

TECHNICAL DATA SHEET

SIBERIAN GINSENG UP 0.8-2.0% DE PR2133

Botanical kind:	Araliaceae Eleutherococcus senticosus (Rupr. and Maxim.) Maxim
Part of the plant:	Underground part
Extraction solvent(s):	Ethanol, Water 30:70 (V/V)
Carrier(s):	Wheat maltodextrin

DESCRIPTION

	Specifications	Methods and references
Appearance	<i>Thin powder</i>	
Color	<i>Light brown to brown</i>	
Solubility	<i>To be tested following the degree of incorporation</i>	

ANALYSES

	Specifications		Method and reference
	Min	Max	
Eleutherosides (B+E) content [%]	<i>0.80</i>	<i>2.00</i>	<i>MO-240 - HPLC, USP42-NF37, "Eleuthero root and rhizome dry extract" monograph</i>
Identification (raw material) (4)	<i>Complies</i>		<i>MO-212 - TLC, Eur. Ph. (01/2008:1419 corrected 7.0), "Eleutherococcus" monograph</i>
Loss on drying [%] (11)	<i>-</i>	<i>8.00</i>	<i>MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)</i>
Bulk density	<i>0.40</i>	<i>0.70</i>	<i>MO-181 - Eur. Ph. (04/2019:20934)</i>
pH (1% in demineralized water) (11)	<i>3.0</i>	<i>6.5</i>	<i>MO-03 - pH-meter, Eur. Ph. (07/2016:20203), "Potentiometric determination of pH" monograph</i>
Screening [% < 500 µm]	<i>95.0</i>	<i>-</i>	<i>MO-184 - Granulometer, internal method</i>

CONTAMINANTS

	Specifications		Method and reference
	Min	Max	
Pb content [ppm] (4)	<i>-</i>	<i>< 3.00</i>	<i>AE-01 - ICP, internal method</i>
Cd content [ppm] (4)	<i>-</i>	<i>< 1.00</i>	<i>AE-01 - ICP, internal method</i>
Hg content [ppm] (4)	<i>-</i>	<i>< 0.10</i>	<i>AE-01 - ICP, internal method</i>
As content [ppm] (4)	<i>-</i>	<i>< 1.00</i>	<i>AE-01 - ICP, internal method</i>

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Pesticides content [ppm] (4)	<i>< Residual Maximum Limit fixed in European regulation 396/2005 and its modifications</i>		<i>AE-02 - GC-MSMS/LC-MSMS, internal method</i>
Benzo(a)pyrene content [ppb] (4)	-	<i>< 10.0</i>	<i>AE-03 - GC-MS-MS, internal method</i>
Pahs (sum of benzo(a) pyrene, benzo(a) anthracene, benzo(b) fluoranthene and chrysene) content [ppb] (4)	-	<i>< 50.0</i>	<i>AE-03 - GC-MS-MS, internal method</i>

MICROBIOLOGY	Specifications		Method and reference
	Min	Max	
Total aerobic microbial count [CFU/g] (1)	-	<i>< 10 000</i>	<i>AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)</i>
Total yeasts/moulds count [CFU/g] (1)	-	<i>< 100</i>	<i>AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)</i>
Salmonella content [/25g]	<i>Absent</i>		<i>AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)</i>
Bile-tolerant Gram negative bacteria content [CFU/g]	-	<i>< 100</i>	<i>AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)</i>
Escherichia coli content [/g]	<i>Absent</i>		<i>AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)</i>

(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/ DMD (in months) : 24

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

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**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