



Batch Release Certificate

Batch 02209916123-1-P4

Product type: Cannabis flos packed as primary product

Cultivar: Cannabis Sativa L. 'SCHROLL-MEDICAL-022099'

Form: Herbal tea/inhalation vapour, herbal drug.

Product name: AMP Classic 25/1 (10 g)

Size: 10 g

Product specification no: 001.112 ver. 3.0

Item number: 4048

Packaging material
001002 - Duma special 250 ml 6525Q
001001 - Duma lid handy cap 6017

Average amount in each container
10.03 g/container

Content: THC: 22.8% CBD: < 0.05%

Date of release: 2024.10.15

Date of manufacture 2024.08.23

Expiry date: 2025.05.23

Irradiation CoP: WO#3613584 Min.abs.dose: 22.7 kGy Max.abs.dose: 29.2 kGy

Original CoA reference: A0383, Q0609

Quality attributes: See next page

Manufacturing site:
Schroll Medical ApS
Kildegårdsvej 32
5792 Årslev
Denmark

E-Beam irradiation:
Sterigenics Denmark A/S
Aa. Louis-Hansens Allé 1.1
3060 Espergerde
Denmark

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

Analysis, stability testing:
QNTM Labs ApS
Unsbjergvej 4A
5220 Odense SØ
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.

2024.10.15

Date: Årslev, 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
ID A - Macroscopic Identification	Ph. Eur. ver. 11.5, Cannabis Flower, 3028*	Complies	Complies
ID B - Microscopic Identification	Ph. Eur. ver. 11.5, Cannabis Flower, 3028*	Complies	Complies
ID C - HPTLC	Ph. Eur. ver. 11.5, Cannabis Flower, 3028*	Complies	Complies
Foreign matter	Ph. Eur. ver. 11.5, Cannabis Flower, 3028*	≤ 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	50 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
Salmonella	Ph. Eur. ver. 11.5, 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. 11.5, ch. 5.1.8 B and 2.6.31	≤ 100 CFU/g	< 10 CFU/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
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 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, Cannabis Flower, 3028*	≤ 0.5 ppm	< 0.25 ppm
Mercury	Ph. Eur. ver. 11.5, Cannabis Flower, 3028*	≤ 0.1 ppm	< 0.05 ppm
Cadmium	Ph. Eur. ver. 11.5, Cannabis Flower, 3028*	≤ 0.3 ppm	< 0.15 ppm
Total ash	Ph. Eur. ver. 11.5, ch. 2.4.16	≤ 20%	9%
Loss on Drying	DAB 2024, Monograph Cannabis Flos	≤ 10%	9.5%
HPLC - Total THC	DAB 2024, Monograph Cannabis Flos	25.0 ± 10% (22.5 - 27.5%)	22.8%
HPLC - Total CBD	DAB 2024, Monograph Cannabis Flos	≤ 1.0%	< 0.05%
HPLC - CBN	DAB 2024, Monograph Cannabis Flos	≤ 1.0%	< 0.05%

*Analyses performed according to Ph. Eur. Cannabis Flower Monograph, 3028 are not in accordance with the specification requirements, but has been accepted by the customer as documented in the batch report.

**For five specific pesticides, the qualification limit in Ph. Eur. could not be reached. The specific pesticides have been assessed and it has been found acceptable, see STAT:0095.