

Freigabezertifikat/ Release certificate
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Produkt <small>Product</small>	Khiriox 25/1 Cannabisextrakt <small>Khiriox 25/1 Cannabis extract</small>
Stärke <small>Strength</small>	THC: 25 mg/ml CBD: ≤ 1 mg/ml
Darreichungsform <small>Dosage form</small>	flüssig <small>Liquid</small>
Charge <small>Batch</small>	202430CE101001
Herstelldatum <small>Manufacturing date</small>	21.04.2023
Verfalldatum <small>Expiry date</small>	31.03.2025
Packungsgröße <small>Packaging size</small>	30 ml

Rezepturarzneimittel zur Abgabe an Apotheken

Analysenergebnisse

Analytical results

Test Item	Method	Specified reference value	Result
1.0 Appearance	DAB 2023	Green or yellow to brown liquid	compliant
2.0 Identity	DAB 2023, Ph.Eur. 2.2.27 (11.2)	Zone sequence	compliant
3.0 Purity			
3.1 Water	DAB 2022, Ph.Eur. 2.5.12 (11.2)	max. 0.5 g/100g	0.1 g/100 g
3.2 Cannabinol (CBN)	DAB 2023, Ph.Eur. 2.2.29 (11.2)	max. 2.5%	<0.10 %
3.3 Residual solvents	Ph. Eur. 2.4.24 (11.2)		
2-Propanol		<5000 ppm	n.n.
Ethanol		<5000 ppm	n.n.
4.0 Assay d9-tetrahydrocannabinol (THC)	DAB 2023, Ph.Eur. 2.2.29 (11.2)	2.37 – 2.89 g/100 g (22.5 – 27.5 mg/ml)	2.52 g/100 g

Test Item	Method	Specified reference value	Result
5.0 Assay Cannabidiol (CBD)	DAB 2023, Ph.Eur. 2.2.29 (11.2)	max. 0.2 g/100 g	<0.10 g/100 g
6.0 Microbiology	Ph. Eur. 5.1.8. – B (11.2)		
6.1 TAMC	Ph.Eur. 2.6.12	max. 50,000 CFU/g	<1,000 CFU/g
6.2 TYMC	Ph.Eur. 2.6.12	max. 500 CFU/g	<10 CFU/g
6.3 Bile salt tolerant gram-negative bacteria	Ph.Eur. 2.6.31	max. 100 CFU/g	<10 CFU/g
6.4 Escherichia coli	Ph.Eur. 2.6.31	absent in 1 g	negative
6.5 Salmonella	Ph.Eur. 2.6.31	absent in 25 g	negative

n.n. below limit of quantification

Die Charge wurde nach den derzeit gültigen Prüfverfahren getestet und erfüllt die Spezifikation.

The batch was tested according to the currently valid testing procedure and fulfils the specification.

Die Charge wurde durch die Sachkundige Person gem. §15 AMG der Pharmadrug Production GmbH

The batch was certified by the Qualified Person acc. to §15 AMG (German Drug Law) of Pharmadrug Production GmbH

gez. A. Danz

Annekathrin Danz

05.10.2023

am on

zertifiziert.

certified.