



## Specification sheet

(version: January 2019)

Product: **Cannabis flos**, ssp. sativa, **variety Bedrocan** (hemp flowers)  
Market: to be sold on the pharmaceutical market  
Strength: tetrahydrocannabinol: approx. 22% cannabidiol: <1.0%  
Dosage form: flowers  
Package size: 5 grams in containers, 250 or 400 grams in bags

	Method	Specification
Appearance	Monograph <sup>1</sup>	Brown green clustered flowers of 1,5 to 3 cm with a characteristic smell
Identity		
<i>microscopy</i>	Monograph	Mainly gland hairs visible
<i>thin layer chromatography</i>	Monograph	Monograph
Foreign material	Monograph	Stalks, insects and other vermin are absent
Fineness	Monograph	<ul style="list-style-type: none"><li>no leaves shooting out more than 20% of the length of the flowers</li><li>stalks are cut away directly under the bottom flowers of the inflorescence</li></ul>
Absence of pesticides	Monograph	Ph. Eur (current ed.) 2.8.13
Microbiological purity	Ph. Eur (current ed.) 5.1.4.	
<i>Total aerobic microbial count (TAMC)</i>	5.1.4.-1.	≤ 10 <sup>2</sup> cfu/gram
<i>Total yeast and moulds count (TYMC)</i>	5.1.4.-1.	≤ 10 cfu/gram
<i>P. aeruginosa, S. aureus and Bile tolerant gram neg bacteria</i>	5.1.4.-1.	absent

<sup>1</sup> Analytical monograph by BMC / Farmalyse, version 7.1 of November 2014



	<b>Method</b>	<b>Specification</b>	
Absence of heavy metals			
<i>lead</i>	Ph. Eur (current ed.) "Heavy metals in herbal drugs and fatty oils" (monograph)	max. 20.0	ppm
<i>mercury</i>		max. 0.5	ppm
<i>cadmium</i>		max. 0.5	ppm
<i>arsenic (indicative)</i>		-	
<i>nickel (indicative)</i>		-	
<i>zinc (indicative)</i>		-	
Absence of aflatoxines	Ph. Eur (current ed.) "Determination of aflatoxins B <sub>1</sub> , B <sub>2</sub> , G <sub>1</sub> and G <sub>2</sub> in herbal drugs" (2.8.18)	<4	µg/kg
Loss on drying	Ph. Eur (current ed.) "Loss on drying" meth. C (2.2.32)	≤10.0	%
Assay (UPLC)			
<i>fingerprint</i>	Monograph	similar	
<i>tetrahydrocannabinol (THC)</i>	Monograph	approx. 22	%
<i>cannabidiol (CBD)</i>	Monograph	<1.0	%
Related substances (UPLC)			
<i>cannabinol (CBN)</i>	Monograph	<1.0	%



## Specification sheet

(version: January 2019)

Product: **Cannabis flos**, ssp. sativa, **variety Bedrobinol** (hemp flowers)  
Market: to be sold on the pharmaceutical market  
Strength: tetrahydrocannabinol: approx. 13.5%                      cannabidiol: <1.0%  
Dosage form: flowers  
Package size: 5 grams in containers, 250 or 400 grams in bags

	<b>Method</b>	<b>Specification</b>
Appearance	Monograph <sup>2</sup>	Brown green clustered flowers of 1,5 to 3 cm with a characteristic smell
Identity		
<i>microscopy</i>	Monograph	Mainly gland hairs visible
<i>thin layer chromatography</i>	Monograph	Monograph
Foreign material	Monograph	Stalks, insects and other vermin are absent
Fineness	Monograph	<ul style="list-style-type: none"><li>• no leaves shooting out more than 20% of the length of the flowers</li><li>• stalks are cut away directly under the bottom flowers of the inflorescence</li></ul>
Absence of pesticides	Monograph	Ph. Eur (current ed.) 2.8.13
Microbiological purity	Ph. Eur (current ed.) 5.1.4.	
<i>Total aerobic microbial count (TAMC)</i>	5.1.4.-1.	≤ 10 <sup>2</sup> cfu/gram
<i>Total yeast and moulds count (TYMC)</i>	5.1.4.-1.	≤ 10 cfu/gram

<sup>2</sup> Analytical monograph by BMC / Farmalyse, version 7.1 of November 2014



