

TECHNICAL DATA SHEET

ST MARY'S THISTLE FR 50-80% DE PR6702

Botanical kind:	Asteraceae (=Compositae) Silybum marianum (L.) Gaertn.
Part of the plant:	Dried fruit (akene)
Extraction solvent(s):	Ethanol
Carrier(s):	None

DESCRIPTION

	Specifications	Methods and references
Appearance	<i>Thin hygroscopic powder</i>	
Color	<i>Light yellow to brown yellowish</i>	
Odor	<i>Characteristic</i>	
Taste	<i>Characteristic</i>	
Solubility	<i>To be tested following the degree of incorporation</i>	

ANALYSES

	Specifications		Method and reference
	Min	Max	
Total silymarin expressed as silibinin content [%]	50.00	80.00	MO-50 - HPLC, Eur. Ph. (01/2008:2071), "Milk thistle dry extract, refined and standardised" monograph
Identification (finished product) (4)	Complies		MO-139 - TLC, Eur. Ph. (01/2014:2071), "Milk thistle dry extract, refined and standardised" monograph
Ethanol residual content [%] (2)	-	0.50	AE-20 - GC-MS, internal method
Hexane residual content [%] (2)	-	0.03	AE-20 - GC-MS, internal method
Ethyl acetate residual content [%] (2)	-	< 0.50	AE-20 - GC-MS, internal method
Loss on drying [%] (11)	-	5.00	MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)
Screening [% < 177 µm]	90.0	-	MO-184 - Granulometer, internal method

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CONTAMINANTS	Specifications		Method and reference
	Min	Max	
Pb content [ppm] (4)	-	< 0.50	AE-01 - ICP, internal method
Cd content [ppm] (4)	-	< 0.50	AE-01 - ICP, internal method
Hg content [ppm] (4)	-	< 0.50	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

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]	-	< 10	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)
Staphylococcus aureus 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

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

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INFORMATION ABOVE AS RECEIVED FROM OUR SUPPLIER

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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**

*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 above mentioned item does not contain TSE/BSE substances