

## TECHNICAL DATA SHEET

### ARTICHOKE LE 4:1 DE PR160

<b>Botanical kind:</b>	Compositae Cynara scolymus L. (= Cynara cardunculus subsp. <i>flavescens</i> Wiklund).
<b>Part of the plant:</b>	Leaf
<b>Ratio plant / final extract:</b>	4 to 1 (a)
<b>Extraction solvent(s):</b>	Water
<b>Carrier(s):</b>	Wheat maltodextrin

#### DESCRIPTION

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

#### ANALYSES

ANALYSES	Specifications		Method and reference
	Min	Max	
<b>Identification (finished product) (4)</b>	<i>Complies</i>		MO-64 - <i>TLC, Eur. Ph. (01/2010:2389), "Artichoke leaf dry extract" monograph</i>
<b>Loss on drying [%] (11)</b>	-	8.00	MO-183 - <i>Eur. Ph. (01/2008:20817) and (02/2008:20816)</i>
<b>Bulk density</b>	0.40	0.75	MO-181 - <i>Eur. Ph. (04/2019:20934)</i>
<b>pH (1% in demineralized water) (11)</b>	4.0	6.5	MO-03 - <i>pH-meter, Eur. Ph. (07/2016:20203), "Potentiometric determination of pH" monograph</i>
<b>Screening [% &lt; 500 µm]</b>	95.0	-	MO-184 - <i>Granulometer, internal method</i>

#### CONTAMINANTS

CONTAMINANTS	Specifications		Method and reference
	Min	Max	
<b>Pb content [ppm] (4)</b>	-	< 3.00	AE-01 - <i>ICP, internal method</i>
<b>Cd content [ppm] (4)</b>	-	< 1.00	AE-01 - <i>ICP, internal method</i>
<b>Hg content [ppm] (4)</b>	-	< 0.10	AE-01 - <i>ICP, internal method</i>
<b>As content [ppm] (4)</b>	-	< 1.00	AE-01 - <i>ICP, internal method</i>

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<b>Pesticides content [ppm] (4)</b>	< Residual Maximum Limit fixed in European regulation 396/2005 and its modification		AE-02 - GC-MSMS/LC-MSMS, internal method
<b>Benzo(a)pyrene content [ppb] (4)</b>	-	< 10.0	AE-03 - GC-MS-MS, internal method
<b>Pahs (sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene) content [ppb] (4)</b>	-	< 50.0	AE-03 - GC-MS-MS, internal method

<b>MICROBIOLOGY</b>	<b>Specifications</b>		<b>Method and reference</b>
	<b>Min</b>	<b>Max</b>	
<b>Total aerobic microbial count [CFU/g] (1)</b>	-	< 10 000	AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)
<b>Total yeasts/moulds count [CFU/g] (1)</b>	-	< 100	AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)
<b>Salmonella content [ /25g]</b>	<i>Absent</i>		AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)
<b>Bile-tolerant Gram negative bacteria content [CFU/g]</b>	-	< 100	AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)
<b>Escherichia coli content [ /g]</b>	<i>Absent</i>		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.

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#### 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.*

- *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*