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P H A R M A C E U T I C A L S			
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# RELEASE CERTIFICATE

## **Certificate of Analysis**

Product Description:	Dried Cannabis flower		
Plant variety	RX11		
Product Code:	N/A		
Batch No:	CP-23-PRD-001		
Specification:	CP-FPS-003		
Date of Manufacture:	09-May-2024		
Retest Date:	24-Oct-2024		
Pack size:	250g		
Manufacturer:	Celadon Pharma Ltd.		
Testing site:	LINNEO HEALTH S.L. GÉNOVA 27, planta 6 <sup>a</sup> , 28004, MADRID, Spain.		

### **Analytical Data**

	Test	Test Method	Specification	Result	Pass / Fail
Appeara	nce	Visual inspection (Ph. Eur. Cannabis Flower monograph current ed. 07 /2024:3028)	From dark green to pale yellow or from light brown to reddish brown	Compliance	Pass
		Microscopic examination (Ph. Eur. Cannabis Flower monograph current ed. 07 /2024:3028)	Complies with characteristics in the test method.	Compliance	Pass
Identific	ation	Identification through High-performance thin- layer chromatography (HPTLC) (Ph. Eur. 2.8.25 / Ph.Eur. Cannabis Flower monograph current ed. 07 /2024:3028 or HPLC)	Complies with the reference solution of the test method.	Contains THC	Pass
	Total Content CBN	HPLC Ph. Eur 2.2.29	NMT 1.0 % w/w	0.1 % w/w	Pass
Assay	Total Content THC		13.5- 16.5 % w/w	15.0 % w/w	Pass
	Total Content CBD		NMT 1 % w/w (dried basis)	0.1 % w/w	Pass

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Test	Test Method	Specification	Result	Pass / Fail	
Foreign matter	Ph. Eur 2.8.2	NMT 2.0 % w/w	0 % w/w	Pass	
Pesticides	Ph. Eur 2.8.13	NMT the limits specified	Compliance	Pass	
Loss on Drying	Ph. Eur 2.2.32	NMT 12 %	7.0%	Pass	
Total Ash	Ph. Eur 2.4.16	NMT 20 %	13.31%	Pass	
Arsenic		NMT 0.2 ppm	<0.2 ppm	Pass	
Cadmium	Ph. Eur 2.4.27	NMT 0.3 ppm	<0.3 ppm	Pass	
Lead		NMT 0.5 ppm	<0.5 ppm	Pass	
Mercury		NMT 0.1 ppm	<0.1 ppm	Pass	
			JUL		
Aflatoxin B1	Ph. Eur 2.8.18 or in house	NMT 2 µg/kg	<2 µg/kg	Pass	
Aflatoxin B1, B2, G1 and G2		NMT 4 µg/kg	<4 µg/kg	Pass	
Ochratoxin A	Ph. Eur 2.8.22 or in house	NMT 20 µg/kg	<20 µg/kg	Pass	
ТАМС	Ph. Eur 5.1.8B	NMT 50,000 CFU/g or 10 <sup>4</sup> CFU/mL	<100 CFU/g	Pass	
түмс	Ph. Eur 5.1.8B	NMT 500 CFU/g or 10 <sup>2</sup> CFU/mL	<10 CFU/g	Pass	
Bile-tolerant Gram- negative bacteria	Ph. Eur 5.1.8B	NMT 10 <sup>2</sup> CFU/g or CFU/mL	Absent in (1 g)	Pass	
Pseudomonas aeruginosa	Ph. Eur 5.1.4-1	Absent in (1 g or 1mL)	Absent in (1 g)	Pass	
Staphylococcus aureus	Ph. Eur 5.1.4-1	Absent in (1 g or 1mL)	Absent in (1 g)	Pass	
Escherichia coli	Ph. Eur 5.1.8B	Absent in (1 g or 1mL)	Absent in (1 g)	Pass	
Salmonella spp.	Ph. Eur 5.1.8B	Absence in (25 g or 25 mL)	Absence in (25 g)	Pass	

#### Investigations/deviations associated with this batch. None.

#### **Approval**

It is hereby certified that the above information is authentic and accurate.

This batch was manufactured, analyzed and checked in accordance with the requirements of the Control Union Medical Cannabis Standard and WHO guidelines on Good Agricultural & Collection Practices (GACP) for medicinal plants (Geneva, 2003) and the specifications of the product.

The batch manufacturing and analysis records were reviewed and complied with the Good Agriculture and Collection Practices (GACP).

Document Approvals

Approved Date:

Author Approval Task Verdict: Approve

Reviewers Approval Task Verdict: Approve

QA Approval Task Verdict: Approve Agata Maj, Senior QA Manager (agata.maj@celadonpharma.co.uk) Quality Assurance Approval 09-Aug-2024 10:50:40 GMT+0000

Shrinath Shah, Senior QA Officer (shrinath.shah@celadonpharma.co.uk)

Author Approval 09-Aug-2024 10:49:35 GMT+0000

Agata Maj, Senior QA Manager (agata.maj@celadonpharma.co.uk)

Management Approval 09-Aug-2024 10:50:21 GMT+0000