Operating Guidelines for Application Fields and Addition Methods of Kudzu Extract

I. Preface

Based on the physicochemical properties, stability rules and application scenarios of Kudzu Extract (Pueraria Lobata Extract), this guideline standardizes the addition principles, processes, dosages, operation key points and quality control in five major fields: pharmaceutical and health care products, health food, functional food, special dietary foods and cosmetics, providing a standardized basis for large-scale production, product research and development, and practical operation.

1.1 Basic Characteristics of Kudzu Extract

- **Form**: Light yellow to brownish-yellow fine powder (conventional extract), microencapsulated dosage form (stabilized modification), water-soluble concentrate (liquid extract).
- **Solubility**: Conventional powder is readily soluble in warm water, slightly soluble in cold water, and hardly soluble in organic solvents such as oils and ethanol; microencapsulated dosage form dissolves rapidly in cold water, suitable for various aqueous systems; concentrate can be directly dissolved in aqueous phase without additional solubilization.
- **Stability**: Sensitive to high temperature (easy inactivation by prolonged heating >60℃) and strong acid/alkali; the activity is most stable at pH 5.0–7.0; microencapsulation can significantly improve heat, acid and alkali resistance, and reduce the loss of puerarin and total isoflavones; avoid long-term contact with strong oxidants and metal ions.
- **Core Activities**: Protecting cardiovascular and cerebrovascular systems, regulating glucose and lipid metabolism, alleviating alcohol intoxication and protecting the liver, anti-oxidation and anti-inflammation, bidirectionally regulating endocrine. After deodorization treatment, it has no strong bitter and astringent taste, moderate palatability, high safety and mild efficacy.

1.2 General Addition Principles

1. **Dosage Form Matching**

For water-soluble systems (beverages, oral liquids, aqueous phases of skin care products), microencapsulated powder or concentrate is preferred; for solid systems (baking, powders, tablets), conventional powder or microcapsules are selected to ensure uniform dispersion without caking, delamination or spots.

2. **Temperature Control**

Conventional addition temperature ≤60℃. For high-temperature processes (baking, high-temperature sterilization, extrusion and expansion), microencapsulated dosage form is preferred, or low-temperature supplementation is adopted at the later stage of the process to maximize the retention of puerarin and total isoflavone activities and prevent efficacy loss.

3. **pH Adaptation**

Addition in neutral to weakly acidic systems with pH 5.0–7.0 is preferred; stability pre-experiments shall be conducted in advance for strong acid (pH<4.0) and strong alkali (pH>8.0) systems, and buffers shall be added to adjust pH if necessary to maintain the stability of active ingredients.

4. **Compatibility Contraindications**

Avoid direct mixing with strong oxidants (hydrogen peroxide, potassium permanganate) and high-concentration alkaline substances; discoloration and inactivation are prone to occur in contact with metal ions such as iron and copper, so stainless steel or food-grade plastic equipment shall be used.

5. **Uniformity Control**

Powdered extract shall be sieved through 80–120 mesh and then pre-mixed step by step. Direct large-scale feeding is prohibited to prevent excessively high local concentration that affects product taste, appearance and efficacy uniformity.

6. **Quality Traceability**

Use extracts conforming to standards such as *Chinese Pharmacopoeia* 2020 Edition, GB 2760, *Safety and Technical Standards for Cosmetics* (2015 Edition) and GB 29922. Select raw materials of corresponding grades according to application scenarios, and keep batch inspection reports (contents of puerarin and total isoflavones, moisture, microorganisms, heavy metals, pesticide residues).

II. Operating Guidelines for Addition in Functional Food Field

2.1 Applicable Categories and Core Functions

- **Health Beverages (anti-alcoholic plant beverages, solid beverages, meal replacement beverages)**: Alleviate alcohol intoxication, protect the liver and nourish the stomach, stabilize blood glucose, suitable for drinking populations, blood sugar control populations and sub-healthy populations.
- **Baked Staple Foods (whole wheat bread, pastries, meal replacement bars)**: Reduce the GI value of staple foods, delay sugar absorption, provide mild nourishment, and create low-GI healthy staple foods.
- **Leisure Snacks (compressed tablets, jelly)**: Portable health preservation, relieve hangover, daily liver protection, in line with fast-paced life, suitable for workplace entertainment populations.

