

TECHNICAL DATA SHEET

GINSENG LE/RO/STE 10% DE PR4815

Botanical kind:	Araliaceae Panax ginseng C.A. Meyer
Part of the plant:	Root and/or leaf and/or stem
Extraction solvent(s):	Ethanol, water 50 : 50 (V/V)
Carrier(s):	Wheat maltodextrin

DESCRIPTION

	Specifications	Methods and references
Appearance	<i>Powder</i>	
Color	<i>White to beige yellowish</i>	
Solubility	<i>To be tested following the degree of incorporation</i>	

ANALYSES

	Specifications		Method and reference
	Min	Max	
Total saponosids, expressed as ginsenoside Rg1 content [%]	> 10.00	-	<i>MO-123 - UV-Vis, Fr. Ph. (1989), "Ginseng" monograph</i>
Identification (raw material) (4)	<i>Complies</i>		<i>MO-257 - TLC, Eur. Ph. (01/2016:1523), "Ginseng root" monograph</i>
Loss on drying [%] (11)	-	8.00	<i>MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)</i>
Bulk density	0.30	0.70	<i>MO-181 - Eur. Ph. (04/2019:20934)</i>
pH (1% in demineralized water) (11)	5.0	8.0	<i>MO-03 - pH-meter, Eur. Ph. (07/2016:20203), "Potentiometric determination of pH" monograph</i>
Screening [% < 500 µm]	95.0	-	<i>MO-184 - Granulometer, internal method</i>

CONTAMINANTS

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

TECHNICAL DATA SHEET

**GINSENG LE/RO/STE 10% DE
PR4815**

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, benz(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/ 24

DMD (in months) :

Storage conditions:

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

TECHNICAL DATA SHEET

**GINSENG LE/RO/STE 10% DE
PR4815**

**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 above mentioned item does not contain TSE/BSE substances*