Quality Control

Certificate of analysis

STADA

CannabiStada Extrakt THC 10/CBD 10 DK, 30 ml solution

Product	00181996	**Batch**	24-0084-RA	**Batch no.**	24-0084-RA
Date of manufacture	07/2024	**Expiry date**	12/2025		

Customer: **STADApharm GmbH**
Variant: **Control CY: Deutschland CU: STADApharm**

Test	Method	Specification	Result
Appearance	visual	light yellow to light brownish liquid	complies
Relative density	Ph.Eur.2.2.5	0.935 - 0.965	0.947
Refractive index	Ph.Eur.2.2.6	1.447 - 1.459	1.452
Water content	Ph.Eur.2.5.12	≤ 0.5 %	< 0.1 %
Residual solvents Ethanol	M0023	≤ 5000 ppm	1345 ppm
Cannabinole	M0024	≤ 2.5 %	< 0.1 %
Tetrahydrocannabinole Identification UHPLC	M0024	has to comply	complies
Tetrahydrocannabinole Assay UHPLC	M0024	9.0 - 11.0 mg/ml	10.2 mg/ml
Cannabidiole Identification UHPLC	M0024	has to comply	complies
Cannabidiole Assay UHPLC	M0024	9.0 - 11.0 mg/ml	10.2 mg/ml
Microbiology TAMC	Ph.Eur. 2.6.12/2.6.31	≤ 10^4 CFU/ml	complies
Microbiology TYMC	Ph.Eur. 2.6.12/2.6.31	≤ 10^2 CFU/ml	complies
Microbiology Bile tolerant gram negative bacteria	Ph.Eur. 2.6.12/2.6.31	≤ 10^2 CFU/ml	complies
Microbiology Escherichia coli	Ph.Eur. 2.6.12/2.6.31	absent/ml	complies
Microbiology Salmonellae	Ph.Eur. 2.6.12/2.6.31	absent/25ml	complies
Manufacture	documentary	has to comply	complies

Closed by: **H. Ziehr**

The batch has been tested according to GMP-Guidelines and complies to the specification.

Date / Signature: 24/09/2024

Dr. Holger Ziehr
Qualified Person

- End of Certificate -

Batch Quality Certificate

(Confirmation concerning Annex 16 EU GMP-Guide)

Product:	CannabiStada Extrakt THC 10/CBD 10 DK, 30 ml solution
Customer:	STADApharm GmbH, Germany
MA-number/reference document:	n/a
Package size:	30 ml extract
Batch no. (finished product):	24-0084-RA
Batch (finished product):	24-0084-RA
Date of manufacture (dd/mm/yyyy):	16.07.2024
Expiry date:	12/2025
Batch STADA (bulk):	24-0084-RA
Batch no. manufacturer (bulk):	COP-24-0084-R-A
Batch size (bulk):	---
Site of bulk production:	Valcon Medical A/S., Denmark
Site of packaging:	Valcon Medical A/S., Denmark
Quantity released:	1 100 packages

☒ The API manufacturer(s) is part of STADA Arzneimittel AG`s current API supplier qualification programme. It is confirmed that this API manufacturer(s) complies with the relevant guidelines and requirements for GMP of API manufacturing.

☒ **Release to market:**

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation of the destination country.

☐ **Release for shipment:**

I hereby confirm that the manufacturing stages referred to in the Technical Quality Agreement have been carried out in full compliance with the GMP requirements of the EU and the terms described in the Agreement for ensuring compliance with the requirements of the Marketing Authorisation(s) as provided by [Contract Giver/manufacturer certifying and releasing the batch].

Deviations concerning the quality and release of the product:

☒ No deviation occurred ☐ Yes, any additional information are enclosed

Comments/remarks:

Date: 24.09.2024

Qualified Person

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USt-IdNr.: DE 112589604