (1000020241)

CANNABIS (3000009556)

CANNABIDIOLIC ACID (1000020242)

TETRAHYDROCANNABIVARINIC ACID (1000020248)

CANNABIS FLOWER (4000016460)

CANNABINOL (1000020249)

CANNABICHROMENIC ACID (1000020245)

TETRAHYDROCANNABIVARIN (3000020337)

CANNABIS SATIVA (1000007491)

CANNABIGEROLIC ACID (1000020243)

TETRAHYDROCANNABINOLIC ACID A (2000019058)

CANNABIS SATIVA FLOWERING TOPS (2000021109)

CANNABIDIOL (1000000540)

CANNABIDIVARIN (1000017580)