



Specification Sheet

Product: **Cannabis flos, variety Bedica** (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, granulated

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

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

	Method	Specification
Odour	Ph. Eur. (current ed.) 2.3.4	Characteristic for Cannabis flower
Appearance	Visual	Dried, fragmented, fully developed female inflorescence of Cannabis sativa L. Stalks are no longer than 2.0 cm and only 20% of the stalks are between 1.5 and 2.0 cm.
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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	Method	Specification	
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 ² CFU/gram
		Total combined yeasts/moulds count (TYMC)	≤ 10 ¹ CFU/gram
		Staphylococcus aureus	Absent (1 gram)
		Pseudomonas aeruginosa	Absent (1 gram)
		Bile-tolerant gram- negative bacteria	Absent (1 gram)