

Batch Release Certificate

Batch 06051848120-1-B1

Product type: Cannabis flos packed as bulk product

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

Form: Herbal tea/inhalation vapour, herbal drug.

Product name: Cannabis 1A 16/1 flos

Size: 1000 g

Product specification no: 001099 ver. 4.0

Item number: 3033

Packaging material: 001200 - PETP/ALU/PE bag 4802118

Content: THC: 15.8% CBD: < 0.1%

Date of harvest: 2021.02.22

Date of release: 2024.09.18

Expiry date: 2025.02.26*

Irradiation CoP: W0# 3613585 Min.abs.dose: 24.0 kGy Max.abs.dose: 28.3 kGy

Original CoA reference: 210-1380308

Quality attributes: See next page

Manufacturing site:
Schroll Medical ApS
Kildegårdsvej 32
5792 Årlev
Denmark

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

Analysis, stability testing:
QSI GmbH
Flughafenamm 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 reduced according to deviation 0132.

2024.10.14

Date

Årlev, Denmark

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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	Ph. Eur. ver. 11.5, ch. 2.8.2	≤ 2%	< 2%
Total Aerobic Microbial Count (TAMC)	Ph. Eur. ver. 11.5, 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. 11.5, ch. 5.1.4 Inhalation use and 2.6.12	≤ 10 CFU/g	< 10 CFU/g
<i>E. Coli</i>	Ph. Eur. ver. 11.5, ch. 5.1.8 B and 2.6.31	Absent in 1 g	Absent in 1 g
<i>Salmonella</i>	Ph. Eur. ver. 11.5, ch. 5.1.8 B and 2.6.31	Absent in 25 g	Absent in 25 g
<i>S. aureus</i>	Ph. Eur. ver. 11.5, 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. 11.5, 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. 11.5, ch. 5.1.4 Inhalation use and 2.6.13	Absent in 1 g	Absent in 1 g
Loss on Drying, DE	DAB 2023, Monograph Cannabis Flos Ph. Eur. ver. 11.5, ch. 2.2.32	≤ 10%	8.8%
UHPLC identification	DLS 2023.3, Monograph Cannabis Flos Ph. Eur. ver. 11.5, ch. 2.2.29	Complies	Complies
HPLC – Total THC	DAB 2023, Monograph Cannabis Flos Ph. Eur. ver. 11.5, ch. 2.2.29	16.0 ± 10% (14.4 – 17.6%)	15.8%
HPLC – Total CBD	DAB 2023, Monograph Cannabis Flos Ph. Eur. ver. 11.5, ch. 2.2.29	≤ 1.0 %	< 0.1%
HPLC – CBN	DAB 2023, Monograph Cannabis Flos Ph. Eur. ver. 11.5, ch. 2.2.29	≤ 1.0 %	< 0.1%
Aflatoxin B1	Ph. Eur. ver. 11.5, ch. 2.8.18	≤ 2 µg/kg	< 0.5 µg/kg
Aflatoxin B1+B2+G1+G2	Ph. Eur. ver. 11.5, ch. 2.8.18	≤ 4 µg/kg	< 2.5 µg/kg
Absence of pesticides	Ph. Eur. ver. 11.5, ch. 2.8.13	Below limits in Ph. Eur.	Below limits in Ph. Eur.**
Lead	Ph. Eur. ver. 11.5, ch. 2.4.27	≤ 5.0 ppm	< 0.1 ppm
Mercury	Ph. Eur. ver. 11.5, ch. 2.4.27	≤ 0.1 ppm	< 0.05 ppm
Cadmium	Ph. Eur. ver. 11.5, ch. 2.4.27	≤ 1.0 ppm	< 0.05 ppm
Arsenic	Ph. Eur. ver. 11.5, ch. 2.4.27	≤ 3.0 ppm	< 0.1 ppm
Total ash	Ph. Eur. ver. 11.5, ch. 2.4.16	≤ 20%	10.1%
Odour	DAB 2023, Monograph Cannabis Flos	Complies	Complies
TLC	DAB 2023, Monograph Cannabis Flos Ph. Eur. ver. 11.5, ch. 2.2.27	Complies	Complies

**For seven 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"