

TECHNICAL DATA SHEET

SAFFRON ST 0.3% DE PR3304

Botanical kind:	Iridaceae Crocus sativus L.
Part of the plant:	Red part of stigma
Extraction solvent(s):	Ethanol, Water 70 : 30 (V/V)
Carrier(s):	Wheat maltodextrin

DESCRIPTION

	Specifications	Methods and references
Appearance	<i>Powder</i>	
Color	<i>Yellow orangish to orange</i>	
Solubility	<i>To be tested following the degree of incorporation</i>	

ANALYSES

	Specifications		Method and reference
	Min	Max	
Safranal content [%]	<i>0.30</i>	<i>-</i>	<i>MO-05 - UV-Vis, internal method</i>
Identification (raw material) (4)	<i>Complies</i>		<i>MO-226 - TLC, Eur. Ph. (07/2014:1624), "Crocus for homoeopathic preparations" monograph</i>
Loss on drying [%] (11)	<i>-</i>	<i>8.00</i>	<i>MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)</i>
Bulk density	<i>0.40</i>	<i>0.80</i>	<i>MO-181 - Eur. Ph. (04/2019:20934)</i>
pH (1% in demineralized water) (11)	<i>3.5</i>	<i>6.5</i>	<i>MO-03 - pH-meter, Eur. Ph. (07/2016:20203), "Potentiometric determination of pH" monograph</i>
Screening [% < 500 µm]	<i>95.0</i>	<i>-</i>	<i>MO-184 - Granulometer, internal method</i>

CONTAMINANTS

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

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Pesticides content [ppm] (4)	< <i>Residual Maximum Limit fixed in European regulation 396/2005 and its modifications</i>		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, benzo(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/ 18

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

- 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*