



Batch Release Certificate

Batch 06051851120-2-P3

Product type: Cannabis flos packed as primary product

Cultivar: *Cannabis Sativa* L. 'SCHROLL-MEDICAL-060518'

Form: Herbal tea/inhalation vapour, herbal drug.

Product name: Cannabis 1A 16/1 flos

Size: 10 g

Product specification no: 001098 ver. 4.0

Item number: 4039

Content: THC: 15.1% CBD: < 0.1%

Date of release: 2024.06.06

Date of manufacture: 2024.03.15

Expiry date: 2024.12.15*

Irradiation CoP: WO# 3522045 Min.abs.dose: 22.8 kGy Max.abs.dose: 29.4 kGy

Original CoA reference: 210-1288613

Quality attributes: See next page

Manufacturing site:
Schroll Medical ApS
Kildegårdsvej 32
5792 Årsløv
Denmark

E-Beam irradiation:
Sterigenics Denmark A/S
Aa. Louis-Hansens Allé 11
3060 Espergærde
Denmark

Analysis, stability testing:
QSI GmbH
Flughafendamm 9a
28199 Bremen
Germany

Analysis, stability testing:
Eurofins Denmark A/S
Ørnebjergvej 1,
2600 Glostrup
Denmark

I hereby certify that the above information is authentic and accurate. The manufacturing stages have been carried out in full compliance with the Danish executive order on cultivation, processing and distribution of cannabis bulk and production of cannabis primary products and the GACP and EU-GMP requirements. The batch processing, packaging and analysis records were reviewed and found to be in compliance with EU-GMP.

*Shelf-life has been set to 9 months according to Deviation 0139 - Batch with shorter shelf-life.

2024.06.06
Date Årsløv, Denmark


Jonas Skov, Delegate Competent Person (DCP)

Batch Release Certificate

Batch 06051851120-2-P3

Quality attributes

Test	Method	Acceptance limits	Results
Produced according to GMP	Produced according to GMP	Produced according to GMP	Produced according to GMP
Macroscopic identification	DAB 2023, Monograph Cannabis Flos	Complies	Complies
Microscopic identification	DAB 2023, Monograph Cannabis Flos	Complies	Complies
Foreign matter	DAB 2023, Monograph Cannabis Flos Ph. Eur. ver. 11.3, ch. 2.8.2	≤ 2%	< 2%
Total Aerobic Microbial Count (TAMC)	Ph. Eur. ver. 11.3, ch. 5.1.4 Inhalation use, and 2.6.12	≤ 100 CFU/g	< 100 CFU/g
Total Yeasts and Moulds Count (TYMC)	Ph. Eur. ver. 11.3, ch. 5.1.4 Inhalation use, and 2.6.12	≤ 10 CFU/g	< 10 CFU/g
<i>E. Coli</i>	Ph. Eur. ver. 11.3, ch. 5.1.8 B and 2.6.31	Absent in 1 g	Absent in 1 g
<i>Salmonella</i>	Ph. Eur. ver. 11.3, ch. 5.1.8 B and 2.6.31	Absent in 25 g	Absent in 25 g
<i>S. aureus</i>	Ph. Eur. ver. 11.3, ch. 5.1.4 Inhalation use and 2.6.13	Absent in 1 g	Absent in 1 g
<i>P. aeruginosa</i>	Ph. Eur. ver. 11.3, ch. 5.1.4 Inhalation use and 2.6.13	Absent in 1 g	Absent in 1 g
Bile-tolerant Gram-negative bacteria	Ph. Eur. ver. 11.3, ch. 5.1.4 Inhalation use and 2.6.13	Absent in 1 g	Absent in 1 g
Loss on Drying	DAB 2023, Monograph Cannabis Flos Ph. Eur. ver. 11.3, ch. 2.2.32	≤ 10%	5.9%
UHPLC identification	DLS 2023.3, Monograph Cannabis Flos Ph. Eur. ver. 11.3, ch. 2.2.29	Complies	Complies
HPLC – Total THC	DAB 2023, Monograph Cannabis Flos, Ph. Eur. ver. 11.3, ch. 2.2.29	16.0 ± 10% (14.4 – 17.6%)	15.1%
HPLC – Total CBD	DAB 2023, Monograph Cannabis Flos, Ph. Eur. ver. 11.3, ch. 2.2.29	≤ 1.0%	< 0.1%
HPLC – CBN	DAB 2023, Monograph Cannabis Flos, Ph. Eur. ver. 11.3, ch. 2.2.29	≤ 1.0%	< 0.1%
Aflatoxin B1	Ph. Eur. ver. 11.3, ch. 2.8.18	≤ 2 µg/kg	< 0.5 µg/kg
Aflatoxin B1+B2+G1+G2	Ph. Eur. ver. 11.3, ch. 2.8.18	≤ 4 µg/kg	< 2.5 µg/kg
Absence of pesticides	Ph. Eur. ver. 11.3, ch. 2.8.13	Below limits in Ph. Eur.	Below limits in Ph. Eur. *
Lead	Ph. Eur. ver. 11.3, ch. 2.4.27	≤ 5.0 ppm	< 0.1 ppm
Mercury	Ph. Eur. ver. 11.3, ch. 2.4.27	≤ 0.1 ppm	< 0.05 ppm
Cadmium	Ph. Eur. ver. 11.3, ch. 2.4.27	≤ 1.0 ppm	< 0.05 ppm
Total ash	Ph. Eur. ver. 11.3, ch. 2.4.16	≤ 20%	10.0%
Odour	DAB 2023, Monograph Cannabis Flos	Complies	Complies
TLC	DAB 2023, Monograph Cannabis Flos, Ph. Eur. ver. 11.3, ch. 2.2.27	Complies	Complies

*For eight specific pesticides, the quantification limit in Ph. Eur. could not be reached. Furthermore, tetradifon is not included due to technical limitations. For elaboration, please request the document "Risk assessment for pesticide analysis in cannabis flowers".