Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 50530 Insp GMP 50530/18599281-0004

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

Issued following an inspection in accordance with :
Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : CELADON PHARMA LIMITED

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

Is an active substance manufacturer that has been inspected in accordance with Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 19/10/2022 , it is considered that it complies with

- The principles of GMP for active substances referred to in Regulation B17 and C17 of the Human Medicines Regulations 2012 (SI 2012/1916)

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

Manufacture of active substance. Names of substances subject to inspection :

- [2000019058] TETRAHYDROCANNABINOLIC ACID A
- [1000020244] CANNABIGEROL
- [1000020248] TETRAHYDROCANNABIVARINIC ACID
- [1000020241] TETRAHYDROCANNABINOLIC ACID B
- [1000000540] CANNABIDIOL
- [1000020246] CANNABICHROMENE

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- [1000017580] CANNABIDIVARIN
- [1000020243] CANNABIGEROLIC ACID
- [1000020247] CANNABIDIVARINIC ACID
- [3000020337] TETRAHYDROCANNABIVARIN
- [1000020245] CANNABICHROMENIC ACID
- [1000020242] CANNABIDIOLIC ACID
- [1000020249] CANNABINOL

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

TETRAHYDROCANNABINOLIC ACID A

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 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.

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

CANNABIGEROL

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 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.

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

TETRAHYDROCANNABIVARINIC ACID

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3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 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.

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

TETRAHYDROCANNABINOLIC ACID B

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 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.

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

CANNABIDIOL

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 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.

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3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

CANNABICHROMENE

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 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.

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

CANNABIDIVARIN

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 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.

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

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CANNABIGEROLIC ACID

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 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.

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3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

CANNABIDIVARINIC ACID

3.2 Processing Activities of Active Substance from Natural Sources

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3.5 General Finishing Steps

3.5.1 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.

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3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

TETRAHYDROCANNABIVARIN

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

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3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

CANNABICHROMENIC ACID

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3.5 General Finishing Steps

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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.

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3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

CANNABIDIOLIC ACID

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 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.

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

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CANNABINOL

3.2 Processing Activities of Active Substance from Natural Sources

3.2.1 Plant Source Extraction

3.5 General Finishing Steps

3.5.1 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.

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

13/01/2023	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential

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