

Product	ADREX 22 GZ COL
Country	Germany
Manufacturing license No.:	DE_RP_01_MIA_2022_0054
Potency	Δ^9 -Tetrahydrocannabinol approx. 22%
	Cannabidiol $\leq 1\%$
Dosage form	Cannabis Flowers, dried; cultivar: Gelato Zkittles
Pack size	15 g metallized PET pouches
	250 g metallized PET pouches
Batch bulk	PS-PT-ARK-290523-B3
Batch	27404

Grower/drier	Pideka SAS, Centro Empresarial Oikos, Km 21 Via Tunja Tocancipa Cundinamarca 251010 Colombia	
Packager	PS Pharma Service GmbH Lise-Meitner-Str. 10 40670 Meerbusch	Manufacturing Date: 10.07.2024
Manufacturing license No.:	DE_NW_03_MIA_2024_0015	

Test	Method	Specification	Result	Complies
Identification A	DAB Monograph	Complies with the description of the DAB monograph	Complies	YES
Identification B	DAB Monograph	Complies with the description of the DAB monograph	Complies	YES
Identification C	DAB Monograph (TLC) EP 2.2.27	Complies with the description of the DAB monograph	Complies	YES
Assay	EP 2.2.29	CBD total: $\leq 1.0\%$ CBN: $\leq 1.0\%$ THC total: 19.8 – 24.2%	< 0.1 % < 0.1 % 20.2 %	YES
Foreign matter	EP 2.8.2	$\leq 2.0 \%$	< 2 %	YES
Loss on drying	EP 2.2.32	$\leq 12.0 \%$	8.1 %	YES
Pesticides	EP 2.8.13	Complies with the requirements EP 2.8.13	n.n.	YES
Aflatoxins	EP 2.8.18	B1: $\leq 2.0 \mu\text{g/kg}$ Sum B1, B2, G1, G2: $\leq 4 \mu\text{g/kg}$	n.n. n.n.	YES
Ochratoxin A	EP 2.8.22	$\leq 20 \mu\text{g/kg}$	n.n.	YES
Heavy metals analysis	EP 2.4.27	Lead: $\leq 5.0 \text{ ppm}$ Mercury: $\leq 0.1 \text{ ppm}$ Cadmium: $\leq 1.0 \text{ ppm}$ Arsenic: $\leq 0.2 \text{ ppm}$	< 0.1 ppm < 0.05 ppm < 0.05 ppm < 0.1 ppm	YES
Microbiological purity		EP 5.1.8.C		YES
TAMC	EP 2.6.12	$\leq 500\,000 \text{ cfu/g}$	250 cfu/g	
TYMC		$\leq 50\,000 \text{ cfu/g}$	35 cfu/g	
Bile tolerant gram neg. bacteria	EP 2.6.31	$\leq 10\,000 \text{ cfu/g}$	< 100 cfu/g	
Escherichia coli		absent /1g	absent /g	
Salmonella species		absent /25g	absent /25g	

n.n. = below limit of quantitation

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

Expiry date	01/2025
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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.


11.07.2024 

Date / Signature Qualified Person