

TECHNICAL DATA SHEET

ORGANIC GINSENG RO 1% DE PR4418

Organic labelling regulation
(UE) 2018/848 - art.32):

BIO = DE-ÖKO-039

Botanical kind:

Araliaceae Panax ginseng C. A. Meyer

Part of the plant:

Root

Extraction solvent(s):

Ethanol, water 60:40 (V/V)

Carrier(s):

Organic wheat maltodextrin

DESCRIPTION

	Specifications	Methods and references
Appearance	<i>Powder</i>	
Color	<i>Beige to light brown</i>	

ANALYSES

	Specifications		Method and reference
	Min	Max	
Total ginsenosids expressed as Rb1 content [%]	1.00	-	MO-63 - HPLC, Eur. Ph. (01/2013:2356), "Ginseng dry extract" monograph
Identification (raw material) (4)	Complies		MO-257 - TLC, Eur. Ph. (01/2016:1523), "Ginseng root" monograph
Loss on drying [%] (11)	-	8.00	MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)
Bulk density	0.30	0.70	MO-181 - Eur. Ph. (04/2019:20934)
Screening [% < 500 µm]	95.0	-	MO-184 - Granulometer, internal method

CONTAMINANTS

	Specifications		Method and reference
	Min	Max	
Pb content [ppm] (4)	-	< 3.00	AE-01 - ICP, internal method
Cd content [ppm] (4)	-	< 1.00	AE-01 - ICP, internal method
Hg content [ppm] (4)	-	< 0.10	AE-01 - ICP, internal method
As content [ppm] (4)	-	< 1.00	AE-01 - ICP, internal method
Pesticides content [ppm] (4)	< detection limit		AE-02 - GC-MSMS/LC-MSMS, internal method
Benzo(a)pyrene content [ppb] (4)	-	< 10.0	AE-03 - GC-MS-MS, internal method

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Pahs (sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene) content [ppb] (4)	-	< 50.0	AE-03 - GC-MS-MS, internal method
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MICROBIOLOGY	Specifications		Method and reference
	Min	Max	
Total aerobic microbial count [CFU/g] (1)	-	< 10 000	MO-191 - Pétrifilm TM / ISO 4833
Total yeasts/moulds count [CFU/g] (1)	-	< 100	MO-192 - Pétrifilm TM / AOAC 997.02
Salmonella content [/25g]	Absent		MO-193 - TECRA TM / ISO 6579
Enterobacteria content [CFU/g]	-	< 100	MO-194 - Pétrifilm TM ISO 21528-2
Escherichia coli content [CFU/g]	-	< 10	MO-195 - Pétrifilm TM / ISO 16649-2

(1) Acceptable maximal count: 5 times the acceptance criterion according to Eur. Ph. VIII° Ed. 5.1.8 Category B

(11) First ten batches

(4) HACCP based control plan defined annually according to risk analysis

Best before/ 24

DMD (in months) :

Storage conditions: Store in closed original packaging at 5 to 25°C in a dry place and protected from light.

Complementary data

This reference is neither an Active Pharmaceutical Ingredient nor an excipient for pharmaceutical use. Responsibility of final labelling lies with the company placing the final product on the market.

- Complies with French decrees (2006-352 and 24th June 2014).

- According to Regulation 1999/3/EC, and its modifications, has not been ionized.

- According to the Regulations 2001/18/EC, 1829/2003 and 1830/2003, and its modifications, the above-mentioned item does not contain deliberately added GMO. (Fortuitous or technically inevitable traces could be detected at less than 0,9%.)

- The product does not contain TSE/BSE substances.