

Batch Release Certificate

Batch 02209905223-1-B1

Product type:	Cannabis flos packed as bulk product		
Cultivar:	<i>Cannabis Sativa</i> L. "SCHROLL-MEDICAL-022099"		
Form:	Herbal tea/inhalation vapour, herbal drug.		
Product name:	Cannabis Flos WEECO 23/1		
Size:	1000 g		
Product specification no:	001114 ver. 4.0		
Item number:	3036		
Content:	THC: 22.6%	CBD: < 0.1%	
Date of harvest:	2023.05.22		
Date of release:	2024.07.31		
Expiry date:	2025.07.09		
Irradiation CoP:	WO# 3585532	Min.abs.dose: 24.8 kGy	Max.abs.dose: 29.2 kGy
Original CoA reference:	210-1354934		
Quality attributes:	See next page		
Manufacturing site:	E-Beam irradiation:	Analysis, stability testing:	Analysis, stability testing:
Schroll Medical ApS Kildegårdsvej 32 5792 Årslev Denmark	Sterigenics Denmark A/S Aa. Louis-Hansens Allé 11 3060 Espergærde Denmark	QSI GmbH Flughafendamm 9a 28199 Bremen Germany	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.

2024.07.31
Date

Årslev, DK
Årslev, Denmark

Mie H. Grundt Christiansen
Mie Hanghøj Grundt Christiansen, Competent Person (CP)

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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
Foreign matter	Ph. Eur. ver. 11.5, ch. 2.8.2	≤ 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
<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	DAB 2023, Monograph Cannabis Flos Ph. Eur. ver. 11.5, ch. 2.2.32	≤ 10%	6.6%
UHPLC identification	DLS 2023.3, Monograph Cannabis Flos Ph. Eur. ver. 11.5, ch. 2.2.29	Complies	Complies
HPLC – Total THC	DAB 2023, Monograph Cannabis Flos Ph. Eur. ver. 11.5, ch. 2.2.29	23.0 ± 10% (20.7 – 25.3%)	22.6%
HPLC – Total CBD	DAB 2023, Monograph Cannabis Flos Ph. Eur. ver. 11.5, ch. 2.2.29	≤ 1.0 %	< 0.1%
HPLC – CBN	DAB 2023, Monograph Cannabis Flos Ph. Eur. ver. 11.5, ch. 2.2.29	≤ 1.0 %	< 0.1%
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
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, ch. 2.4.27	≤ 5.0 ppm	< 0.1 ppm
Mercury	Ph. Eur. ver. 11.5, ch. 2.4.27	≤ 0.1 ppm	< 0.05 ppm
Cadmium	Ph. Eur. ver. 11.5, ch. 2.4.27	≤ 1.0 ppm	< 0.05 ppm
Arsenic	Ph. Eur. ver. 11.5, ch. 2.4.27	≤ 3.0 ppm	< 0.1 ppm
Total ash	Ph. Eur. ver. 11.5, ch. 2.4.16	≤ 20%	9.8%
Odour	DAB 2023, Monograph Cannabis Flos	Complies	Complies
TLC	DAB 2023, Monograph Cannabis Flos Ph. Eur. ver. 11.5, 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"