

Product	ADREX 15 day COL
Country	Germany
Manufacturing license No.:	DE_RP_01_MIA_2022_0054
Potency	Δ^9 -Tetrahydrocannabinol approx. 15% Cannabidiol \leq 1%
Dosage form	Cannabis Flowers, dried; cultivar: Gelato 45
Pack size	15 g metallized PET pouches 500 g metallized PET pouches
Batch bulk	PTL2Q102F03181023
Batch	45402

Growing/drying/primary packaging	Pideka SAS, Centro Empresarial Oikos, Km 21 Via Tunja Tocancipa Cundinamarca 251010 Colombia	
Labelling	PS Pharma Service GmbH Lise-Meitner-Str. 10 40670 Meerbusch	Manufacturing Date: 26.11.2024
Manufacturing license No.:	DE_NW_03_MIA_2024_0035	

Test	Method	Specification	Result	Complies
Identification A	EP 3028	Complies with the description of the monograph	Complies	YES
Identification B	DAB	Complies with the description of the monograph	Complies	YES
Identification C	EP 2.2.27 (TLC)	Complies with the description of the monograph	Complies	YES
Assay	EP 3028 (HPLC)	CBD total: \leq 1.0% CBN: \leq 1.0% THC total: 13.5% – 16.5%	< 0.1 % 0.1 % 15.4 %	YES
Foreign matter	EP 3028	\leq 2.0%	< 2 %	YES
Loss on drying	EP 3028	\leq 12.0%	10.0 %	YES
Pesticides	EP 2.8.13	Complies with the requirements EP 2.8.13	n.n.	YES
Aflatoxins	EP 2.8.18	B1: \leq 2 μ g/kg Sum B1, B2, G1, G2: \leq 4 μ g/kg	n.n. n.n.	YES
Ochratoxin A	EP 2.8.22	\leq 20 μ g/kg	n.n.	YES
Heavy metals analysis	EP 2.4.27	Arsenic: \leq 0.2 ppm Cadmium: \leq 0.3 ppm Lead: \leq 0.5 ppm Mercury: \leq 0.1 ppm	< 0.1 ppm < 0.05 ppm < 0.1 ppm < 0.05 ppm	YES
Microbiological purity		EP 5.1.8C		YES
TAMC	EP 2.6.12	\leq 500 000 cfu/g	50 000 cfu/g	
TYMC		\leq 50 000 cfu/g	35 000 cfu/g	
Bile tolerant gram neg. bacteria	EP 2.6.31	\leq 10 000 cfu/g	< 1000 cfu/g	
Escherichia coli		absent / 1 g	absent / g	
Salmonella species		absent / 25 g	absent / 25g	

n.n. = below limit of quantitation

Examined by: QSI International GmbH, Flughafendamm 9a, 28199 Bremen

Expiry date	04/2025
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I hereby declare that this batch of the medicinal product has been manufactured and tested in compliance with the applicable GMP regulations and in accordance with the master documents approved by the client and has been tested in compliance with recognized pharmaceutical regulations pursuant to § 6 No. 3 ApBetrO and is hereby released for marketing pursuant § 16 AMWHV.

All starting materials and intermediate products used have been tested and were approved.

27.11.2024



Dr. Klaus-Uwe Pechar

Date / Signature Qualified Person