# Milk Thistle Extract Specification Sheet

## 1.1 Product Definition

This product is a fine powdered extract prepared from the mature fruits of *Silybum marianum* (L.) Gaertn. (Asteraceae) through cleaning, impurity removal, crushing, extraction, concentration, purification, drying, re-crushing and sieving. It mainly retains hepatoprotective active ingredients including silybin and total flavonoids, without any preservatives, colorants or flavors. It is widely used in food, health food, dietary supplements, skincare products and feed, complies with international food ingredient access standards and safety specifications, and features high safety, controllability and stability.

## 1.2 Basic Product Information

- Product Name: Milk Thistle Extract
- English Name: Milk Thistle Extract
- Latin Name: *Silybum marianum* (L.) Gaertn.
- INCI Name: Silybum Marianum Seed Extract
- CAS No.: 65666-07-1 (silybin); 84604-20-6 (milk thistle extract)
- EN No.: 283-456-6
- UN No.: None (non-hazardous goods, no UN number)
- Part Used: Mature fruit
- Extraction Solvent: Food-grade ethanol-water mixture, food-grade pure water (adjustable as required)
- Specifications:
    - Total flavonoids ≥80%, silybin ≥60% (detected by HPLC)
    - Total flavonoids ≥70%, silybin ≥30% (standard type)
    - Total flavonoids ≥30%, silybin ≥10% (economic type)

The above indicators can be customized according to application scenarios.

- Extraction Ratio: 10:1, 20:1; customizable from 5:1 to 30:1

## 1.3 Characteristics

- Appearance: Fine yellowish-brown to light yellow powder, free from caking and visible foreign impurities
- Odor: Characteristic odor of milk thistle, no pungent, moldy or rancid odor
- Taste: Slightly bitter and astringent, consistent with natural characteristics, no off-odor
- Solubility: Soluble in ethanol and dilute ethanol; water-soluble modification available for some grades; excellent dispersibility, suitable for food and health food processing

## 1.4 Active Ingredients

- Total flavonoids: ≥80% (dry basis), detected by UV/HPLC
- Silybin: ≥60% (dry basis), detected by HPLC
- Silymarin: ≥80% (dry basis), detected by HPLC
- Polyphenols: ≥5.0% (dry basis), detected by Folin-Ciocalteu method
- Amino acids: ≥2.0% (dry basis), detected by HPLC

## 1.5 Physicochemical Indicators

- Particle size: 95% pass 80/100 mesh; customizable 60–120 mesh, detected by sieving (GB/T 5507)
- Loss on drying: ≤7.0%, detected at 105°C for 2 h (GB 5009.3)
- Residue on ignition (ash): ≤5.0%, detected by incineration weighing (GB 5009.4)
- Total heavy metals: ≤20 mg/kg, detected by AAS/ICP-MS
- Pb: ≤0.5 mg/kg, detected by AAS/ICP-MS (GB 5009.12)
- As: ≤0.5 mg/kg, detected by AAS/ICP-MS (GB 5009.11)
- Cd: ≤0.2 mg/kg, detected by AAS/ICP-MS (GB 5009.15)
- Hg: ≤0.1 mg/kg, detected by AAS/ICP-MS (GB 5009.17)
- Residual solvent: Ethanol ≤0.5%, no methanol, meets food grade, detected by GC
- Pesticide residues: HCH and DDT ≤0.05 mg/kg each, complies with GB 2763

## 1.6 Microbiological Indicators

Complies with US FDA, EU EFSA and China national food safety standards

- Total plate count: ≤10000 CFU/g, GB 4789.2
- Molds & yeasts: ≤50 CFU/g, GB 4789.15
- Coliforms: ≤100 CFU/g, GB 4789.3
- Salmonella: Negative / 25 g, GB 4789.4
- *Staphylococcus aureus*: ≤100 CFU/g, GB 4789.10

## 1.7 Nutrition Information (per 100 g, dry basis)

| **Item** | **Content** | **NRV% (Ref.)** |
|---|---|---|
| Energy | 1580 kJ | ≈18.81% |
| Protein | 12.5 g | 21% |
| Fat | 3.2 g | 5% |
| Carbohydrates | 78.0 g | 26% |
| Dietary Fiber | 4.5 g | 18% |
| Sodium | 15 mg | 1% |
| Note: NRV% calculated per GB 28050-2011, EU 90/496/EEC and FDA, for reference only. | | |

## 1.8 Application Fields

### 1.8.1 Functional Food

Used in solid drinks, tableted candies, meal replacements, healthy teas, milk drinks for liver protection, anti-oxidation, free radical scavenging and hangover relief.