2.2 Dosage Form Selection and Addition Methods

(1) Conventional Kudzu Extract Powder (total isoflavones ≥20%, puerarin ≥5%)

Application: Baked food, solid beverages, rice and flour products, ordinary snacks, suitable for medium and low functional demand scenarios with controllable costs.

Addition Methods:

- **Solid systems (baking, solid beverages)**: Pre-mix with flour, maltodextrin, oat flour and other powder raw materials (sieved through 80–120 mesh) to ensure no caking, then add to the formula and stir evenly to ensure dispersibility.
- **Liquid systems (beverages, sauces)**: Dissolve with warm water at 40–60℃ at a solid-liquid ratio of 1:5–1:10, stir for 20–30 minutes until completely dispersed, filter to remove impurities, then slowly add to the system and stir continuously for 10–15 minutes until uniform.
- **Process nodes**: Dough mixing stage for baking, later stage of beverage preparation; avoid prolonged high-temperature baking, baking temperature ≤180℃, duration ≤25 minutes.

Reference Dosage: 0.5%–0.7g/100g for baked food; 0.10%–0.15% for plant beverages; 1%–3% for solid beverages; 100–200mg per tablet for compressed

tablets.

(2) Microencapsulated Kudzu Extract (embedding rate ≥90%)

Application: High-temperature process foods (high-temperature sterilized beverages, baked food), instant beverages, scenarios requiring improved stability and dispersibility of active ingredients, suitable for high-end functional food.

Addition Methods:

- **Beverages/oral liquids**: Directly add to aqueous phase and stir for 10–15 minutes without additional solubilization; resistant to short-time sterilization at 85℃ (≤15 minutes), active ingredient retention rate ≥85%.
- **Baked food**: Pre-mix with powder materials (temperature ≤60℃), control the whole process temperature ≤70℃ to reduce damage to active ingredients by high temperature.

Reference Dosage: 0.1%–0.8% for functional beverages; 0.4%–0.6% for baked food, and the dosage can be reduced by 10%–20% compared with conventional powder.

(3) Kudzu Extract Concentrate

Application: Liquid beverages, oral liquids, sauces, scenarios requiring rapid dissolution and simplified processes, suitable for large-scale production.

Addition Methods: Directly add to aqueous phase or sauce system, stir for 10–15 minutes until uniform; can be added synchronously with sweeteners and acidity regulators, adjust pH to 5.0–7.0 to improve stability.

Reference Dosage: 0.2%–1.5% for beverages; 0.5%–3% for oral liquids.

2.3 Operation Key Points and Quality Control

1. **Temperature Control**: Conventional addition temperature ≤60℃; microencapsulated dosage form is preferred for high-temperature processes; avoid prolonged high-temperature cooking and baking to prevent inactivation of active ingredients.
2. **Uniformity**: Powder shall be sieved and pre-mixed, and liquid systems shall be fully stirred to avoid excessively high local concentration and ensure consistent efficacy of each product.
3. **Compound Synergy**: Compound with Hovenia dulcis, Poria cocos and Licorice to enhance anti-alcoholic and liver-protective effects; compound with

dietary fiber and whole wheat flour to improve blood sugar and lipid control effects.

4. **Taste Optimization**: Compound a small amount of sweeteners and fruit flavor agents at high addition levels to cover slight bitterness and astringency, improve palatability without affecting product flavor.
5. **Compliance**: Strictly comply with GB 2760; as a homologous material of medicine and food, Kudzu Extract shall be used appropriately according to production needs; functional addition shall comply with relevant regulations, and the content of active ingredients shall be clearly labeled.

