

TECHNICAL DATA SHEET

ORGANIC PASSION FLOWER AP 3.5% DE PR3223

**Organic labelling regulation
((UE) 2018/848 - art.32):**

BIO = DE-ÖKO-039

Botanical kind:

Organic Passifloraceae Passiflora incarnata L. (=Passiflora edulis Sims)

Part of the plant:

Aerial part

Extraction solvent(s):

Ethanol, Water 30 : 70 (V/V)

Carrier(s):

Organic wheat maltodextrin

DESCRIPTION

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

ANALYSES

	Specifications		Method and reference
	Min	Max	
Total flavonoids, expressed as vitexin content [%]	> 3.50	-	MO-09 - UV-Vis, Fr. Ph. (1993), "Extrait de passiflore (sec)" monograph
Hyperosid content [%] (4)	<i>Indicative value</i>		AE-23 - HPLC, internal method
Vitexin content [%] (4)	<i>Indicative value</i>		AE-37 - HPLC, internal method
Identification (raw material) (4)	<i>Complies</i>		MO-71 - TLC, Eur. Ph. (01/2008 :1882), "Passion flower 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	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

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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
Pesticides content [ppm] (4)	< detection limit		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/ 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.*

- *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*