

TECHNICAL DATA SHEET

KUDZU RO 40% DE PR993

Botanical kind:	<i>Fabaceae Pueraria montana var. lobata (Willd.) Maesen & S.M. Almeida ex Sanjappa & Predeep</i>
Part of the plant:	<i>Root</i>
Extraction solvent(s):	<i>Ethanol, water 30 : 70 (V/V)</i>
Carrier(s):	<i>Wheat maltodextrin</i>

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

ANALYSES	Specifications		Method and reference
	Min	Max	
Total isoflavones content [%]	<i>40.00</i>	<i>-</i>	<i>MO-288 - UV, internal method</i>
Identification (finished product) (2)	<i>Complies with a characteristics phytochemical profile of "Fabaceae Pueraria montana var. lobata (Willd.) Maesen & S.M. Almeida ex Sanjappa & Predeep", root</i>		<i>AE-11 - HPLC or HPTLC, internal method</i>
Loss on drying [%]	<i>-</i>	<i>8.00</i>	<i>MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)</i>
Bulk density	<i>0.30</i>	<i>0.70</i>	<i>MO-181 - Eur. Ph. (04/2019:20934)</i>
pH (1% in demineralized water)	<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] (2)	<i>-</i>	<i>< 3.00</i>	<i>AE-01 - ICP, internal method</i>
Cd content [ppm] (2)	<i>-</i>	<i>< 1.00</i>	<i>AE-01 - ICP, internal method</i>
Hg content [ppm] (2)	<i>-</i>	<i>< 0.10</i>	<i>AE-01 - ICP, internal method</i>
As content [ppm] (2)	<i>-</i>	<i>< 1.00</i>	<i>AE-01 - ICP, internal method</i>

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Pesticides content [ppm] (2)	< <i>Residual Maximum Limit fixed in European regulation 396/2005 and its modifications</i>		AE-02 - GC-MSMS/LC-MSMS, 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
Benzo(a)pyrene content [ppb] (2)	-	< 10.0	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

(2) On request

Shelf life/ 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.*

- 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*