III. Operating Guidelines for Addition in Health Food Field

3.1 Applicable Categories and Core Functions

- **Health Care Products (tablets, capsules, powders)**: Protect cardiovascular and cerebrovascular systems, stabilize blood pressure, regulate blood lipids, suitable for middle-aged and elderly people, sub-healthy populations with three highs.
- **Liver-Protective Health Products (compressed tablets, oral liquids)**: Alleviate alcohol intoxication, repair liver cells, reduce transaminase, suitable for entertainment and staying-up late populations.
- **Female Conditioning Products (oral liquids, capsules)**: Regulate endocrine, relieve menopausal discomfort, soothe nerves and improve sleep, suitable for perimenopausal women.

3.2 Dosage Form Selection and Addition Methods

(1) Health Food Grade Kudzu Extract Powder (total isoflavones ≥30%, puerarin ≥8%)

Application: Capsules, tablets, powders, granules, suitable for conventional health food with stable activity and high cost performance.

Addition Methods:

- **Capsules/tablets**: Mix with microcrystalline cellulose, lactose and magnesium stearate, adopt dry/wet granulation (granulation temperature ≤50℃), tableting or capsule filling, with mixing uniformity conforming to clean production specifications.

- **Powders/granules**: Pre-mix by equal incremental method, sieve through 100 mesh to ensure no caking and delamination, operate at room temperature throughout the process.
- **Process nodes**: Preparation mixing stage; avoid high temperature and strong light, operate in clean environment to prevent pollution.

Reference Dosage: 300mg per capsule; 200–250mg per tablet; 100–300mg per bag for powders; 150mg per branch for oral liquids.

(2) Water-Soluble Kudzu Extract Concentrate

Application: Oral liquids, beverages, scenarios requiring rapid dissolution and high activity, suitable for liquid dosage form health products.

Addition Methods: Dissolve in warm water at 40–50℃, add sweeteners and stabilizers, adjust pH to 5.0–7.0, aseptically filter and fill to ensure sterility.

Reference Dosage: Daily intake of 10–20mL for oral liquids, convert the addition amount according to product specifications.

3.3 Operation Key Points and Quality Control

1. **Clean Production**: Maintain clean production environment with special equipment to avoid cross-contamination; operators strictly implement hygiene specifications.
2. **Stability**: Finished products shall be stored in a light-shielded, sealed and cool place; shelf life ≥24 months, and the content of active ingredients shall be tested regularly.
3. **Content Control**: Test the contents of puerarin and total isoflavones for each batch with deviation ≤±5%; test heavy metals, microorganisms and solvent residues to meet health food standards.
4. **Safety**: Clearly specify inappropriate populations (infants, pregnant women, lactating women), and label applicable populations, consumption dosage and precautions.
5. **Efficacy Verification**: Health products shall complete relevant tests to ensure efficacy meets standards and comply with health food filing and registration requirements.

IV. Operating Guidelines for Addition in Pharmaceutical Field

4.1 Applicable Categories and Core Functions

- **Pharmaceutical Preparations (capsules, tablets)**: Adjuvant intervention for chronic cardiovascular and cerebrovascular diseases, repair of chemical liver injury, regulation of impaired glucose tolerance.
- **Clinical Adjuvant Products**: Stabilize blood pressure and lipids, relieve myocardial ischemia, improve microcirculation, assist western medicine treatment.

4.2 Dosage Form Selection and Addition Methods

(1) Pharmaceutical Grade Kudzu Extract Powder (total isoflavones ≥30%, puerarin ≥8%; high-activity type: total isoflavones ≥60%, puerarin ≥40%)

Application: Pharmaceutical capsules and tablets with high purity, few impurities and stable activity, conforming to pharmacopoeia standards.

Addition Methods:

- Mix step by step with pharmaceutical excipients, adopt wet or dry granulation (granulation temperature ≤50℃), tableting and capsule filling, complying with GMP specifications throughout the process.
- **Process nodes**: Preparation mixing and granulation stages; low temperature, light avoidance and aseptic operation throughout the process to eliminate pollution.

Reference Dosage: 300mg per pharmaceutical capsule, twice a day, 1 capsule each time; 250mg per liver-protective tablet, 2–3 times a day, 1–2 tablets each time.

