



Specification Sheet

(Valid until implementation of EP Monograph 7/2024:3028 Cannabis flower according to CC2024-003)

Product: **Cannabis flos, variety Bedrobinol** (hemp flowers)
Market: to be sold on the pharmaceutical market
Strength: tetrahydrocannabinol: ca. 13,5% cannabidiol: ≤ 1.0%
Dosage form: flowers
Package size: 5 grams in containers, 400 grams in bags
Analytical Monograph: OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021

	Method	Specification
Odour	Ph. Eur. (current ed.) 2.3.4	Characteristic for Cannabis flower
Appearance	Visual	Leaves shoot out no more than 20% of the length of the flower and stalks are mostly cut off directly under the bottom site of the flowers
Identification		
<i>Macroscopic botanical characters</i>	Visual	Brown, green clustered flowers of about 1.5 to 3.0 cm length
<i>Microscopic botanical characters</i>	Monograph	Gland hairs are mainly observed
<i>Thin-layer chromatography</i>	Ph. Eur. (current ed.) 2.2.27, Monograph	Comparable with reference
Loss on drying	Ph. Eur. (current ed.) 2.2.32	≤ 10.0 %
Foreign material	Visual	Free from insects and other vermin
Aflatoxins	Monograph	Aflatoxin B1 ≤ 2 µg/kg
		Sum of aflatoxins B1, B2, G1 and G2 ≤ 4 µg/kg
Pesticides	Ph. Eur. (current ed.) 2.8.13	≤ Limits Ph. Eur. 2.8.13

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	Method	Specification	
Heavy metals	Ph. Eur. (current ed.) 2.4.27, 2.2.58	Lead	≤ 20.0 ppm
		Cadmium	≤ 0.5 ppm
		Mercury	≤ 0.5 ppm
Assay	Ph. Eur. (current ed.) 2.2.29, Monograph	Tetrahydrocannabinol (THC, total eq.)	13.5% [10.8 – 16.2]
		Cannabidiol (CBD, total eq.)	≤ 1.0%
Related substances	Ph. Eur. (current ed.) 2.2.29, Monograph	Cannabinol (CBN, total eq.)	≤ 1.0%
Microbial contamination	Ph. Eur. (current ed.) 2.6.12, 2.6.13	Total aerobic microbial count (TAMC)	≤ 10 ² CFU/gram
		Total combined yeasts/moulds count (TYMC)	≤ 10 ¹ CFU/gram
		<i>Staphylococcus aureus</i>	Absent (1 gram)
		<i>Pseudomonas aeruginosa</i>	Absent (1 gram)
		Bile-tolerant gram-negative bacteria	Absent (1 gram)