

TECHNICAL DATA SHEET

CALIFORNIA POPPY AP 5:1 DE PR1344

Botanical kind:	Papaveraceae <i>Eschscholzia californica</i> Cham.
Part of the plant:	Aerial part
Ratio plant / final extract:	5 to 1 (a)
Extraction solvent(s):	Water
Carrier(s):	Wheat maltodextrin (max 30%)

DESCRIPTION

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

ANALYSES

	Specifications		Method and reference
	Min	Max	
Total alkaloids expressed as californidine content [ppm] (4)	<i>Indicative value</i>		<i>AE-38 - Titrimetry, Fr. Ph. (January 1996 adapted), "Eschscholtzia (partie aérienne fleurie)" monograph</i>
Californidine content [%] (4)	<i>Indicative value</i>		<i>AE-139 - LC-MS, internal method</i>
Identification (raw material) (4)	<i>Complies</i>		<i>MO-81 - TLC, Fr. Ph. (1996), "Eschscholtzia (parties aériennes fleuries d')" monograph</i>
Loss on drying [%]	-	8.00	<i>MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)</i>
Bulk density	0.40	0.80	<i>MO-181 - Eur. Ph. (04/2019:20934)</i>
Total ash content [%]	-	< 12.00	<i>MO-01 - Muffle furnace, Eur. Ph. (01/2008:20416), "Total ash" adapted monograph</i>
pH (1% in demineralized water)	3.0	7.0	<i>MO-03 - pH-meter, Eur. Ph. (07/2016:20203), "Potentiometric determination of pH" monograph</i>
Screening [% < 200 µm]	95.0	-	<i>MO-184 - Granulometer, internal method</i>

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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
As content [ppm] (4)	-	< 1.00	AE-01 - ICP, internal method
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
Pyrrolizidine alkaloids content [ppb]	-	< 5 000	AE-61 - LC-MSMS, 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

(4) HACCP based control plan defined annually according to risk analysis

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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	(a): Variable indicative raw material ratio depending on productions and / or variability of the raw material. Non contractual data. <i>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.</i> <i>- Complies with French decrees (2006-352 and 24th June 2014)</i> <i>- According to Regulation 1999/3/EC, and its modifications, has not been ionized.</i> <i>- 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%)</i> <i>- The product does not contain TSE/BSE substances</i>