4.3 Operation Key Points and Quality Control

1. **GMP Specifications**: Produce in GMP clean workshops throughout the process, equipment sterilization treatment, operators hold certificates to post, and strictly implement aseptic operation.
2. **Stringent Quality Control**: Heavy metals ≤1ppm, microorganisms ≤10CFU/g, no pesticide residues and solvent residues, complying with *Chinese Pharmacopoeia* 2020 Edition standards.
3. **Stability Control**: Control batch activity fluctuation ≤3%, store finished products in sealed and light-shielded conditions to prevent active degradation.
4. **Clinical Adaptation**: No western medicine or hormones added in the formula, mildly adapted to the physique of chronic disease patients, and

coordinated with western medicine for synergistic conditioning.

V. Operating Guidelines for Addition in Special Dietary Food Field

5.1 Applicable Categories and Core Functions

- **Special dietary powder for the elderly, special diet for three-high populations**: Stabilize sugar and lipids, protect cardiovascular and cerebrovascular systems, supplement nutrition, suitable for the elderly with weak gastrointestinal tract and pre-chronic disease populations.
- **Special dietary supplements**: Mildly regulate metabolism, reduce physical burden, balance nutrition and health care.

5.2 Dosage Form Selection and Addition Methods

(1) Special Dietary Grade Kudzu Extract (total isoflavones ≥25%, puerarin ≥7%)

Application: Special dietary powder, special meal replacements, nutritional supplements, complying with GB 29922 special dietary standards.

Addition Methods:

- Pre-mix with tartary buckwheat, Chinese yam, coix seed, multivitamins, dietary fiber and other raw materials, sieve through 100 mesh and stir evenly.
- Make independent small packages, ready for brewing with warm water; operate at room temperature throughout the process to avoid high temperature damage to nutrition and active ingredients.

Reference Dosage: 120mg per bag (20g) for special dietary powder, addition proportion 0.5%–1.0%.

5.3 Operation Key Points and Quality Control

1. **Compliance**: Strictly comply with GB 29922 standards; no western medicine, sucrose, pigments or flavors, suitable for the physique of special populations.
2. **Easy Digestion and Absorption**: Fine powder texture without increasing gastrointestinal burden, suitable for long-term consumption by the elderly and infirm populations.

3. **Balanced Nutrition**: Balance conditioning efficacy and nutritional supplementation, avoid single nourishment and prevent malnutrition.

VI. Operating Guidelines for Addition in Cosmetics and External Application Field

6.1 Applicable Categories and Core Functions

Skin Care Products (essence, emulsion, cream, facial mask):

Anti-oxidation, anti-aging, brighten skin tone, soothe sensitivity, repair skin barrier.

Washing and Care Products: Mild maintenance, soothe skin, suitable for sensitive skin, early aging skin and staying-up late skin.

6.2 Dosage Form Selection and Addition Methods

(1) Cosmetic Grade Kudzu Extract (total isoflavones ≥25%, puerarin ≥6%, hypoallergenic refined type)

Application: Creams, emulsions, essences, facial masks, toners, mild and non-irritating, suitable for all skin types.

Addition Methods:

- **Oil phase systems (creams, emulsions)**: After oil phase preparation, cool to 40–45℃, add extract dissolved in aqueous phase, homogenize for 3–5 minutes (rotating speed 2000–3000r/min) to ensure uniform dispersion.
- **Aqueous phase systems (essences, toners, facial masks)**: Pre-dissolve with glycerin and propylene glycol, add to aqueous phase (≤40℃), stir for 20–30 minutes until uniform.
- **Process nodes**: Late emulsification stage, batching stage; avoid high temperature (>50℃) causing inactivation of active ingredients, pH controlled at 5.5–6.5.

Reference Dosage: 1.0%–3.0% for essences; 0.5%–2.0% for emulsions and creams; 0.3%–1.0% for facial masks and toners.

