



Batch 02209944424-1-P1

Manufacturing site: Schroll Medical ApS Kildegårdsvej 32 5792 Årsløv 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
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2025.05.13

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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
ID A - Macroscopic Identification Includes appearance and odour	Ph. Eur. ver. 11.7, Cannabis Flower, 3028	Complies	Complies
ID B - Microscopic Identification**	Ph. Eur. ver. 11.7, Cannabis Flower, 3028	Complies	Complies
ID C - HPTLC	Ph. Eur. ver. 11.7, Cannabis Flower, 3028	Complies	Complies
Foreign matter**	Ph. Eur. ver. 11.7, Cannabis Flower, 3028	≤ 2% Seeds are absent No leaves > 1.0 cm	< 2% Complies Complies
Total Aerobic Microbial Count (TAMC)	Ph. Eur. ver. 11.7, 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. 11.7, ch. 5.1.4 Inhalation use and 2.6.12	≤ 10 CFU/g	< 10 CFU/g
<i>E. Coli</i>	Ph. Eur. ver. 11.7, ch. 5.1.8 B and 2.6.31	Absent in 1 g	Absent in 1 g
<i>Salmonella</i>	Ph. Eur. ver. 11.7, ch. 5.1.8 B and 2.6.31	Absent in 25 g	Absent in 25 g
<i>S. aureus</i>	Ph. Eur. ver. 11.7, 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. 11.7, 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. 11.7, ch. 5.1.4 Inhalation use and 2.6.13	Absent in 1 g	Absent in 1 g
Loss on Drying	Ph. Eur. ver. 11.7, Cannabis Flower, 3028	≤ 12.0%	8.6%
HPLC - Total THC	Ph. Eur. ver. 11.7, Cannabis Flower, 3028	23.0 ± 10% (20.7 - 25.3%)	22.5%
HPLC - Total CBD	Ph. Eur. ver. 11.7, Cannabis Flower, 3028	≤ 1.0 %	< 0.1%
HPLC - Total CBN	Ph. Eur. ver. 11.7, Cannabis Flower, 3028	≤ 1.0 %	< 0.1%
Aflatoxin B1	Ph. Eur. ver. 11.7, ch. 2.8.18	≤ 2 µg/kg	< 0.5 µg/kg
Aflatoxin B1+B2+G1+G2	Ph. Eur. ver. 11.7, ch. 2.8.18	≤ 4 µg/kg	< 2.5 µg/kg
Ochratoxin A	Ph. Eur. ver. 11.7, ch. 2.8.22	≤ 20 µg/kg	< 0.5 µg/kg
Absence of pesticides**	Ph. Eur. ver. 11.7, ch. 2.8.13	Below limits in Ph. Eur.	Below limits in Ph. Eur.*
Lead**	Ph. Eur. ver. 11.7, Cannabis Flower, 3028	≤ 0.5 ppm	< 0.25 ppm
Mercury**	Ph. Eur. ver. 11.7, Cannabis Flower, 3028	≤ 0.1 ppm	< 0.05 ppm
Cadmium**	Ph. Eur. ver. 11.7, Cannabis Flower, 3028	≤ 0.3 ppm	< 0.15 ppm
Arsenic**	Ph. Eur. ver. 11.7, Cannabis Flower, 3028	≤ 0.2 ppm	< 0.1 ppm

*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.

**Non-stability indicating parameters are tested on the batch immediately after harvest, see CoA containing microscopic identification (ID B).