



## Specification Sheet

Product: **Cannabis flos, variety Bedrocan** (hemp flowers)  
**THC-dominant type**

Market: to be prescribed to patients as a medicinal product.

Strength: tetrahydrocannabinol:  $\geq 5.0\%$                       cannabidiol:  $\leq 1.0\%$

Dosage form: flowers

Package size: 5 grams in containers, 400 grams in bags

Analytical Monograph: European Pharmacopoeia (Ph. Eur.) 07/2024:3028

	<b>Method</b>	<b>Specification</b>
Odour	Ph. Eur. (current ed.) 2.3.4	Characteristic for Cannabis flower
Appearance	Visual	Dried, whole, fully developed female inflorescence of Cannabis sativa L.  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>	Monograph	Conform Identification A.
<i>Microscopic botanical characters</i>	Monograph	Conform Identification B.
<i>High-performance thin-layer chromatography</i>	Monograph	Comparable with reference and test solutions THC-dominant type. Conform Identification C.
Loss on drying	Monograph	$\leq 12.0 \%$
Foreign material	Monograph	Maximum 2 per cent. It does not contain any seeds or other foreign elements and the whole herbal drug does not contain any leaves more than 1.0 cm in length.

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	<b>Method</b>	<b>Specification</b>	
Aflatoxins	Ph. Eur. 2.8.18 (current ed.)	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	
Heavy metals	Monograph	Arsenic	≤ 0.2 ppm
		Cadmium	≤ 0.3 ppm
		Lead	≤ 0.5 ppm
		Mercury	≤ 0.1 ppm
Assay	Monograph	Tetrahydrocannabinol (THC, total eq.)	≥ 5.0%
		Cannabidiol (CBD, total eq.)	≤ 1.0%
Related substances	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 <sup>2</sup> CFU/gram
		Total combined yeasts/moulds count (TYMC)	≤ 10 <sup>1</sup> CFU/gram
		Staphylococcus aureus	Absent (1 gram)
		Pseudomonas aeruginosa	Absent (1 gram)
		Bile-tolerant gram- negative bacteria	Absent (1 gram)