

Batch Release Certificate

Batch 06051846120-1-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. 5.0
Item number: 3033
Packaging material: 001200 - PETP/ALU/PE bag 4802118

Content: THC: 16.2% CBD: < 0.2%

Date of harvest: 2021.02.08

Date of release: 2024.11.21

Date of Manufacture: 2024.10.16

Expiry date: 2025.04.16*

Irradiation CoP: WO# 3645299 Min.abs.dose: 23,7 kGy Max.abs.dose: 27,9 kGy

Original CoA reference: Q0585

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
Flughafenallee 9a
28199 Bremen
Germany

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

*Shelf life reduced according to deviation 0132.

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.

2024.11.21

Date: Årslev, Denmark

Schroll Medical ApS
Kildegårdsvej 32
5792 Årslev
Denmark

Telephone: +45 20 14 11 44
E-mail: info@schroll-medical.com
Website: www.schroll-medical.com
CVR: 33487183

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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
<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	Ph. Eur. ver. 11.5, Cannabis Flower, 3028	≤ 12.0%	8.3%
HPLC - Total THC	Ph. Eur. ver. 11.5, Cannabis Flower, 3028	16.0 ± 10% (14.4 - 17.6%)	16.2%
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%	0.4%
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
Ochratoxin A	Ph. Eur. ver. 11.5, ch. 2.8.22	≤ 20 µg/kg	< 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, Cannabis Flower, 3028	≤ 0.2 ppm	< 0.1 ppm
Total ash	Ph. Eur. ver. 11.5, ch. 2.4.16	≤ 20%	10 %

*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.0035.