

PRODUCT SPECIFICATIONS

Product: MILK THISTLE DRY EXTRACT, 80% SILYMARIN

Product Code: N31408904

Botanical name: *Silybum marianum*

Plant Part Used: Seeds

Description: Light yellow powder without characteristic odor.**

Observations: ADDITIVE: FLAVOURING COMPOUNDS for all animal species: 2b Silybum marianum (L.) Gaertn: Milk thistle extract CoE 551

ANALYSIS	SPECIFICATION	METHODS
Identification	Conforms to standard	HPTLC
Assay (%)	Min. 80,0 Silymarin	Spectrophotometry
Loss on drying (%)	≤ 5,0	Eu. Pharm c.v. (2.8.17)
Residual solvents		
Ethanol (ppm)	< 5000	Eu. Pharm. v.v. (2.4.24)
Microbiology		
Bile-tolerant gram-negative bacteria (cfu/g)	≤ 100	Eu. Pharm. v.v. (2.6.31)
Escherichia coli (1 g)	Absence	Eu. Pharm. v.v. (2.6.31)
Salmonella (25 g)	Absence	Eu. Pharm. v.v. (2.6.31)
Heavy metals*		
Lead (ppm)	≤ 3,0	Eu. Pharm. v.v. (2.4.27)
Arsenic (ppm)	≤ 2,0	Eu. Pharm. v.v. (2.4.27)
Mercury (ppm)	≤ 0,1	Eu. Pharm. v.v. (2.4.27)
Cadmium (ppm)	≤ 1,0	Eu. Pharm. v.v. (2.4.27)
Pesticides*	According to Directive 2002/32/EC and amendments	SANTE/12682/2019
Micotoxins**		
Aflatoxins B1 (ppb)	≤2.0	Eur. Pharm. (2.8.18)
Aflatoxins B1+B2+G1+G2 (ppb)	≤4.0	Eur. Pharm. (2.8.18)
Ochratoxin A (ppb)	≤10.0	Eur. Pharm. (2.8.22)

Storage: Store in dry place and keep away from strong light and heat

Country of origin: Spain

Observations: * These parameters are determined in every three batches and at least once a year according to the sampling plan established in our HACCP system. **This is an herbal product; therefore, it is subject to color variations from batch to batch derived from natural, raw material color deviations. Color change has no effect on the quality, purity, potency, chemical profile or efficacy of the product.

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