

Phyto Group International BV
Candropharm International
Bosscheweg 60A -Unit 6-
5735GW Aarle-Rixtel Netherlands
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Report date: 15 July 2024

Product name:	Soft Gels Melatonin	Method of testing:	See result tables below
Manufacturing date:	July 2024	Sample identification number:	19190724
Best Before Date	July 2026	Batch number:	2725
Date of receipt sample:	15 July 2024	Sample material:	Capsules
Starting date analysis:	15 July 2024	Further information:	NA
Contract testing by:	Candropharm's in-house method	Limit of quantification:	0.01%

CANNABINOIDS			ANALYTICAL METHOD:		HPLC-UV	
Test	Compound		Results	Unit	Specification	Result
CBD potency	CBD	Cannabidiol	3,71	% (w/w)	Informative	Pass
	CBDA	Cannabidiolic acid	<LOQ	% (w/w)	Informative	Pass
	CBDV	Cannabidivarin	<LOQ	% (w/w)	Informative	Pass
	CBDVA	Cannabidivarinic Acid	<LOQ	% (w/w)	Informative	Pass
Other minors	CBG	Cannabigerol	<LOQ	% (w/w)	Informative	Pass
	CBGA	Cannabigerol Acid	<LOQ	% (w/w)	Informative	Pass
	CBN	Cannabinol	0,01	% (w/w)	Informative	Pass
	CBNA	Cannabinolic Acid	<LOQ	% (w/w)	Informative	Pass
	CBC	Cannabichromene	<LOQ	% (w/w)	Informative	Pass
	BCA	Cannabichromenic Acid	<LOQ	% (w/w)	Informative	Pass
	CBL	Cannabicyclol	<LOQ	% (w/w)	Informative	Pass
	CBLA	Cannabicyclolic Acid	<LOQ	% (w/w)	Informative	Pass
	CBE	Cannabielsoin	<LOQ	% (w/w)	Informative	Pass
	CBL	Cannabicyclol	<LOQ	% (w/w)	Informative	Pass
THC potency	Δ9-THC	Delta 9-Tetrahydrocannabinol	<LOQ	% (w/w)	Informative	Pass
	Δ8-THC	Delta 8-Tetrahydrocannabinol	<LOQ	% (w/w)	Informative	Pass
	THCA	Tetrahydrocannabinolic acid	<LOQ	% (w/w)	Informative	Pass
	THCV	Tetrahydrocannabivarin	<LOQ	% (w/w)	Informative	Pass
	THCVA	Tetrahydrocannabivarinic Acid	<LOQ	% (w/w)	Informative	Pass
Others	HHC-9R	9R-Hexahydrocannabinol	<LOQ	% (w/w)	Informative	Pass
	HHC-9S	9S-Hexahydrocannabinol	<LOQ	% (w/w)	Informative	Pass
	HHCP*	Hexahydrocannabiphorol*	<LOQ	% (w/w)	Informative	Pass
	H4CBD*	Tetrahydrocannabidiol*	<LOQ	% (w/w)	Informative	Pass

Remarks:

Melatonin 1,01 mg per soft gel

Footnote:

*) Stereoisomers results on request. **) LOQ = not detectable. The measured value was below the limit of detection of 0.01 % (w/w) or 100 mg/kg.
The expected measurement uncertainty varies with substance and concentration and can be assumed to be a maximum of 10 %.
For the calculations of the equivalent sums, the respective acid forms were multiplied by the factor 0.877 or 0.878 to conclude the equivalent amount of the neutral form. Analytical methods: HPLC-DAD, GC-FID and GC mass spectrometry (European Pharmacopoeia: 2.2.28, 2.2.29 and 2.2.43).
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Further information: NA

HEAVY METALS

ICP-MS (Inductively Coupled Plasma Mass Spectrometry)

Element	Result	Action Level	LOD	LOQ	Units	Result
Lead (Pb)	<LOQ	3 mg/kg	0.01	0.08	mg/kg	Pass
Mercury (Hg)	<LOQ	0.1 mg/kg	0.01	0.04	mg/kg	Pass
Cadmium (Cd)	<LOQ	1 mg/kg	0.02	0.08	mg/kg	Pass
Arsenic (As)	<LOQ	0.375 mg/kg	0.03	0.08	mg/kg	Pass

Remarks:

NA

MICRO BIOLOGY

Element	Result	Unit	Specification	Testing Method
TAMC	< 10 _i	cfu/gram	Informative	SO 4833-1 (general colony count at 30 °C) / Ph. Eur. 2.6.12
TYMC	< 10 _i	cfu/gram	Informative	ISO 21527-1 / Ph. Eur. 2.6.12
E. coli	Absent	cfu/gram	Absent gram	ISO 16649-2 (β-glucuronidase positive E. coli)
S. aureus	Absent	cfu/gram	Absent gram	ISO 6888-1
p. aeruginosa	Absent	cfu/gram	Absent gram	ISO 22717
Salmonella spp	Absent	cfu/gram	Absent gram	ISO 6579-1

Remarks:

NA

RESIDUAL SOLVENTS

HS GC

Element	Result	Unit	Specification	Result
Ethanol	< 25	mg/kg	Informative	Pass
2-Propanol	< 10	mg/kg	Informative	Pass
Acetone	<100	mg/kg	Informative	Pass
n-Heptane	< 1	mg/kg	Informative	Pass
n-Hexane	< 1	mg/kg	Informative	Pass
n-Pentane	<100	mg/kg	Informative	Pass

Remarks:

NA

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PESTICIDES		ANALYTICAL METHOD:		GC/MS	LC/MS
Analytical method	Component	Concentration	Unit	Spec.	Result
GC-MS/MS Multiresidue method for pesticides screen	No pesticide detected above the reporting limit ₂	-----		mg/kg	Pass
LC-MS/MS Multiresidue method for pesticides screen	No pesticide detected above the reporting limits	-----		mg/kg	Pass

Remarks:

*See Candropharm pesticides analysis package (can be obtained by sending us an email):
Please note: The analysis is not executed under GMP. The LOQ is 7.5 times higher than mentioned in the package due to the applied matrix.
2 Following pesticides could not be analyzed: Azinphos-ethyl, Fenpropathrin, Iprodione, Lethophos, Nitralin, Tetradifon, Allethrin, Pyraclofos, Methoxychlor-p'p, Piperonyl- butoxide, Tetramethrin.
3 Following pesticide could not be analyzed: Triconazole.

AFLATOXINS		ANALYTICAL METHOD:		LC/MS
Compound	Results	Unit	Result	
Remarks:				
B ₁	< 2.0	ug/kg	Pass	
B ₂	< 0.5	ug/kg	Pass	
G ₁	< 1.0	ug/kg	Pass	
G ₂	< 0.5	ug/kg	Pass	
Sum B ₁ , B ₂ , G ₁ and G ₂	< 4.0	ug/kg	Pass	

Remarks:

NA

Aarle-Rixtel 15-7-2024

Mw. W. Meulendijks

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