

TECHNICAL DATA SHEET

ST JOHN'S WORT FT 0.30 - 0.35% DE PR304

Botanical kind:	Hypericaceae Hypericum perforatum L.
Part of the plant:	Flowering top
Extraction solvent(s):	Ethanol, water 60 : 40 (V/V)
Carrier(s):	Wheat maltodextrin

DESCRIPTION

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

ANALYSES

	Specifications		Method and reference
	Min	Max	
Hypericin content [%]	0.30	0.35	MO-30 - UV-Vis, internal method
Identification (raw material) (4)	Complies		MO-219 - TLC, Eur. Ph. (07/2013:1438), "St John's wort" 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)
Total ash content [%] (11)	-	< 15.00	MO-01 - Muffle furnace, Eur. Ph. (01/2008:20416), "Total ash" adapted monograph
pH (1% in demineralized water) (11)	4.0	7.5	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] (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

TECHNICAL DATA SHEET

ST JOHN'S WORT FT 0.30 - 0.35% DE PR304

Pesticides content [ppm] (4)	< Residual Maximum Limit fixed in European regulation 396/2005 and its modification		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.

TECHNICAL DATA SHEET

**ST JOHN'S WORT FT 0.30 - 0.35% DE
PR304**

**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