

TECHNICAL DATA SHEET

BLACK HOREHOUND FAP 5:1 DE PR509

Botanical kind:	Lamiaceae Ballota nigra L.
Part of the plant:	Flowering aerial part
Ratio plant / final extract:	5 to 1 (a)
Extraction solvent(s):	Ethanol, water 50 : 50 (V/V)
Carrier(s):	Wheat maltodextrin

DESCRIPTION

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

ANALYSES

ANALYSES	Specifications		Method and reference
	Min	Max	
Loss on drying [%] (11)	-	8.00	<i>MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)</i>
Bulk density	0.30	0.70	<i>MO-181 - Eur. Ph. (04/2019:20934)</i>
pH (1% in demineralized water) (11)	4.0	6.0	<i>MO-03 - pH-meter, Eur. Ph. (07/2016:20203), "Potentiometric determination of pH" monograph</i>
Screening [% < 500 µm]	95.0	-	<i>MO-184 - Granulometer, internal method</i>

CONTAMINANTS

CONTAMINANTS	Specifications		Method and reference
	Min	Max	
Pb content [ppm] (2)	-	< 3.00	<i>AE-01 - ICP, internal method</i>
Cd content [ppm] (2)	-	< 1.00	<i>AE-01 - ICP, internal method</i>
Hg content [ppm] (2)	-	< 0.10	<i>AE-01 - ICP, internal method</i>
As content [ppm] (2)	-	< 1.00	<i>AE-01 - ICP, internal method</i>
Pesticides content [ppm] (2)	<i>< Residual Maximum Limit fixed in European regulation 396/2005 and its modifications</i>		<i>AE-02 - GC-MSMS/LC-MSMS, internal method</i>

TECHNICAL DATA SHEET

BLACK HOREHOUND FAP 5:1 DE PR509

Benzo(a)pyrene content [ppb] (2)	-	< 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] (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	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

(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 (a): Variable indicative raw material 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.

- 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