

TECHNICAL DATA SHEET

GINKGO BILOBA LE 24%/6% DE AR8329

Botanical kind:	Ginkgoaceae Ginkgo biloba L.
Part of the plant:	Leaf
Extraction solvent(s):	Ethanol, Water 70:30 (V/V)
Carrier(s):	None

DESCRIPTION	Specifications		Methods and references
	Min	Max	
Appearance	<i>Powder</i>		
Color	<i>Brown to greenish</i>		
Solubility	<i>To be tested following the degree of incorporation</i>		

ANALYSES	Specifications		Method and reference
	Min	Max	
Flavonoids, expressed as flavone glycosides content [%]	24.00	-	AE-40 - HPLC, Eur. Ph. (04/2008:1827), "Ginkgo dry extract, refined and quantified" monograph
Terpene lactones content [%]	6.00	-	AE-40 - HPLC, Eur. Ph. (04/2008:1827), "Ginkgo dry extract, refined and quantified" monograph
Ginkgolic acid content expressed as ginkgolic acid C17 [ppm]	-	5.00	AE-40 - HPLC, Eur. Ph. (04/2008:1827), "Ginkgo dry extract, refined and quantified" 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] (2)	-	< 3.00	AE-01 - ICP, internal method
Cd content [ppm] (2)	-	< 1.00	AE-01 - ICP, internal method
Hg content [ppm] (2)	-	< 0.10	AE-01 - ICP, internal method

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Pesticides content [ppm] (2)	< Residual Maximum Limit fixed in European regulation 396/2005 and its modification		AE-02 - GC-MSMS/LC-MSMS, internal method
Benzo(a)pyrene content [ppb] (2)	-	< 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] (2)	-	< 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	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
Staphylococcus aureus content [CFU/g]	-	< 10	MO-279 - Pétrifilm TM / ISO 6888

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

(11) First ten batches

(2) On request with additional cost

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.

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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.*

- 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*