



TECHNICAL DATA SHEET

GERMAN CHAMOMILE FL 4:1 DE PR605

Botanical kind: Compositae (= Asteraceae) Matricaria recutita L. (= Matricaria chamomilla

L.) (= Chamomilla recutita (L.) Rauschert)

Part of the plant: Flower Ratio plant / final extract: 4 to 1 (a) **Extraction solvent(s):** Water

Wheat maltodextrin Carrier(s):

DESCRIPTION	Specifications	Methods and references
Appearance	Powder	
Color	Beige to brown	
Solubility	To be tested following the degree of incorporation	

	Specifications		Made ad and reference
ANALYSES	Min	Max	Method and reference
Total apigenin 7- glucoside content [%] (4)	Indicativ	e value	MO-49 - HPLC, Eur. Ph. (01/2016:0404), "Matricaria flower" monograph
Alpha-bisabolol content [ppm] (4)	Indicativ	e value	AE-42 - GC-MS, internal method
Identification (raw material) (4)	Сотр	olies	MO-127 - TLC, Eur. Ph. (04/2016:0404), "Matricaria flower" monograph
Loss on drying [%]	-	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)	3.0	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

	Specifications		Mathed and reference
CONTAMINANTS	Min	Max	Method and reference
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

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As content [ppm] (4)	-	< 1.00	AE-01 - ICP, internal method
Pesticides content [ppm] (4)	< Residual Maximo European regulatio its modifio	n 396/2005 and	AE-02 - GC-MSMS/LC-MSMS, 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
Benzo(a)pyrene content [ppb] (4)	-	< 10.0	AE-03 - GC-MS-MS, internal method

MICROBIOLOGY	Specifications		
	Min	Max	Method and reference
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

Shelf life/ DMD

24

(in months):

Store in closed original packaging at 5 to 25°C in a dry place and protected from light.

Storage conditions:

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





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Complementary data

(a) Variable indicative ratio depending on productions and / or variability of the raw material. Non contractual 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

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