6.3 Operation Key Points and Quality Control

1. **Hypoallergenic Safety**: Select refined deodorized extract with no impurities or heavy metal pollution; addition amount ≤2% for sensitive skin

products, and skin irritation test shall be conducted in advance.

2. **Compatibility Safety**: Avoid direct mixing with high-concentration fruit acids and strong oxidants; compound with sodium hyaluronate and panthenol for synergistic moisturizing and repair.
3. **Stability**: Add a small amount of antioxidants, store products in light-shielded and sealed conditions to prevent inactivation of active ingredients and ensure stable efficacy within shelf life.
4. **Compliance**: Comply with *Safety and Technical Standards for Cosmetics*, test heavy metals and microorganisms, no prohibited ingredients, and standardly label ingredient information.

VII. Storage and Transportation Specifications

1. **Storage Conditions**

Store in a sealed, light-shielded, cool and dry place at temperature ≤25℃ and humidity ≤60%; avoid high temperature, high humidity and direct strong light. Shelf life of conventional powder ≥24 months, shelf life of concentrate ≥12 months.

2. **Packaging Requirements**

Powder is packed in aluminum foil bags and cardboard drums lined with polyethylene bags for moisture and leakage prevention; concentrate is packed in sealed plastic drums or aluminum cans; all packages are labeled with product name, specification, active content, batch number, production date and shelf life.

3. **Transportation Requirements**

Avoid exposure, rain and high temperature; prohibit mixed transportation with toxic and harmful substances, strong oxidants and alkaline substances, keep ventilation and prevent damage and leakage.

4. **Batch Management**

Implement the first-in first-out principle, keep usage records and inspection reports for each batch to facilitate quality traceability.

VIII. Quality Inspection and Abnormality Handling

8.1 Mandatory Inspection Items

- **Activity Inspection**: Contents of puerarin and total isoflavones, tested in accordance with industry standards and pharmacopoeia methods to ensure compliance.
- **Physicochemical Indicators**: Moisture, ash, pH, solubility, heavy metals (lead, arsenic, mercury, cadmium), complying with corresponding national standards.
- **Microbiological Indicators**: Total bacterial count, molds, yeasts, pathogenic bacteria, complying with food, pharmaceutical and cosmetic grade standards.
- **Stability**: Accelerated test to detect active retention rate, with retention rate ≥80% within shelf life.

8.2 Abnormality Handling

1. **Inactivation of Active Ingredients**: Causes (high temperature, strong acid/alkali, contact with contraindicated substances); Treatments (control temperature ≤60℃, adjust pH to 5.0–7.0, replace with microencapsulated dosage form, avoid incompatible compatibility).
2. **Caking and Uneven Dispersion**: Causes (moisture absorption, unsieved, insufficient stirring); Treatments (sealed moisture protection, sieving before addition, step-by-step pre-mixing, prolong stirring time).
3. **Product Discoloration**: Causes (contact with metal ions, photo-oxidation); Treatments (switch to stainless steel equipment, light-shielded storage, add antioxidants).
4. **Uneven Efficacy**: Causes (uneven feeding, insufficient mixing); Treatments (strict step-by-step dilution, standardized stirring process).
5. **Bitter and Astringent Taste**: Causes (excessively high addition amount, non-deodorized); Treatments (select deodorized raw materials, control addition amount, compound sweeteners for masking).

IX. Supplementary Provisions

1. This guideline is a standardized operation specification. Enterprises can optimize and adjust the addition amount and process parameters according to their own product characteristics, process equipment, regulatory requirements, combined with laboratory and pilot tests to ensure product quality and efficacy.
2. The optimal range of Kudzu Extract addition amount shall be determined through laboratory tests, and large-scale production shall be carried out after verifying stability and efficacy via pilot tests to avoid batch quality problems and reduce production costs.
3. Matters not covered in this guideline shall be implemented with reference to relevant national standards, regulations and product specifications of Kudzu Extract manufacturers.
4. This guideline is applicable to teaching operations, enterprise production guidance and product research and development reference, with content conforming to industry consensus and national standard requirements.