

TECHNICAL DATA SHEET

PURPLE CONEFLOWER AP 4% DE PR4821

Botanical kind:	Compositae Echinacea purpurea (L.) Moench
Part of the plant:	Aerial part
Extraction solvent(s):	Ethanol, water 30 : 70 (V/V)
Carrier(s):	Wheat maltodextrin

DESCRIPTION

	Specifications	Methods and references
Appearance	<i>Hygroscopic powder</i>	
Color	<i>Brown orangish to brown greenish</i>	
Solubility	<i>To be tested following the degree of incorporation</i>	

ANALYSES

	Specifications		Method and reference
	Min	Max	
Total polyphenols expressed as pyrogallol content [%]	4.00	-	MO-43 - UV-Vis, Eur. Ph. (01/2008:20814), "Tannins in herbal drugs" 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	6.5	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] (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
Pesticides content [ppm] (2)	< Residual Maximum Limit fixed in European regulation 396/2005 and its modifications		AE-02 - GC-MSMS/LC-MSMS, internal method

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Benzo(a)pyrene content [ppb] (2)	-	< 10.0	AE-03 - GC-MS-MS, internal method
Paahs (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

(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.

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