### 1.8.2 Health Food / Dietary Supplements

Used in liver protection, anti-hangover, anti-oxidation and immune-enhancing products (capsules, tablets, granules, oral liquids), complies with USP, EP and Chinese health

food standards.

#### 1.8.3 Beauty & Skincare

Used in anti-aging essences, repair creams, soothing lotions, anti-oxidation masks, oral beauty products for anti-oxidation, soothing and repairing dull sensitive skin.

#### 1.8.4 Feed Additive

Used in livestock and aquaculture feed to protect liver, enhance immunity and reduce stress.

#### 1.8.5 Others

Natural antioxidant to replace synthetic antioxidants; used in special dietary foods, sports nutrition and products for people staying up late; customizable.

### 1.9 Compliance Statement

#### 1.9.1 Standards

- International: ISO 20483, ISO 6496
- EU & US: USP, EP, FDA 21 CFR, EU Food Supplement Directive 2002/46/EC
- China: Pharmacopoeia of PRC, GB 14881, GB 28050-2011, GB 2760

#### 1.9.2 Certifications

ISO 9001, HACCP, Kosher, Halal, Organic (optional: ECOCERT, USDA Organic)

#### 1.9.3 Additional Claims

- Non-GMO
- Allergen-free (EU allergen directive)
- Non-irradiated
- No preservatives, colorants, flavors or harmful solvent residues
- No animal ingredients, suitable for vegan & Halal

## 1.10 Packaging & Storage

- Packaging: 1 kg/5 kg aluminum foil bag; 25 kg fiber drum (double PE liner); customizable small packages; with deoxidizer.
- Storage: Sealed, cool, dry, ventilated; avoid light & high temperature (>30℃); keep away from odor and toxic materials.
- Shelf life: 24 months unopened; use within 30 days after opening.

## 1.11 International Market Notes

- Active ingredients: Total flavonoids, silybin, silymarin are key QC items for EU, US, Japan, Korea; customizable methods and limits.
- Heavy metals & microbes: Comply with EU 1881/2006, FDA cGMP; CMA/CNAS reports available.
- Documents: COA, MSDS, botanical origin certificate, third-party test report; customizable for target markets.

## Appendix: Grades by Application

1. Food Grade (GB-F01)
    - Application: Solid drinks, tablets, tea, meal replacements
    - Specs: Water/low-alcohol extraction, total flavonoids ≥70%, silybin ≥30%
2. Health Food Grade (GB-H02)
    - Application: Liver capsules, hangover products, antioxidant supplements
    - Specs: Total flavonoids ≥80%, silybin ≥60%, membrane purified
3. Cosmetic Grade (GB-C03)
    - Application: Essences, creams, masks, oral beauty
    - Specs: Low-temp refined, strict heavy metals & microbes
4. Feed Grade (GB-FD04)
    - Application: Livestock & aquaculture feed
    - Specs: Cost-effective, stable, liver protection
5. High-End Custom Grade (GB-CU05)
    - Application: Export supplements, special diets, pharma intermediates
    - Specs: Supercritical $CO_2$ / multi-stage membrane; silybin 80–98%; customizable particle size, solubility, dosage form

# Analysis of Milk Thistle Extract Manufacturing Process

Milk thistle is a classic hepatoprotective medicinal and edible plant internationally recognized. Its extract is rich in silybin, silymarin, total flavonoids and other strong antioxidant and liver-protecting ingredients, widely used in functional food, health food, skincare and feed additives. This document analyzes the full modern production process from raw material to finished product, systematically presenting process principles, core technologies, QC standards and advantages, providing professional and reliable reference for customers.

