

Batch Release Certificate

Certificate Number	BRC-014-24		
Name of Product	Rua Aio 30/1	Importing Country	Germany
Strength / Potency	31.6 % w/w THC / ≤1.0% w/w CBD	Dosage form	Dried Cannabis Flower
Package size and type	10g Bag	Batch Number	D11501
Date of manufacture	7 th November 2024	Expiry date	08/2025

Manufacturing Sites	Alphafarma Operations Limited, Factory MRH 012B, Mriehel Industrial Estate, Birkirkara, BKR3000, Malta Licence Number: ASID 006/2020 GMP Certificate Number: MT/051HM/2024
Quality Control Sites	ASG Pharma Limited, ADC Buildings, Level 3, Triq L-Esportaturi, Central Business District, Birkirkara, CBD1040, Malta Licence Number: CMRU003/R2023 GMP Certificate Number: MT/005HM/2023
Results of Analysis	Refer to attached CoA for Rua Aio 30/1 10g Germany Batch D11501 dated 10 th December 2024.
Comments	N/A

Certification Statement

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above-mentioned site(s) in full compliance with EU GMP requirements, the requirements of the local Regulatory Authority and with the specifications of the Product License. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Name and position/title of person authorising the batch release	
Signature of person authorising the batch release	
Date of signature	

Certificate of Analysis
Rua Aio 30/1
10g Germany

Material Name	Rua Aio 30/1		
Material Code	F070		
Material description	10g Dried Cannabis Flower Strain 8 Ball Kush (R040) In Finished Product Packaging		
Batch number	D11501	Certificate of Analysis Version	01
Packaging date	07-Nov-2024		
Contract Laboratory Analysis Date	27-Nov-2024	Contract Laboratory Certificate No.	LN24F/0357 V1
API Batch number	D09104		
Storage	15-25°C, dry and protected from light		
Shelf-life	9 months (Stability studies in progress)		

Test	Method	Acceptance Criteria	Results
Labelling	Visual Inspection	Packaged product label is correctly aligned. Packaged product label conforms to the approved label artwork.	Complies
Variable Data	BPR information, Visual Inspection	The variable data matches the batch specific data specified in the BPR. Variable data includes: Strain name Cannabinoid Content Quantity - The printed quantity on the label is 10 grams. Batch No. Expiry Date PZN Number	Complies
Expiry date	BPR information, Visual Inspection	Printed expiry date is the packaging date of the product + the shelf-life determined from stability studies.	Complies
Serial No.	BPR information, Visual Inspection	The serial number is present and includes 10 alphanumeric characters.	Complies
Physical characteristics	Visual inspection	There are no visible damages or markings to the packaged product or the labels.	Complies
Seal integrity	Functional check	The bag cannot be opened due to the presence of the intact seal.	Complies
Identification A: Macroscopic Properties	Ph. Eur. 3028 "Cannabis Flower"	Conforms to description in the monograph.	Complies
Identification B: Microscopic Properties	Ph. Eur. 3028 "Cannabis Flower" Ph. Eur. 2.8.23	Conforms to description in the monograph.	Complies
Identification C: HPTLC	Ph. Eur. 3028 "Cannabis Flower" Ph. Eur. 2.8.25	Conforms to description in the monograph.	Complies
Assay and related substances	HPLC (In-house method) Ph. Eur. 2.2.29	Total Δ ⁹ -tetrahydrocannabinol (sum of THCA + THC on dried basis)	90.0 – 110.0% of the label claim (30% w/w) 105.4% (31.61% w/w)* % w/w

Test	Method	Acceptance Criteria	Results
Foreign Matter	Ph. Eur. 3028 "Cannabis Flower" Ph. Eur. 2.8.2	Cannabidiol (CBD) ≤1.0% w/w	0.2* % w/w
		Cannabinol (CBN) ≤1.0% w/w	0.0* % w/w
		The sample is free from moulds, insects, and other animal contamination (e.g. vermin), as well as other foreign matter.	0 %
		The sample does not contain any seeds and does not contain any leaves more than 1.0 cm in length.	Complies
Loss on Drying	Ph. Eur. 3028 "Cannabis Flower" Ph. Eur. 2.2.32	NMT 12% (m/m)	9 %
Aflatoxins	Ph. Eur. 2.8.18	Aflatoxin B1 NMT 2 µg/kg	<LOQ (0.3 µg/kg) µg/kg
		Sum of Aflatoxins B1, B2, G1, G2 NMT 4 µg/kg	<LOQ (0.3 µg/kg) µg/kg
Pesticide residues	Ph. Eur. 2.8.13	Complies with Ph. Eur. requirements	Complies*
Heavy Metals	Ph. Eur. 3028 "Cannabis Flower" Ph. Eur. 2.4.27	Arsenic (As) NMT 0.2 ppm	<LOQ (<0.1004) ppm
		Cadmium (Cd) NMT 0.3 ppm	<LOQ (<0.1004) ppm
		Lead (Pb) NMT 0.5 ppm	<LOQ (<0.0998) ppm
		Mercury (Hg) NMT 0.1 ppm	<LOQ (<0.0500) ppm
Microbiological Contamination Ph. Eur. 5.1.4 Ph. Eur. 5.1.8 (C)	Ph. Eur. 2.6.12	TAMC NMT 10 ⁵ CFU/g or CFU/ml	95 <input checked="" type="checkbox"/> CFU/g <input type="checkbox"/> CFU/ml
		TYMC NMT 10 ⁴ CFU/g or CFU/ml	1000 <input checked="" type="checkbox"/> CFU/g <input type="checkbox"/> CFU/ml
	Ph. Eur. 2.6.13 Ph. Eur. 2.6.31	Bile tolerant gram-negative Bacteria NMT 10 ⁴ CFU/g or CFU/ml	<10 <input checked="" type="checkbox"/> CFU/g <input type="checkbox"/> CFU/ml
		<i>E. coli</i> Ph. Eur. 5.1.8 (C) Absence per 1 g or 1 ml	Absent <input checked="" type="checkbox"/> /g <input type="checkbox"/> /mL
		<i>Salmonella</i> Ph. Eur. 5.1.8 (C) Absence per 25 g or 25 mL	Absent <input checked="" type="checkbox"/> /25g <input type="checkbox"/> /25mL
		<i>Staphylococcus aureus</i> Ph. Eur. 5.1.4 Absence per 1 g or 1 ml	Absent <input checked="" type="checkbox"/> /g <input type="checkbox"/> /mL
		<i>Pseudomonas aeruginosa</i> Ph. Eur. 5.1.4 Absence per 1 g or 1 ml	Absent <input checked="" type="checkbox"/> /g <input type="checkbox"/> /mL

Certificate of Analysis
Rua Aio 30/1
10g Germany

Comments:

*Test results transposed from raw material CoA (D09104 V1).

Author	Signature	Date
[Redacted]	[Redacted]	10/12/2024
Reviewer	[Redacted]	10/12/2024
The material is	<input type="checkbox"/> Other - See Comments	
Approver	[Redacted]	10/12/2024