I. Elderberry Extract Specification Sheet

1.1 Product Definition

Elderberry Extract is a natural plant extract produced from the ripe berries of *Sambucus nigra* (Caprifoliaceae, Sambucus) via standardized industrial processes, including screening, washing, crushing and pulping, enzymatic hydrolysis, dual fermentation, ultrasonic-assisted extraction, membrane separation and purification, low-temperature freeze-drying, pulverization, and sieving.

The product is rich in anthocyanins, bioflavonoids, phenolic acids, vitamins, minerals, and other active ingredients, retaining the original nutrition and physiological activity of elderberry. It complies with industry standards for food, dietary supplements, cosmetics, and pharmaceutical raw materials, and can be widely used in various fields.

1.2 Basic Product Information

- Product Name: Elderberry Extract
- English Name: Elderberry Extract
- Botanical Name: *Sambucus nigra* L.
- INCI Name: Sambucus Nigra Fruit Extract
- CAS No.: 84603-58-7
- Plant Source: *Sambucus nigra* L. (Caprifoliaceae, Sambucus)
- Part Used: Ripe berries (without stems or leaves; fresh or frozen ripe fruits preferred)

1.3 Core Specifications

- Anthocyanins (calculated as Cyanidin-3-glucoside, HPLC): 1%, 2%, 4% (regular); 5%–25% (high-content customizable)
- Bioflavonoids (calculated as Quercetin, UV): 3.0%–6.0%
- Phenolic Acids (calculated as Gallic acid, UV): 1.5%–3.0%
- Extraction Ratio: 10:1, 20:1, 50:1 (customizable on request)
- Particle Size: 80 mesh, 100 mesh (100–200 mesh customizable)

1.4 Physical and Chemical Properties

- Appearance: Fine dark purple to purplish-black powder, no visible foreign impurities, characteristic elderberry odor, no off-odor or caking
- Particle Size: ≥95% passes through 80-mesh sieve; 100–200 mesh customizable
- Loss on Drying (Moisture): ≤6.0%
- Residue on Ignition (Ash): ≤5.0%
- pH (1% aqueous solution): 3.0–5.0
- Solubility: Freely soluble in warm water and dilute ethanol; partly soluble in cold water; insoluble in petroleum ether and diethyl ether

1.5 Hygiene Indicators

- Total Heavy Metals: ≤20 ppm
- Lead (Pb): ≤0.5 ppm; Arsenic (As): ≤0.3 ppm; Cadmium (Cd): ≤0.1 ppm; Mercury (Hg): ≤0.1 ppm
- Microorganisms: Total plate count ≤1000 cfu/g; Molds & yeasts ≤100 cfu/g; Coliforms, Salmonella: Not detected
- Solvent Residues: No organic solvent residues in enzymatic hydrolysis & fermentation process; Ethanol residue ≤0.5% for ethanol extraction, complying with European Pharmacopoeia and Chinese Pharmacopoeia standards

1.6 Application Scope

1. **Functional Foods**: Solid drinks, compressed tablets, oral liquids, meal replacements, dietary supplements, mainly for antioxidant, immune-enhancing, and respiratory soothing effects.
2. **Dietary Supplements**: Raw material for immune-regulating, antioxidant, anti-fatigue health foods, suitable for "Blue Hat" product registration.
3. **Cosmetics**: Antioxidant, brightening, soothing & repairing essences, creams, masks, oral liquids, etc., suitable for sensitive-skin products.
4. **Pharmaceutical Intermediates**: Raw material for topical soothing, antioxidant, mucosal care ointments and preparations.
5. **Other Fields**: Pet health products, feed additives, oral care products (mouthwash, toothpaste).

1.7 Packaging

0.5–5 kg sterile aluminum foil bags; 25 kg fiber drums (lined with double-layer sterile polyethylene bags; packaging customizable per customer requirements)

1.8 Storage

Store in a cool, dry, dark, and sealed place, avoid direct sunlight, high temperature (>30°C), and humidity to prevent moisture absorption, oxidation, and color fading.

1.9 Shelf Life

24 months (under sealed storage and specified conditions)

II. Nutrition Facts of Elderberry Extract

This nutrition facts sheet is compiled based on test data of mainstream elderberry extract (anthocyanins ≥4%). It is applicable for quality control and labeling of food and dietary supplement raw materials, complying with relevant requirements of National Health Commission and GB 28050 (General Rules for Nutrition Labeling of Prepackaged Foods).