	<b>Method</b>	<b>Specification</b>	
<i>P. aeruginosa</i> , <i>S. aureus</i> and <i>Bile tolerant gram neg bacteria</i>	5.1.4.-1.	absent	
Absence of heavy metals			
<i>lead</i>	Ph. Eur (current ed.)	max. 20.0	ppm
<i>mercury</i>	"Heavy metals in herbal drugs and fatty oils" (monograph)	max. 0.5	ppm
<i>cadmium</i>		max. 0.5	ppm
<i>arsenic (indicative)</i>		-	
<i>nickel (indicative)</i>		-	
<i>ninc (indicative)</i>		-	
Absence of aflatoxines	Ph. Eur (current ed.) "Determination of aflatoxins B <sub>1</sub> , B <sub>2</sub> , G <sub>1</sub> and G <sub>2</sub> in herbal drugs" (2.8.18)	<4	µg/kg
Loss on drying	Ph. Eur (current ed.) "Loss on drying" meth. C (2.2.32)	≤10.0	%
Assay (UPLC)			
<i>fingerprint</i>	Monograph	Similar	
<i>tetrahydrocannabinol (THC)</i>	Monograph	approx. 13.5	%
<i>cannabidiol (CBD)</i>	Monograph	<1.0	%
Related substances (UPLC)			
<i>cannabinol (CBN)</i>	Monograph	<1.0	%



## Specification sheet

(version: January 2019)

Product: **Cannabis flos**, ssp. sativa, **variety Bediol** (hemp flowers)  
Market: to be sold on the pharmaceutical market  
Strength: tetrahydrocannabinol: approx. 6.3%      cannabidiol: approx. 8%  
Dosage form: flowers, granulated  
Package size: 5 grams in containers, 250 or 400 grams in bags

	<b>Method</b>	<b>Specification</b>
Appearance	Monograph <sup>3</sup>	Brown green granulated material of the flowers (about 5 mm) with a characteristic smell
Identity		
<i>microscopy</i>	Monograph	Mainly gland hairs visible
<i>thin layer chromatography</i>	Monograph	Monograph
Foreign material	Monograph	Insects and other vermin are absent
Fineness	Monograph	Stalks are not longer than 2.0 cm Only 20% of the stalks is between 1.5 and 2.0 cm
Absence of pesticides	Monograph	Ph. Eur (current ed.) 2.8.13
Microbiological purity	Ph. Eur (current ed.) 5.1.4.	
<i>Total aerobic microbial count (TAMC)</i>	5.1.4.-1.	≤ 10 <sup>2</sup> cfu/gram
<i>Total yeast and moulds count (TYMC)</i>	5.1.4.-1.	≤ 10 cfu/gram
<i>P. aeruginosa, S. aureus and Bile tolerant gram neg bacteria</i>	5.1.4.-1.	absent

<sup>3</sup> Analytical monograph by BMC / Farmalyse, version 7.1 of November 2014



	Method	Specification	
Absence of heavy metals			
<i>lead</i>	Ph. Eur (current ed.) "Heavy metals in herbal drugs and fatty oils" (monograph)	max. 20.0	ppm
<i>mercury</i>		max. 0.5	ppm
<i>cadmium</i>		max. 0.5	ppm
<i>arsenic (indicative)</i>		-	
<i>nickel (indicative)</i>		-	
<i>zinc (indicative)</i>		-	
Absence of aflatoxines	Ph. Eur (current ed.) "Determination of aflatoxins B <sub>1</sub> , B <sub>2</sub> , G <sub>1</sub> and G <sub>2</sub> in herbal drugs" (2.8.18)	<4	µg/kg
Loss on drying	Ph. Eur (current ed.) "Loss on drying" meth. C (2.2.32)	≤10.0	%
Assay (UPLC)			
<i>fingerprint</i>	Monograph	Similar	
<i>tetrahydrocannabinol (THC)</i>	Monograph	approx. 6.3	%
<i>cannabidiol (CBD)</i>	Monograph	approx. 8	%
Related substances (UPLC)			
<i>cannabinol (CBN)</i>	Monograph	<1.0	%



## Specification sheet

(version: January 2019)

Product: **Cannabis flos**, ssp. indica, **variety Bedica** (hemp flowers)  
Market: to be sold on the pharmaceutical market  
Strength: tetrahydrocannabinol: approx. 14%                      cannabidiol: <1.0%  
Dosage form: flowers, granulated  
Package size: 5 grams in containers, 250 or 400 grams in bags

