Buckton Scott Deutschland

TECHNICAL DATA SHEET

GINSENG RO 4% DE
PR1986

Botanical kind: Araliaceae Panax ginseng C.A. Meyer

Part of the plant: Root

Extraction solvent(s): Water

Carrier(s): Wheat maltodextrin

DESCRIPTION

	Specifications	Methods and references
Appearance	*Hygroscopic fine powder*	
Color	*Beige to brown*	
Solubility	*To be tested following the degree of incorporation*	

ANALYSES

	Specifications		Method and reference
	Min	Max	
Total ginsenosids expressed as Rg1 content [%]	*4.00*	-	*MO-97 - UV-Vis, German Ph.,"Ginseng radix" monograph*
Identification (finished product) (4)	*Complies*		*MO-108 - TLC, Eur. Ph. (01/2013:2356), "Ginseng dry extract" 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)*
pH (1% in demineralized water) (11)	*3.5*	*7.5*	*MO-03 - pH-meter, Eur. Ph. (07/2016:20203),"Potentiometric determination of pH" monograph*
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*

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Pesticides content [ppm] (4)	*< Residual Maximum Limit fixed in European regulation 396/2005 and its modifications*		*AE-02 - GC-MSMS/LC-MSMS, internal method*
Benzo(a)pyrene content [ppb] (4)	-	*< 10.0*	*AE-03 - GC-MS-MS, internal method*
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*

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

(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 at 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