

RELEASE CERTIFICATE 25.11.2020 10:05

Certificate of Analysis - Certificate of Compliance

Product: Medicinal Cannabis (flowers), variety Aurora 1/12
Batch: 19-335A
Expiry date: 09/2021

Parameter	Method	Specification	Result	Evaluation
Identity				
Macroscopic description	Visual	Whole or fragmented, dried inflorescences of dark green, grey-green to brown-green colour, forming dense panicles. Small flowers are covered with bracts that are covered with glandular trichomes at the upper side.	Complies	Complies
Thin layer chromatography	ČL 2.2.27 (= Ph.Eur. 2.2.27)	Visual evaluation	Complies	Complies
Purity				
Foreign material	ČL 2.8.2 (= Ph.Eur. 2.8.2)	Max. 2 % (m/m)	Complies	Complies
Loss on Drying	ČL 2.2.32 (= Ph.Eur. 2.2.32)	Max. 10.0 %	7.3 %	Complies
Pesticides	ČL 2.8.13 (= Ph.Eur. 2.8.13)	Comply with limits specified in ČL 2.8.13 (= Ph.Eur. 2.8.13)	Complies	Complies
Absence of heavy metals	ČL 2.4.27 (= Ph.Eur. 2.4.27)			
Lead (Pb)		Max. 5.0 µg/g (ppm)	< 0.1 ppm	Complies
Mercury (Hg)		Max. 0.1 µg/g (ppm)	< 0.05 ppm	Complies
Cadmium (Cd)		Max. 1.0 µg/g (ppm)	0.07 ppm	Complies
Aflatoxins	ČL 2.8.18 (= Ph.Eur. 2.8.18)			
Aflatoxin B1		Max. 2 µg/kg (ppb)	< 0.5 ppb	Complies
Sum of Aflatoxins B1, B2, G1 and G2		Max. 4 µg/kg (ppb)	< 0.7 ppb	Complies
Microbiological purity	ČL 2.6.12 and 2.6.13 (= Ph.Eur. 2.6.12 and 2.6.13)	Comply with Ph.Eur. 5.1.4		
Total aerobic microbial count (TAMC)		Max. 10 ³ cfu/g	< 100 cfu/g	Complies
Total yeast and molds count (TYMC)		Max. 10 ² cfu/g	< 10 cfu/g	Complies
Related substance	HPLC, ČL 2.2.29 (= Ph.Eur. 2.2.29)			
Cannabinol (CBN)		Max. 1 %	< 0.1 %	Complies
Assay				
Dronabinol (THC)	HPLC, ČL 2.2.29 (= Ph.Eur. 2.2.29)	≤ 1%	0.5 %	Complies
Cannabidiol (CBD)	HPLC, ČL 2.2.29 (= Ph.Eur. 2.2.29)	12% ± 20% (9.6 – 14.4%)	11.5 %	Complies

Berlin, 25.11.2020



Sven Lehsing
 Qualified Person/Sachkundige Person nach § 14 AMG

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Strength: Dronabinol (THC): ≤ 1%
Cannabidiol (CBD): 12% ± 20% (9.6 - 14.4 %)
Dosage Form: Dried Flowers
Package size: 10 grams
Destination: Czech Republic

Manufacturer: AURORA Cannabis Enterprises Inc.
Canada

Batch Release: AURORA Deutschland GmbH
Wilmsdorfer Str. 98/99
D-10629 Berlin
GMP Certificate No.: DE_BE_01_GMP_2020_0027

Irradiation site: Iotron Industries Canada Inc.

Irradiation date: 14.08.2019

Irradiation dose: 10.8 – 11.2 kGy

Testing method: DAB Monograph *Cannabisblüten* (current edition)
Ph.Eur. Monograph <1433> *Herbal Drugs* (current edition)

Testing sites: Quality Services International GmbH
Flughafendamm 9a
D-28199 Bremen

Storage: Tightly closed, protected from light, below 25 °C.

Remark: We recommend the indication of the THC concentration “as it is” on the label of the bottle which is intended to be delivered to the patient.

Conclusion: Meets the requirements of Czech Decree 236/2015 Coll.

I hereby certify that the information is authentic and accurate. This batch of product has been produced, including packaging and quality control, in full compliance with GMP requirements and with the specifications as stated in this document. The batch processing, packaging and analysis records were reviewed and found to be in full compliance with GMP.

Berlin, 25.11.2020


Sven Lehsing
Qualified Person/Sachkundige Person nach § 14 AMG