

Product Name:	Remexian 30/1 JUC 400g
Batch no.:	JC02RM4FP02
Strain:	Jungle Cake
Cultivar:	Cannabis Sativa L.
Storage Conditions:	Temperature: 15-25°C
Expiry Date:	03/2025
Packaging:	PET/ALU/PE – 12/8/100 µm

TESTING RESULTS

Test parameter	Method	Acceptance Criteria	Test Results
Appearance	DAB.2018 Cannabis Flos – Visual	Complies	Complies
Identification	A: DAB.2018 Cannabis Flos – Visual, amplified	Complies	Complies
	B: DAB.2018 Cannabis Flos – Visual, Microscopic;	Complies	Complies
	C: DAB.2018 Cannabis Flos – TLC; Eur. Ph. [2.2.27]	Positive Identification	Positive Identification
Purity: Foreign Matter	DAB.2018 Cannabis Flos; Eur. Ph. [2.8.2]	≤ 2% w/w	0% (w/w)
Purity: Loss on Drying	DAB.2018 Cannabis Flos; Eur. Ph. [2.2.32]	≤ 10%	0%
Purity: HPLC - CBN	DAB.2018 Cannabis Flos; Eur. Ph. [2.2.29]	≤ 1.0% d.b.	0,02%
Purity: HPLC – Total THC	DAB.2018 Cannabis Flos; Eur. Ph. [2.2.29]	30% ± 10% d.b.	27,6%
Purity: HPLC – Total CBD	DAB.2018 Cannabis Flos; Eur. Ph. [2.2.29]	≤ 1.0% d.b.	0,13%
Total Ash	Eur. Ph. [2.4.16]	≤ 20% w/w	8% (w/w)
Absence of Pesticides	Eur. Ph. [2.8.13]	Below limits in Ph. Eur.	Complies
Heavy Metals As Cd Hg Ni Pb Zn	Eur. Ph. 1433 – Herbal Drugs 1434 – Plant Based Preparations to Medicinal	Arsenic (As) ≤ 3 ppm	< 0,020 ppm (LOQ)
		Cadmium (Cd) ≤ 1,0 ppm	< 0,005 ppm (LOQ)
		Mercury (Hg) ≤ 0.1 ppm	< 0,050 ppm (LOQ)
		Nickel (Ni) Informative	< 2,000 ppm (LOQ)

Test parameter	Method	Acceptance Criteria	Test Results
	Drugs 1435 – Medicinal Herbal Teas [2.4.20 and 2.4.27]	Lead (Pb) ≤ 5 ppm	< 0,020 ppm (LOQ)
		Zinc (Zn) Informative	43,354 ppm
Aflatoxins B ₁ and sum of B ₁ , B ₂ , G ₁ , G ₂	Eur. Ph. - 2.8.18	≤ 2 µg / kg	< 0,25 µg/kg (LOD)
		≤ 4 µg / kg	< 0,5 µg/kg (LOQ)
TAMC	Eur. Ph [2.6.31 + 5.1.8.c]	< 10 ⁶ CFU/g (Max. 500 000 CFU/g)	3,00 X 10 ² CFU/g
TYMC	Eur. Ph [2.6.31 + 5.1.8.c]	< 10 ⁶ CFU/g (Max. 50 000 CFU/g)	1,50 X 10 ² CFU/g
Bile tolerant gram-negative bacteria	Eur. Ph. [2.6.31 + 5.1.8.c]	≤ 10 ⁴ CFU/g	<10 CFU/g
<i>Salmonella spp</i>	Eur. Ph. [2.6.31 + 5.1.8.c]	Absent / 25 g	Absent/25g
<i>E. Coli</i>	Eur. Ph. [2.6.31 + 5.1.8.c]	Absent / 1 g	Absent/g
<i>Pseudomonas Aeruginosa</i>	Eur. Ph. [2.6.13]	Absent / 1 g	Absent/g
<i>Staphylococcus. Aureus</i>	Eur. Ph. [2.6.13]	Absent / 1 g	Absent/g

ND - Not detected | NMT - Not More Than | db - Dried Basis | w/w - weight / weight | CFU - Colony forming units

ELABORATED BY QUALITY CONTROL	Name: ELISABETE ANACLETO	Signature		DATE: 24/09/2024
APPROVED BY QUALIFIED PERSON	Name: JOÃO LOPES	Signature	Assinado por: João Carlos da Conceição Lopes Num. de Identificação: 08962904 Data: 2024.09.24 14:36:47+01'00'	DATE:

PRODUCT RELEASE

Ed: 03 Page 1 | 1

Client:	Remexian Pharma GmbH	Destination Country:	Germany
Product Name:	Remexian 30/1 JUC	Batch:	IC02RM4FP02

Pharmaceutical Form:	Cannabis dried inflorescences	Released Quantity [units]:	129
Concentration Strength:	30% THC/<1% CBD	Manufacturing Date:	19/09/2024
Pouch <input checked="" type="checkbox"/> Jar <input type="checkbox"/> Content [g]:	400	Labelling date:	19/09/2024
Storage conditions:	<25°C protected from light in a tight container	Expiry date:	03/2025

Name and address(s) of the manufacturer of cannabis-based substances and preparations	MHI Cultivo Medicinal SA Horta da Chancarina SN, Campo Maior, Portugal Holder of GMP Certificate no.: F071/S1/MH/001/2022 (EudraGMDP Document Reference Number 143461)
Name and address[s] of analysis' site[s]	Laboratório de Estudos Farmacêuticos R. das Ferrarias del Rei, nº 6, Urbanização da Fábrica da Pólvora, Barcarena, Portugal Holder of GMP Certificate no.: F032/S1/MH/001/2022 (EudraGMDP Document Reference Number 147895)
This batch has not been treated with ionizing radiation	

QP STATEMENT:

By MHI Cultivo Medicinal SA – Company licensed for the manufacture of cannabis-based substances and preparations by INFARMED – National Authority of Medicine and Health Products, IP, with authorization no. F071/001/2022, I, João Carlos da Conceição Lopes, EU QP register number 10745 at INFARMED IP, hereby declare that all information about this batch is authentic and rigorous and certify that all the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the regulatory requirements of the destination country.

APPROVED BY QUALIFIED PERSON:	<i>Batch release</i> Assinado por: João Carlos da Conceição Lopes Num. de identificação: 08962904 Data: 2024.09.24 14:38:24+01'00'
DATE:	Localização: MHI Cultivo Medicinal S.A., Campo Maior, Portugal