The process adopts: selected raw fruits + low-temperature pretreatment + directional extraction + multi-stage membrane purification + deep impurity removal + low-temperature drying. It maximizes retention of thermosensitive silybin under mild conditions, removes crude fiber, oil, pigments, pesticide residues and heavy metals, complies with food/health/cosmetic grades, and ensures high purity, activity, safety and stability.

## I Raw Material Control

### 1.1 Origin & Harvest

Authentic *Silybum marianum* mature dry fruits; discard damaged, moldy, shriveled ones; select current-year full grains with high silybin & flavonoids; non-GMO.

### 1.2 Ecological Sourcing

High-quality areas in China & Europe; fertile soil, no industrial pollution; direct sourcing + instant low-temp drying to avoid mold and activity loss.

### 1.3 Incoming Inspection

- Sensory: No mold, insects, sand, odor
- Physicochemical: Moisture ≤12%, ash ≤8%
- Safety: Pesticides & heavy metals meet GB, EU EFSA, FDA
- Activity: Total flavonoids & silybin qualified

Unqualified rejected.

## II Pretreatment: Cleaning & Cell Break

### 2.1 Cleaning

High-pressure countercurrent spraying + mechanical screening + manual sorting; water temp ≤25℃; quickly drained to avoid active loss.

### 2.2 Low-Temp Crushing

Ultra-fine grinding ≤40℃, 40–60 mesh; break cell wall gently; avoid oxidation; sealed storage.

## III Core Extraction

### 3.1 Ethanol-Water Low-Temp Extraction (health food)

50–70% food-grade ethanol; solid-liquid ratio 1:10–1:15; 40–60℃; 2–3 times × 1–2 h; closed stirring; high enrichment.

### 3.2 Pure Water Extraction (food grade)

Purified water; 30–50℃; no solvent residue.

### 3.3 Supercritical $CO_2$ Extraction (high-end)

No organic solvent; activity retention >90%; purity >90%; for pharma/cosmetics.

### 3.4 Ultrasonic/Microwave Assisted

Time reduced 50%, yield +25%; low temp, less oxidation.

## IV Purification

### 4.1 Filtration & Centrifugation

Plate filtration + high-speed centrifugation; remove residue, starch, colloid.

### 4.2 Multi-Stage Membrane Purification

Ultrafiltration: remove macromolecules; nanofiltration: enrich silybin & flavonoids, desalt; physical separation, no flocculant.

### 4.3 Decolorization & Deodorization

Food-grade activated carbon ≤50℃; light color, mild odor.

**4.4 Pesticide & Heavy Metal Removal**

Resin adsorption & membrane separation; meet export standards.

## V Low-Temp Concentration

Vacuum low-temp dual-effect concentration; ≤60℃; vacuum -0.08~-0.09 MPa; solid content 15–25%; avoid degradation.

## VI Drying

**6.1 Spray Drying (mainstream)**

Inlet 160–180℃, outlet 60–80℃; fine powder; moisture ≤7.0%; 24-month shelf life.

**6.2 Vacuum Drying (custom)**

50–60℃; for high-viscosity extract.

**6.3 Freeze Drying (high-end)**

-40℃ pre-freeze + sublimation; activity >95%; excellent solubility.

**6.4 Post-Treatment**

Low-temp crushing, sieving, 3D blending; uniform, stable, no caking.

## VII Quality Control

**7.1 Key Control Points**

Raw material, crushing temp, extraction, membrane, concentration, drying, finished product.

**7.2 Full Inspection**

Activity (flavonoids, silybin, silymarin); physicochemical; safety (heavy metals, pesticides, solvents); microbes; CMA/CNAS reports available.

## VIII Process Advantages

1. Activity: Retention >90%, high-end >95%
2. Quality: High purity, good solubility, no odor
3. Safety: Low residues, compliant with international standards
4. Stability: Consistent batches, long shelf life
5. Customization: Content, ratio, mesh, solubility, dosage form
6. Eco-friendly: Solvent recycling, low carbon

## IX Conclusion

Milk thistle extract features high purity, activity, safety and stability. Based on professionalism, rigor, naturality and compliance, we continuously optimize modern extraction technology to provide stable, high-quality and cost-effective raw materials for global functional food, health food, skincare and feed industries, supporting product innovation and competitiveness.

## Appendix: Simplified Flow Chart of Milk Thistle Extract Manufacturing Process