2.1 Basic Nutrition (per 100 g)

Item	Value	NRV%
Energy	1464 kJ / 350 kcal	17.5%
Protein	3.2 g	5.3%
Fat	0.6 g	1.0%
— Saturated Fat	0.2 g	1.0%
— Trans Fat	0 g	—
Carbohydrate	84.0 g	28.0%
— Total Sugars	75.5 g	—
— Dietary Fiber	7.2 g	28.8%
Sodium	8 mg	0.4%

2.2 Core Active Components (per 100 g)

(1) Anthocyanins

- Total Anthocyanins (as Cyanidin-3-glucoside): 1.0–25.0 g
- Cyanidin-3-glucoside: 0.3–8.0 g
- Cyanidin-3-sambubioside: 0.2–5.0 g

(2) Flavonoids and Phenolic Acids

- Bioflavonoids (as Quercetin)：3.0–6.0 g
- Total Phenolic Acids (as Gallic acid)：1.5–3.0 g
- Quercetin：0.5–1.2 g
- Kaempferol：0.3–0.8 g

(3) Vitamins (per 100 g)

- Vitamin C：0.3–0.8 g
- Vitamin A：80–120 μg RE
- B Vitamins (B1+B2+B6)：0.05–0.12 g

(4) Minerals (per 100 g)

- Potassium (K): 800–1200 mg
- Calcium (Ca): 60–100 mg
- Magnesium (Mg): 40–70 mg
- Iron (Fe): 2.0–4.0 mg

2.3 Safety Limits (per 100 g)

- Lead (Pb): ≤0.05 mg
- Cadmium (Cd): ≤0.01 mg
- Arsenic (As, inorganic): ≤0.03 mg
- Mercury (Hg): ≤0.01 mg
- Total Plate Count: ≤1000 CFU/g
- Molds & Yeasts: ≤100 CFU/g
- Coliforms: ≤10 MPN/g
- Salmonella: 0/25g

2.4 Label Compliance and Application Value Summary

● **Compliance**: Fully complies with GB 28050, QB/T 4079-2010 (General Technical Requirements for Plant Extracts), Chinese Pharmacopoeia, and US CTFA standards. Complete labeling items, accurate data, and standardized expressions for direct product registration.

● **Differentiated Value**: Core selling point of high anthocyanin content; quality advantages of high activity, low heavy metals, and no harmful solvent residues, distinguishing from common elderberry products and highlighting technical barriers and quality superiority.

● **Application Adaptability**: Nutritional and safety indicators fully cover four major scenarios: food, dietary supplements, cosmetics, and pharmaceutical raw materials. Label data can be directly used for product registration, promotion, customs declaration, and customer quality audits, with strong practicability and authority.

III. Manufacturing Process of Elderberry Extract

This process adopts international mainstream industrial production standards, combining enzymatic pretreatment + dual fermentation + ultrasonic-assisted extraction + membrane separation & purification + low-temperature freeze-drying.

The core goal is to maximally retain anthocyanins, bioflavonoids, and other active ingredients in elderberry, complying with EU, US FDA, and Chinese Pharmacopoeia production specifications, suitable for large-scale production of elderberry extract with various specifications.

Low-temperature, light-proof, and low-oxygen operation throughout the process avoids degradation of active ingredients and ensures stable product quality.

3.1 Core Process Principles

- **Activity Priority**: Low-temperature operation ≤50°C throughout; stabilizes structure of anthocyanins and flavonoids; active ingredient retention rate ≥95%.
- **Green Extraction**: Purified water as main extraction medium; no toxic solvents in enzymatic hydrolysis & fermentation; recyclable solvent in ethanol extraction, meeting environmental requirements.
- **Fine Purification**: Four-stage membrane separation effectively removes pigments, macromolecular impurities, and heavy metals, improving purity and color.
- **Full Process Control**: Full coverage of Critical Control Points (CCP); compliant with GMP; traceable and controllable production.

3.2 Detailed Process Steps

- **Raw Material Pretreatment (CCP1)**

Ripe berries of *Sambucus nigra* with maturity ≥90% are selected. Rotten fruits, stems, leaves, and impurities are removed manually or mechanically. Berries are rinsed 2–3 times with purified water to remove sediment, dust, and pesticide residues, then drained.

Fresh fruits are directly crushed and pulped; dried fruits are rehydrated with 15–30 times purified water before crushing to 2–5 mm and pulping. Microbial control is implemented to exclude rotten or pesticide-contaminated raw materials.

- **Gradient Temperature-Controlled Enzymatic Hydrolysis**

The pulp is transferred to an enzymatic tank with a solid-liquid ratio of 1:8–12. A complex enzyme system of 0.5–1 wt% cellulase and 0.07–0.1 wt% pectinase is added.

Conditions: 45–50°C, stirring at 30–50 r/min for 1.5–2.5 h. Enzyme inactivation at 85°C for 10 min. Plant cell walls are broken to fully release active ingredients, increasing extraction rate by 18%–28%.

● **Dual Fermentation (CCP2)**

① **Yeast Fermentation**: Hydrolyzate cooled to 18–23°C, inoculated with 2–5 wt% high-activity dry yeast. Fermentation in dark, stirred 2–3 times daily, stopped when alcohol content reaches 5.5–8.7° vol. Macromolecules converted to small molecules, improving solubility and bioavailability.

