



SCHROLL
MEDICAL

Batch Release Certificate

Batch 06051826224-1-P1

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. 8.0
Item number: 4028
Packaging material: 001002 - Duma special 250 ml 65250
001001 - Duma lid handy cap 6017
Average amount in each container: 10.03 g/container
Content: THC: 18.0% CBD: < 0.05%
Date of release: 2024.11.15
Date of manufacture: 2024.10.18

Expiry date: 2025.07.18

Irradiation CoP: WD#3645298 Min.abs.dose: 22.4 kGy Max.abs.dose: 28.8 kGy

Original CoA reference: Q0690

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 11
3060 Espergærde
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.

2024.11.15

Date

Årslev, Denmark

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Denmark

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CVR: 39467135

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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	< 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
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	< 0.25 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
Arsenic	Ph. Eur. ver. 11.5, ch. 2.8.13	≤ 0.2 ppm	< 0.1 ppm
Total ash	Ph. Eur. ver. 11.5, ch. 2.4.16	≤ 20%	11.0%
Loss on Drying	Ph. Eur. ver. 11.5, Cannabis Flower, 3028*	≤ 12%	8.9%
HPLC - Total THC	Ph. Eur. ver. 11.5, Cannabis Flower, 3028*	25.0 ± 10% (22.5 - 27.5%)	18.0%
HPLC - Total CBD	Ph. Eur. ver. 11.5, Cannabis Flower, 3028*	≤ 1.0%	< 0.2%
HPLC - Total CBN	Ph. Eur. ver. 11.5, Cannabis Flower, 3028*	≤ 1.0%	0.1%

*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.0025.