	<b>Method</b>	<b>Specification</b>
Appearance	Monograph <sup>4</sup>	Brown green granulated material of the flowers (about 5 mm) with a characteristic smell
Identity		
<i>microscopy</i>	Monograph	Mainly gland hairs visible
<i>thin layer chromatography</i>	Monograph	Monograph
Foreign material	Monograph	Insects and other vermin are absent
Fineness	Monograph	Stalks are not longer than 2.0 cm Only 20% of the stalks is between 1.5 and 2.0 cm
Absence of pesticides	Monograph	Ph. Eur (current ed.) 2.8.13
Microbiological purity	Ph. Eur (current ed.) 5.1.4.	
<i>Total aerobic microbial count (TAMC)</i>	5.1.4.-1.	≤ 10 <sup>2</sup> cfu/gram
<i>Total yeast and moulds count (TYMC)</i>	5.1.4.-1.	≤ 10 cfu/gram
<i>P. aeruginosa, S. aureus and Bile tolerant gram neg bacteria</i>	5.1.4.-1.	absent

<sup>4</sup> Analytical monograph by BMC / Farmalyse, version 7.1 of November 2014



	Method	Specification	
Absence of heavy metals			
<i>lead</i>	Ph. Eur (current ed.) "Heavy metals in herbal drugs and fatty oils" (monograph)	max. 20.0	ppm
<i>mercury</i>		max. 0.5	ppm
<i>cadmium</i>		max. 0.5	ppm
<i>arsenic (indicative)</i>		-	
<i>nickel (indicative)</i>		-	
<i>zinc (indicative)</i>		-	
Absence of aflatoxines	Ph. Eur (current ed.) "Determination of aflatoxins B <sub>1</sub> , B <sub>2</sub> , G <sub>1</sub> and G <sub>2</sub> in herbal drugs" (2.8.18)	<4	µg/kg
Loss on drying	Ph. Eur (current ed.) "Loss on drying" meth. C (2.2.32)	≤10.0	%
Assay (UPLC)			
<i>fingerprint</i>	Monograph	similar	
<i>tetrahydrocannabinol (THC)</i>	Monograph	approx. 14	%
<i>cannabidiol (CBD)</i>	Monograph	<1.0	%
Related substances (UPLC)			
<i>cannabinol (CBN)</i>	Monograph	<1.0	%





## Specification sheet

(version: January 2019)

Product: **Cannabis flos**, ssp. sativa, **variety Bedrolite** (hemp flowers)  
Market: to be sold on the pharmaceutical market  
Strength: tetrahydrocannabinol: < 1.0%                      cannabidiol: approx. 9.0%  
Dosage form: flowers, granulated  
Package size: 5 grams in containers, 250 or 400 grams in bags

	<b>Method</b>	<b>Specification</b>
Appearance	Monograph <sup>5</sup>	Brown green granulated material of the flowers (about 5 mm) with a characteristic smell
Identity		
<i>microscopy</i>	Monograph	Mainly gland hairs visible
<i>thin layer chromatography</i>	Monograph	Monograph
Foreign material	Monograph	Insects and other vermin are absent
Fineness	Monograph	Stalks are not longer than 2.0 cm Only 20% of the stalks is between 1.5 and 2.0 cm
Absence of pesticides	Monograph	Ph. Eur (current ed.) 2.8.13
Microbiological purity	Ph. Eur (current ed.) 5.1.4.	
<i>Total aerobic microbial count (TAMC)</i>	5.1.4.-1.	≤ 10 <sup>2</sup> cfu/gram
<i>Total yeast and moulds count (TYMC)</i>	5.1.4.-1.	≤ 10 cfu/gram

<sup>5</sup> Analytical monograph by BMC / Farmalyse, version 7.1 of November 2014



	<b>Method</b>	<b>Specification</b>	
<i>P. aeruginosa</i> , <i>S. aureus</i> and <i>Bile tolerant gram neg bacteria</i>	5.1.4.-1.	absent	
Absence of heavy metals			
<i>lead</i>	Ph. Eur (current ed.) "Heavy metals in herbal drugs and fatty oils" (monograph)	max. 20.0	ppm
<i>mercury</i>		max. 0.5	ppm
<i>cadmium</i>		max. 0.5	ppm
<i>arsenic (indicative)</i>		-	
<i>nickel (indicative)</i>		-	
<i>zinc (indicative)</i>		-	
Absence of aflatoxines	Ph. Eur (current ed.) "Determination of aflatoxins B <sub>1</sub> , B <sub>2</sub> , G <sub>1</sub> and G <sub>2</sub> in herbal drugs" (2.8.18)	<4	µg/kg
Loss on drying	Ph. Eur (current ed.) "Loss on drying" meth. C (2.2.32)	≤10.0	%
Assay (UPLC)			
<i>fingerprint</i>	Monograph	similar	
<i>tetrahydrocannabinol (THC)</i>	Monograph	< 1.0	%
<i>cannabidiol (CBD)</i>	Monograph	approx. 9.0	%
Related substances (UPLC)			
<i>cannabinol (CBN)</i>	Monograph	<1.0	%