② **Acetic Acid Bacteria Fermentation**: Fermentation broth inoculated with 8–10 wt% acetic acid bacteria (viable count ≥1×10^8 cfu/g). Sterile air 0.06–0.08 vvm, 28–33°C, fermented to pH 2.8–3.0. Further degrades impurities and enhances antioxidant activity.

● **Low-Temperature Ultrasonic-Assisted Extraction (CCP3)**

Purified water as solvent, solid-liquid ratio 1:10–15, extracted twice:

① After yeast fermentation: 40–45°C, ultrasonic power 200–300 W, frequency 20–40 kHz, 1–2 h; plate-frame filtration to obtain primary filtrate.

② After acetic acid bacteria fermentation: second extraction with same parameters; filtrates combined to obtain crude extract. Low-temperature operation ensures no degradation of anthocyanins.

● **Filtration and Clarification (CCP4)**

Crude extract processed by plate-frame filtration → centrifugation (3000 r/min) → ceramic membrane clarification (pore size 100–800 nm, pressure 0.04–0.13 MPa, 20–40°C) to remove suspended solids, macromolecular proteins, pectin, and residues.

● **Membrane Separation and Purification**

Clarified solution adjusted to pH 3.5–4.5, processed by triple ultrafiltration + nanofiltration:

① Ultrafiltration (5000–20000 Da, 1.0–2.0 MPa) to remove macromolecular impurities.

② Ultrafiltration retention (500–2000 Da, 0.5–1.2 MPa) to enrich active ingredients.

③ Nanofiltration concentration (1.5–2.5 MPa) to 15–20% solid content, increasing active ingredient concentration and reducing freeze-drying energy consumption.

● **Low-Temperature Freeze-Drying (CCP5)**

Concentrate pre-frozen at -40 to -35°C for 2–3 h, then sublimation-dried at 10–30 Pa for 8–12 h until moisture ≤6.0%, yielding loose dark purple powder.

Premium pharmaceutical/health-grade products use freeze-drying (highest activity retention); food/cosmetic grades may use spray-drying (inlet 160–180°C, outlet 70–80°C).

● **Pulverization, Sieving, and Blending**

Powder pulverized to 80–100 mesh (100–200 mesh customizable), sieved to ≥95% pass rate, then blended in a 3D mixer for 15–20 min to ensure uniform active ingredient distribution.

● **Testing, Packaging, and Warehousing**

① Semi-finished product testing: active ingredients, moisture, particle size, etc.

② Finished product testing: full-index test (appearance, physicochemistry, microbes, heavy metals, solvent residues); non-conforming products reprocessed or discarded.

③ Packaging: sterile aluminum foil bags or double PE bags, then fiber drums, tightly sealed and labeled.

④ Storage: cool, dry, ventilated, dark warehouse (15–25°C, RH ≤60%), regular re-testing.

3.3 Critical Control Points (CCP)

Critical Control Point	Control Index	Control Requirement
Raw Material Pretreatment	Freshness, microbes, pesticide residues	No rot, no pesticide residues, qualified total plate count
Enzymatic Hydrolysis	Temperature, time, enzyme dosage	45–50°C, 1.5–2.5 h, proportional enzyme addition, qualified extraction rate
Fermentation	Temperature, pH, alcohol content	Yeast: 18–23°C; Acetic acid bacteria: 28–33°C; pH 2.8–3.0; alcohol 5.5–8.7° vol
Ultrasonic Extraction	Temperature, power, time	40–45°C, 200–300 W, 1–2 h per cycle; activity retention ≥95%
Membrane Separation	Pressure, temperature, pore size	Controlled per stage; regular membrane cleaning, no blockage
Freeze-Drying / Drying	Moisture, temperature, vacuum	Moisture ≤6.0%; freeze-drying: -40 to -35°C, 10–30 Pa
Finished Product Testing	Active ingredients, microbes, heavy metals	Comply with all specification requirements

3.4 Process Quality Control Nodes

- **Raw Material QC**: Qualified raw materials, no rot, no pesticide residues, qualified microbes.
- **Enzymolysis QC**: Controlled temperature and time for sufficient cell wall breakage and high extraction rate.
- **Fermentation QC**: Strict temperature and pH control for full fermentation and improved bioavailability.
- **Extraction QC**: Low temperature to avoid anthocyanin degradation and ensure thorough extraction.
- **Membrane Separation QC**: Controlled pressure and temperature for effective impurity removal and high purity.
- **Drying QC**: Moisture ≤6.0% to maximize activity retention and prevent moisture absorption.
- **Finished Product QC**: Full-index testing; non-conforming products not warehoused.
- **Warehousing QC**: Regular re-testing to ensure stable quality within 24-month shelf life.

3.5 Manufacturing Flow Chart

