Operational Guidelines for the Application and Addition of Ginseng Extract

I. Scope and Normative References

This guideline specifies the raw material access, addition dosage, process control, quality requirements, safety and compliance points of ginseng extract in four major fields: health food, general food, cosmetics and pharmaceuticals. It is applicable to formula R&D, production operation and quality control of manufacturing enterprises.

Normative References:

Food Safety Law of the People's Republic of China;

Health Food Raw Material Catalogue – Ginseng (2023);

Announcement No. 18 of 2024 issued by the State Administration for Market Regulation (SAMR);

Safety Technical Specifications for Cosmetics (2015 Edition);

Pharmacopoeia of the People's Republic of China 2020 Edition Volume IV;

Technical Requirements for the Registration of New Cosmetic Raw Materials by NMPA.

II. Basic Raw Material and Grading Requirements

(I) Definition and Core Components

Ginseng extract refers to the powder / extract obtained from ginseng roots / stems and leaves via water or ethanol extraction, concentration and drying. Its core active ingredients are total ginsenosides (GPS) and ginseng polysaccharides, along with volatile oil, amino acids, etc.

(II) Raw Material Grading

Grade	Total Ginsenosides (calculated as Re)	Application Fields	Remarks
Food Grade	≥3.0%	General food, beverages, candies	Water-soluble preferred
Health Care Grade	≥8.0%	Health food (registration / filing)	Complies with SAMR Announcement No. 18 of 2024
Cosmetic Grade	≥10.0%	Leave-on / rinse-off cosmetics	No heavy metal or microbial risks
Pharmaceutical Grade	≥15.0% (or quantified index ingredients)	Pharmaceuticals, clinical preparations	In accordance with pharmacopoeia and drug registration standards

(III) Key Indicators for Raw Material Acceptance

- **Organoleptic**: Powder is yellowish-white to light brown, odorless; extract is brown, uniform without stratification.
- **Physicochemical**: Moisture ≤8.0%; Ash ≤5.0%; Heavy metals (Pb≤1.0 mg/kg, Cd≤0.3 mg/kg); Pesticide residues comply with national food safety standards.
- **Microbiological**:

Food / health care grade: Total plate count ≤10^4 CFU/g, molds & yeasts ≤100 CFU/g; *Salmonella* and *Staphylococcus aureus* shall not be detected.

Cosmetic grade: Implemented in accordance with *Safety Technical Specifications for Cosmetics*.

- **Marker Components**: Total ginsenosides or designated monomers (e.g., Rg1, Re, Rb1) shall be tested batch by batch.

III. Specifications for Addition in Various Fields

(I) Health Food Field

1. **Access and Efficacy Positioning**
    - Legal Basis: *Health Food Raw Material Catalogue – Ginseng*; *Technical Requirements for Filing Products of Health Food Raw Materials Ginseng, American Ginseng and Ganoderma Lucidum* (2024 Edition, implemented May 1, 2024) issued by SAMR.

- Allowed claimed efficacy: Enhancing immunity, relieving physical fatigue, improving sleep, anti-oxidation (subject to registration / filing approval).
- Key Restriction: Ginseng raw materials included in the catalogue shall not be used in general food production (SAMR).

2. **Addition Dosage and Conversion**
   - Recommended daily intake (as ginseng extract): 100–500 mg/day (as labeled on finished products).
   - Formula Conversion Example: Hard capsules (0.5 g/capsule), extract addition 20%–50%, 1–2 capsules per day, ensuring compliance with the above range.
   - Excipient Restriction: Only excipients listed in the annex of SAMR Announcement No. 18 of 2024 (e.g., maltodextrin, lactose, magnesium stearate) are allowed.
3. **Key Production Processes**
   - Mixing: Solid preparations adopt the method of equal-volume increment; mixing uniformity (total ginsenosides RSD ≤5.0%).
   - Granulation: Temperature ≤60℃ for water-containing formulas to avoid saponin degradation.
   - Drying: Vacuum drying ≤60℃; or spray drying with inlet air ≤180℃ and outlet air ≤80℃.
   - Packaging: Nitrogen-filled packaging, light-proof and moisture-proof (RH≤60%, below 25℃).
4. **Labeling and Filing**
   - Mandatory Labeling: Raw material source (cultivated /wild ginseng, with compliant certificates), daily intake, content of marker components (e.g., total ginsenosides), unsuitable 人群.
   - Unsuitable 人群: Infants, pregnant women, lactating women (mandatory labeling).

(II) General Food Field

1. **Scope and Restrictions**
   - Principle: Parts / preparations not included in the general food raw material catalogue shall not be added without authorization; only approved applications in local specialty foods or compliance pilot programs are permitted (SAMR).
   - Common compliant carriers: Beverages, pastries, candies, condiments (subject to local regulatory requirements).

2. **Addition Dosage (Reference)**
    - Beverages: 0.1%–0.5% (as extract, same below), to avoid bitter taste.
    - Candies / Pastries: 0.5%–3.0%, can be compounded with sweeteners to mask bitterness.
    - Functional food (pilot): Implemented in accordance with the dosage approved by local regulatory authorities.
3. **Process Control**
    - Solubility: Water-soluble extracts are preferred; fully dissolve and homogenize in beverages to prevent precipitation.
    - Thermal Stability: Ginsenosides are stable below 100℃; high-temperature sterilization (e.g., 121℃/15 min) requires verification of activity retention rate ⩾85%.
    - Flavor Adjustment: Add honey, citric acid, flavors to improve bitterness; sensory testing is recommended in advance.

