Milk Thistle Extract (Silybum marianum) – Silibinin (silybin) 29–98%

Silybum marianum · Asteraceae

DOCUMENT	PRODUCT CODE	DOCUMENT NO.	REVISION	PRODUCT FORM
Technical Data Sheet	AP1127	TDS-AP1127	1.0 · 24 October 2026	Standardized Extract

1 Product description

Milk Thistle extract is produced from the seed of Silybum marianum (Asteraceae family) and supplied as a standardized extract powder, standardized to Silibinin (silybin). Available grades: 29%, 50%, 98%. Typical sourcing: Argentina, China. Intended for B2B formulation in nutraceuticals & supplements, pharmaceutical.

29% 50% 98%

2 Identification

Botanical source	*Silybum marianum* (Asteraceae)
Common name(s)	Milk thistle
Plant part used	Seed
Typical origin	Argentina, China
Marker compound	Silibinin (silybin) (Flavanonols & flavonolignans)
CAS number	22888-70-6
Manufacturing process	Water and/or hydro-alcoholic (ethanol) extraction, concentration and spray-drying; the solvent system for each grade is stated on the CoA
Standardisation	29–98% (HPLC)
Assay method	HPLC
Pharmacopoeia & standards	USP, Ph. Eur. (EP), British Pharmacopoeia, Chinese Pharmacopoeia, EMA herbal monograph, ESCOP monograph, WHO monograph

3 Specification

PARAMETER	SPECIFICATION	METHOD
Appearance	Yellow to greenish-yellow powder	Visual
Odour	Characteristic	Organoleptic
Identification	Conforms (HPTLC / HPLC fingerprint vs. reference)	HPTLC / HPLC
Assay – Silibinin (silybin)	Not less than the labelled grade (29%, 50%, 98%)	HPLC
Loss on drying	≤ 5.0%	USP ‹731›
Total ash	≤ 5.0%	USP ‹561›
Particle size	≥ 95% through 80 mesh (180 µm)	USP ‹786›
Bulk density	Report (typically 0.40–0.70 g/mL)	USP ‹616›
Residual solvents	Complies with ICH Q3C / USP ‹467›	GC-HS
Lead (Pb)	≤ 3.0 mg/kg	ICP-MS
Arsenic (As)	≤ 2.0 mg/kg	ICP-MS
Cadmium (Cd)	≤ 1.0 mg/kg	ICP-MS
Mercury (Hg)	≤ 0.1 mg/kg	ICP-MS
Pesticide residues	Complies with USP ‹561› and Regulation (EC) No 396/2005	GC-MS/MS, LC-MS/MS

Aflatoxins	B1 ≤ 2 µg/kg; sum of B1, B2, G1, G2 ≤ 4 µg/kg	HPLC-FLD
Total aerobic microbial count	≤ 10,000 cfu/g	USP ‹2021›
Yeasts & moulds	≤ 1,000 cfu/g	USP ‹2021›
Escherichia coli	Absent in 10 g	USP ‹2022›
Salmonella spp.	Absent in 25 g	USP ‹2022›
Staphylococcus aureus	Absent in 10 g	USP ‹2022›

Limits above are the standard release specification for this product class. Each lot is released against its Certificate of Analysis, which is the governing document and is available on request.

4 Grades & pack sizes

GRADE	SKU PREFIX	PACK SIZES
29%	AP1127-29	Sample (50 g) · 250 g · 1 Kg · 5 Kg · 25 Kg
50%	AP1127-50	Sample (50 g) · 250 g · 1 Kg · 5 Kg · 25 Kg
98%	AP1127-98	Sample (1 g) · 50 g · 250 g · 1 Kg

Made-to-order grades: 50%.

5 Packaging

- Samples: food-grade HDPE jar or aluminium-laminate pouch.
- 250 g – 1 Kg: food-grade LDPE bag sealed in an aluminium-laminate pouch.
- 5 Kg – 25 Kg: double food-grade LDPE bags in a fibre drum or HDPE pail.
- Packaging may vary by lot and is stated on the packing list.

6 Storage & shelf life

- Shelf life: 24 months from date of manufacture in the original, unopened packaging.
- Store in a cool (below 25 °C), dry place, protected from light.
- Hygroscopic: reseal immediately after use and minimise exposure to humid air.

7 Applications

Industries	Nutraceuticals & Supplements, Pharmaceutical
Formulation focus	Liver & Detox
Traditional systems	Traditional Chinese Medicine, European herbal tradition

Use levels depend on the finished product and the target market. The customer is responsible for establishing safe and permitted use levels and for any claims made on finished products.

8 Regulatory & compliance

- Pharmacopoeia / standard references: USP, Ph. Eur. (EP), British Pharmacopoeia, Chinese Pharmacopoeia, EMA herbal monograph, ESCOP monograph, WHO monograph.
- Allergen information: not derived from a source listed in Annex II of Regulation (EU) No 1169/2011.
- Regulatory status for food, supplement, cosmetic or pharmaceutical use (e.g. EU novel food, US NDI/GRAS, FSSAI) must be confirmed by the customer for the intended market and use.

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