



Batch 06051832121-2-P3

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: Eurofins Denmark A/S Ørnebjergvej 1, 2600 Glostrup Denmark
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Kayla Glud, Delegate Competent Person (dCP)

Batch Release Certificate

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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. 11.4, ch. 2.8.2	≤ 2%	< 2%
Total Aerobic Microbial Count (TAMC)	Ph. Eur. ver. 11.4, 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. 11.4, ch. 5.1.4 Inhalation use and 2.6.12	≤ 10 CFU/g	< 10 CFU/g
<i>E. Coli</i>	Ph. Eur. ver. 11.4, ch. 5.1.8 B and 2.6.31	Absent in 1 g	Absent in 1 g
<i>Salmonella</i>	Ph. Eur. ver. 11.4, ch. 5.1.8 B and 2.6.31	Absent in 25 g	Absent in 25 g
<i>S. aureus</i>	Ph. Eur. ver. 11.4, 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. 11.4, 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. 11.4, 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. 11.4, ch. 2.2.32	≤ 10%	7.0%
UHPLC identification	DLS 2023.3, Cannabis monograph Ph. Eur. ver. 11.4, ch. 2.2.29	Complies	Complies
HPLC – Total THC	DAB 2023, Monograph Cannabis Flos, Ph. Eur. ver. 11.4, ch. 2.2.29	18.0 ± 10% (16.2 – 19.8%)	18.2%
HPLC – Total CBD	DAB 2023, Monograph Cannabis Flos, Ph. Eur. ver. 11.4, ch. 2.2.29	≤ 1.0 %	< 0.1%
HPLC – CBN	DAB 2023, Monograph Cannabis Flos, Ph. Eur. ver. 11.4, ch. 2.2.29	≤ 1.0 %	< 0.1%
Aflatoxin B1	Ph. Eur. ver. 11.4, ch. 2.8.18	≤ 2 µg/kg	< 0.5 µg/kg
Aflatoxin B1+B2+G1+G2	Ph. Eur. ver. 11.4, ch. 2.8.18	≤ 4 µg/kg	< 2.5 µg/kg
Absence of pesticides	Ph. Eur. ver. 11.4, ch. 2.8.13	Below limits in Ph. Eur.	Below limits in Ph. Eur.*
Lead	Ph. Eur. ver. 11.4, ch. 2.4.27	≤ 5.0 ppm	< 0.1 ppm
Mercury	Ph. Eur. ver. 11.4, ch. 2.4.27	≤ 0.1 ppm	< 0.05 ppm
Cadmium	Ph. Eur. ver. 11.4, ch. 2.4.27	≤ 1.0 ppm	< 0.05 ppm
Total ash	Ph. Eur. ver. 11.4, ch. 2.4.16	≤ 20%	9.3%
Odour	DAB 2023, Monograph Cannabis Flos	Complies	Complies
TLC	DAB 2023, Monograph Cannabis Flos, Ph. Eur. ver. 11.4, 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".