



SCHROLL
MEDICAL

Batch Release Certificate

Batch 06051832121-2-P4

Product type: Cannabis-flos packed as primary product
Cultivar: Cannabis Sativa L, 'SCHROLL-MEDICAL-060518'
Form: Herbal tea/inhalation vapour, herbal drug
Product name: AMP classic 18/1 primary
Size: 10 g
Product specification no: 001075 ver. 7.0.
Item number: 4028
Content: THC: 18.2% CBD: < 0.1%
Date of release: 2024.07.25
Date of manufacture: 2024.05.23
Expiry date: 2025.02.23
Irradiation CoP: WO# 3561681 Min.abs.dose: 22.8 kGy Max.abs.dose: 29.4 kGy
Original CoA reference: 210-1930591
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.

2024.07.25

Date

Årsløv, Denmark

Jonas Skov, Delegate Competent Person (DCP)

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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
Macroscopic Identification	DLS 2023.3, Monograph Cannabis Flos	Complies	Complies
Microscopic Identification	DLS 2023.3, Monograph Cannabis Flos	Complies	Complies
Foreign matter	Ph. Eur. ver. 11.4, ch. 2.8.2	≤ 2%	< 2%
Total Aerobic Microbial Count (TAMC)	Ph. Eur. ver. 11.4, 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. 11.4, ch. 5.1.4 Inhalation use and 2.6.12	≤ 10 CFU/g	< 10 CFU/g
<i>E. coli</i>	Ph. Eur. ver. 11.4, ch. 5.1.8 B and 2.6.31	Absent in 1 g	Absent in 1 g
<i>Salmonella</i>	Ph. Eur. ver. 11.4, ch. 5.1.8 B and 2.6.31	Absent in 25 g	Absent in 25 g
Bile-tolerant Gram-negative bacteria	Ph. Eur. ver. 11.4, ch. 5.1.8 B and 2.6.31	≤ 100 CFU/g	< 10 CFU/g
<i>S. aureus</i>	Ph. Eur. ver. 11.4, 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. 11.4, 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. 11.4, 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. 11.4, ch. 2.2.32	≤ 12%	7.0%
UHPLC Identification	DLS 2023.3, Cannabis monograph Ph. Eur. ver. 11.4, ch. 2.2.29	Complies	Complies
HPLC – Total THC	DAB 2023, Monograph Cannabis Flos, Ph. Eur. ver. 11.4, ch. 2.2.29	18.0 ± 10% (16.2 – 19.8%)	18.2%
HPLC – Total CBD	DAB 2023, Monograph Cannabis Flos, Ph. Eur. ver. 11.4, ch. 2.2.29	≤ 1.0 %	< 0.1%
HPLC – CAN	DAB 2023, Monograph Cannabis Flos, Ph. Eur. ver. 11.4, ch. 2.2.29	≤ 1.0 %	< 0.1%
Aflatoxin B1	Ph. Eur. ver. 11.4, ch. 2.8.18	≤ 2 µg/kg	< 0.5 µg/kg
Aflatoxin B1+B2+G1+G2	Ph. Eur. ver. 11.4, ch. 2.8.18	≤ 4 µg/kg	< 2.5 µg/kg
Absence of pesticides	Ph. Eur. ver. 11.4, ch. 2.8.13	Below limits in Ph. Eur.	Below limits in Ph. Eur.*
Lead	Ph. Eur. ver. 11.4, ch. 2.4.27	≤ 5.0 ppm	< 0.1 ppm
Mercury	Ph. Eur. ver. 11.4, ch. 2.4.27	≤ 0.1 ppm	< 0.05 ppm
Cadmium	Ph. Eur. ver. 11.4, ch. 2.4.27	≤ 1.0 ppm	< 0.05 ppm
Total ash	Ph. Eur. ver. 11.4, ch. 2.4.16	≤ 20%	9.3%
Odour	DAB 2023, Monograph Cannabis Flos	Complies	Complies
TLC	DAB 2023, Monograph Cannabis Flos, Ph. Eur. ver. 11.4, 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".