

## Batch Release Certificate

Batch 02209925224-1-P2

**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:** 001118 ver. 6.0

**Item number:** 4048

**Packaging material:** 001002 - Duma special 250 ml 65250  
001001 - Duma lid handy cap 6017

**Average amount in each container:** 10.00 g/container

**Content:** THC: 24.1%      CBD: < 0.05%

**Date of release:** 2024.11.15

**Date of manufacture:** 2024.10.21

**Expiry date:** 2025.07.21

**Irradiation CoP:** WOH3645298      Min.abs.dose: 22.4 kGy      Max.abs.dose: 28.8 kGy

**Original CoA reference:** 210-1408256

**Quality attributes:** See next page

<b>Manufacturing site:</b> Schroll Medical ApS Kildegårdsvej 32 5792 Årslev Denmark	<b>E-Beam irradiation:</b> Sterigenics Denmark A/S Aa. Louis-Hansens Allé 11 3050 Espergårde Denmark	<b>Analysis, stability testing:</b> QSI GmbH Flughafendamm 9a 28199 Bremen Germany	<b>Analysis, stability testing:</b> QNTM Labs ApS Unsbjergvej 4A 5220 Odense SØ Denmark
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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.

2024.11.15

Date: \_\_\_\_\_  
Årslev, Denmark



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Batch 02209925224-1-P2

## 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	< 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
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	< 2.5 µg/kg
Ochratoxin A	Ph. Eur. ver. 11.5, ch. 2.8.18	≤ 20 µg/kg	< 0.5 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, Cannabis Flower, 3028*	≤ 0.5 ppm	< 0.1 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	0.06 ppm
Arsenic	Ph. Eur. ver. 11.5, ch. 2.8.13	≤ 0.3 ppm	< 0.1 ppm
Total ash	Ph. Eur. ver. 11.5, ch. 2.4.16	≤ 20%	10.5%
Loss on Drying	Ph. Eur. ver. 11.5, Cannabis Flower, 3028*	≤ 12%	9.2%
HPLC – Total THC	Ph. Eur. ver. 11.5, Cannabis Flower, 3028*	25.0 ± 10% (22.5 – 27.5%)	24.1%
HPLC – Total CBD	Ph. Eur. ver. 11.5, Cannabis Flower, 3028*	≤ 1.0%	< 0.1%
HPLC – Total CBN	Ph. Eur. ver. 11.5, Cannabis Flower, 3028*	≤ 1.0%	< 0.1%

\*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".