

PRODUCT RELEASE

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<b>Client:</b>	Remexían Pharma GmbH	<b>Destination Country:</b>	Germany
<b>Product Name:</b>	Remexían 30/1 BNM	<b>Batch:</b>	BN08RB4FP01

<b>Pharmaceutical Form:</b>	Cannabis dried inflorescences	<b>Released Quantity [units]:</b>	55
<b>Concentration   Strength:</b>	30% THC/<1% CBD	<b>Manufacturing Date:</b>	29/08/2024
<b>Pouch <input checked="" type="checkbox"/>   Jar <input type="checkbox"/> Content [g]:</b>	250	<b>Labelling date:</b>	29/08/2024
<b>Storage conditions:</b>	<25°C protected from light in a tight container	<b>Expiry date:</b>	02/2025

<b>Name and address(s) of the manufacturer of cannabis-based substances and preparations</b>	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)
<b>Name and address[s] of analysis' site[s]</b>	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.

<b>APPROVED BY QUALIFIED PERSON:</b>	<i>Batch release</i> Assinado por: <b>João Carlos da Conceição Lopes</b> Num. de identificação: 08962904
<b>DATE:</b>	Data: 2024.09.06 18:07:59+01'00' Localização: MHI Cultivo Medicinal, S.A., Campo Maior, Portugal



FINISHED PRODUCT - DRIED INFLORESCENCES MEDICINAL CANNABIS

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<b>Product Name:</b>	Remexían 30/1 BNM 250g
<b>Batch no.:</b>	BN08RB4FP01
<b>Strain:</b>	Bananimal
<b>Cultivar:</b>	Cannabis Sativa L.
<b>Storage Conditions:</b>	<b>Temperature: 15-25°C</b>
<b>Expiry Date:</b>	02/2025
<b>Packaging:</b>	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	Complies
Purity: Foreign Matter	DAB.2018 Cannabis Flos; Eur. Ph. [2.8.2]	≤ 2% w/w	0%
Purity: Loss on Drying	DAB.2018 Cannabis Flos; Eur. Ph. [2.2.32]	≤ 10%	7%
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.	28,1%
	DAB.2018 Cannabis Flos; Eur. Ph. [2.2.29]		
Purity: HPLC – Total CBD	DAB.2018 Cannabis Flos; Eur. Ph. [2.2.29]	≤ 1.0% d.b.	0,1%
Total Ash	Eur. Ph. [2.4.16]	≤ 20% w/w	9%
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	<0,020ppm (LOQ)
		Cadmium (Cd) ≤ 1,0 ppm	<0,005ppm (LOQ)
		Mercury (Hg) ≤ 0.1 ppm	<0,050ppm (LOQ)
		Nickel (Ni) Informative	<2,000ppm (LOQ)

Test parameter	Method	Acceptance Criteria	Test Results
	Drugs   1435 – Medicinal Herbal Teas [2.4.20 and 2.4.27]	Lead (Pb) ≤ 5 ppm	<0,020ppm (LOQ)
		Zinc (Zn) Informative	42,410ppm
Aflatoxins B <sub>1</sub> and sum of B <sub>1</sub> , B <sub>2</sub> , G <sub>1</sub> , G <sub>2</sub>	Eur. Ph. - 2.8.18	≤ 2 µg / kg	<0,5µg/Kg (LOQ)
		≤ 4 µg / kg	<0,5µg/Kg (LOQ)
TAMC	Eur. Ph [2.6.31 + 5.1.8.c]	< 10 <sup>6</sup> CFU/g (Max. 500 000 CFU/g)	< 100 CFU/g
TYMC	Eur. Ph [2.6.31 + 5.1.8.c]	< 10 <sup>5</sup> CFU/g (Max. 50 000 CFU/g)	< 10 CFU/g
Bile tolerant gram-negative bacteria	Eur. Ph. [2.6.31 + 5.1.8.c]	≤ 10 <sup>4</sup> CFU/g	< 10 CFU/g
<i>Salmonella spp</i>	Eur. Ph. [2.6.31 + 5.1.8.t]	Absent / 25 g	Absent/25g
<i>E. Coll</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	EA	DATE:	09/09/2024
APPROVED BY QUALIFIED PERSON	Name:	JOÃO LOPES	Signature	Assinado por: João Carlos da Conceição Lopes Num. de Identificação: 08962904 Data: 2024.09.09 14:29:46+01'00'	DATE:	