(III) Cosmetics Field

1. **Raw Materials and Uses**
    - INCI Name: *Panax Ginseng Root Extract*; new raw materials shall complete NMPA registration (e.g., black ginseng extract, National Cosmetic Raw Material Registration No. 20230042) (NMPA).
    - Main Uses: Anti-oxidation, anti-wrinkle, moisturizing, skin protection (mainly leave-on products) (NMPA).
2. **Addition Dosage (by Product Type)**

Product Type	**Recommended Usage Level**	**Remarks**
Facial leave-on products (cream / serum)	0.5%–2.0%	≤1.0% for sensitive skin formulas
Eye products	0.2%–0.8%	Eye irritation test required
Rinse-off products (cleanser / body wash)	0.1%–0.5%	Balance between cost and efficacy
Hair products (shampoo / conditioner)	0.2%–1.0%	Focus on scalp care

3. **Key Formula and Process**
    - Compatibility: Avoid coexistence with strong acids (pH<3.5) and strong oxidants to prevent saponin degradation; recommended formula pH 5.0–7.0.

- Addition Timing: Dissolve in water phase heated to 60–80℃, add below 45℃ to avoid high-temperature activity damage.
- Stability: Add humectants (glycerin, sodium hyaluronate) and antioxidants (vitamin E, niacinamide) to improve activity retention.
- Safety Assessment: Leave-on products require skin irritation and sensitization tests in accordance with *Safety Technical Specifications for Cosmetics*; eye products require additional eye irritation tests.

(IV) Pharmaceutical Field (Prescription / Over-the-Counter Drugs)

1. **Access and Standards**
   - Basis: *Pharmacopoeia of the People's Republic of China* 2020 Edition Volume IV, drug registration standards; extracts shall meet pharmaceutical-grade requirements and be registered as pharmaceutical excipients.
   - Indications: Cardiovascular diseases, nervous system diseases, hypoimmunity, etc. (subject to drug registration approval).
2. **Dosage and Preparations**
   - Dosage: Specified by drug registration standards, used under medical advice, no self-adjustment.
   - Common Preparations: Tablets, capsules, injections (strict purification required), granules.
   - Process: Comply with drug GMP; key steps (extraction, purification, drying) shall be verified to ensure batch consistency.
3. **Quality Control**
   - Index Components: Quantitative control required (e.g., ginsenoside Rg1≥2.0%, Re≥1.5%, Rb1≥4.0%).
   - Impurity Control: Residual solvents (ethanol ≤0.5%), heavy metals, pesticide residues comply with pharmaceutical standards; sterile preparations meet sterility test requirements.

IV. General Safety and Operational Specifications

(I) Safety Warnings

- Overdose Risk: Long-term high intake may cause insomnia, palpitations, elevated blood pressure; strict addition in accordance with recommended dosage.
- Contraindicated 人群: Infants, pregnant women, lactating women, hypertension patients, insomnia patients (mandatory labeling for

health food /food).

- Cross-allergy: Risk of cross-allergy with Araliaceae plants such as American ginseng and notoginseng; cosmetics shall be labeled.

(II) Production Operation (General GMP)

1. **Raw Material Storage**: Sealed, light-proof, dry (RH≤60%; 2–8℃ refrigeration extends shelf life); shelf life generally 12–24 months (per manufacturer standard).
2. **Weighing**: Use calibrated balance (accuracy ≤0.01 g), double-check, record batch number and weight.
3. **Mixing**: Ensure uniformity; sample after mixing to test marker component uniformity (RSD ≤5.0%).
4. **Cleaning Validation**: Production equipment shall be cleaned to avoid cross-contamination with other raw materials; residue ≤10 ppm.
5. **Retention Samples**: Retain samples of each batch of raw materials and finished products for 6 months after shelf life for traceability.

(III) Testing and Release

- Raw Material Release: Test organoleptic, physicochemical, microbiological and marker components; use only after meeting grading standards.
- Finished Product Release: Test in accordance with field standards; health food requires efficacy component test report, cosmetics requires safety assessment report, pharmaceuticals requires drug inspection report.

V. Compliance and Traceability Management

1. **Raw Material Traceability**: Obtain raw material origin certificates, harvest time, extraction process and test reports when purchasing ginseng extract to ensure legal sources.
2. **Label Compliance**: Labels in all fields shall comply with corresponding regulations; no false efficacy claims (e.g., cosmetics shall not claim "disease treatment").
3. **Record Management**: Retain formula sheets, production records, test reports, sales records for at least 2 years after shelf life (pharmaceuticals in accordance with GMP).
4. **Regulatory Updates**: Monitor the latest announcements of SAMR and NMPA, adjust formulas and processes timely (e.g., update of

health food excipient catalogue).

VI. Appendix (Common Reference Tables)

Appendix A: Quick Reference Table of Addition Dosage in Various Fields

Field	Product Type	Extract Addition	Daily Intake (Health Food)
Health Food	Capsules / Tablets	20%–50%	100–500 mg
General Food	Beverages	0.1%–0.5%	-
Cosmetics	Facial Serum	0.5%–2.0%	-
Pharmaceuticals	Tablets / Capsules	As per registration standard	As directed by a physician

Appendix B: List of Key Regulations

1. SAMR Announcement No. 18 of 2024 (Technical Requirements for Health Food Raw Materials)
2. *Health Food Raw Material Catalogue – Ginseng* (2023)
3. *Safety Technical Specifications for Cosmetics* (2015 Edition)
4. *Pharmacopoeia of the People's Republic of China* 2020 Edition Volume IV
5. NMPA Measures for the Administration of Registration of New Cosmetic Raw Materials