

Berberine Hydrochloride Dietary Supplement Formulation Application Manual from HiSiaddi

Applicable to: Health food, cross-border dietary supplements, tablets / capsules / powder / oral liquid

Preface

This manual takes naturally extracted Berberine Hydrochloride (Berberine HCl, 97%/98% HPLC) from *Coptis chinensis* and *Phellodendron chinensis* as core raw material, covering compliant dosage, classic compound formulas, dosage form processes, stability control, label compliance, population adaptation, contraindications and safety instructions. It meets domestic blue hat health food standards, US DSHEA dietary supplement standards and EU Food Supplement export standards.

CAS No.: 633-65-8; Active Substance: Berberine Hydrochloride Dihydrate

Part 1: Basic Raw Material Standards (Precondition for Formula Design)

1.1 Raw Material Quality Control Indicators for Dietary Supplements

1. Active Content: 97.0%~98.5% HPLC
2. Loss on Drying: $\leq 12.0\%$
3. Heavy Metals: Pb<10ppm, As<2ppm, Cd<0.5ppm, Hg<0.1ppm
4. Microorganisms: Salmonella and Escherichia coli absent; Total aerobic bacteria $\leq 1000\text{CFU/g}$
5. Residual Solvents: Methanol and Dichloromethane meet ICH Q3C limits
6. Impurity Control: Palmatine $\leq 1.0\%$, Jatrorrhizine $\leq 1.0\%$, Total alkaloid impurity peaks $\leq 2.0\%$

1.2 Safe Recommended Dosage for Dietary Supplements (General Industry Compliance Range)

Daily Basic Maintenance (Intestinal and Metabolic Stabilization)

Single dose: 250mg Berberine Extract (equivalent to 242~246mg pure berberine)

Total daily dosage: 500mg (divided into 2 doses after breakfast and dinner)

Enhanced Regulation Formula (Blood Glucose, Blood Lipid & Weight Management Compound Products)

Single dose: 500mg extract, maximum 1000mg per day split into 2 servings

Safety Reminder: Daily intake of dietary supplements shall not exceed 1000mg extract; after 3 consecutive months of consumption, stop taking for 7 days.

1.3 Influence of Raw Material Physicochemical Properties on Formulation

1. Extremely bitter yellow powder, easy to stain and irritate gastrointestinal tract; Must be taken after meals; Formulas need embedding excipients and sustained-release carriers to reduce irritation
2. Prone to oxidation and discoloration under strong light and high humidity; Finished products require light-proof and moisture-proof packaging
3. Alkaloid property: Chelates with iron, calcium, zinc minerals; Intake shall be separated by 2 hours or adopt layered separation in formula

Part 2: Standardized Formulas for Four Mainstream Dosage Forms (Mass Production Grade)

Dosage Form 1: Hard Capsule (Size 0 Capsule, Most Popular Cross-border Dietary Product)

Formula 1-1 Basic Intestinal Maintenance Capsule (Single-Ingredient, Net Filling 350mg per capsule)

表格

Raw Material	Dosage per Capsule	Function Description
98% Berberine Hydrochloride Extract	250mg	Core antibacterial agent, regulates intestinal flora
MCC 102 Microcrystalline Cellulose	85mg	Filler, improves flowability
Magnesium Stearate	3mg	Flow aid, anti-sticking during molding
Silicon Dioxide	2mg	Anti-caking and moisture absorption

Pure berberine content per capsule: 245mg; 2 capsules daily after morning and evening meals

Formula 1-2 Metabolic Enhancement Compound Capsule (Popular Blood Glucose & Lipid Regulating Product, 450mg per capsule)

表格

Raw Material	Dosage per 2 Capsules	Functional Synergy Logic
98% Berberine Extract	500mg	Improves insulin sensitivity, regulates blood lipid

Raw Material	Dosage per 2 Capsules	Functional Synergy Logic
White Kidney Bean Extract (α -Amylase Inhibitor)	200mg	Blocks carbohydrate absorption, matches weight management
Cinnamon Extract (30:1)	100mg	Stabilizes postprandial blood glucose synergistically
Chromium Yeast (200 μ g Chromium)	200 μ g	Assists glucose metabolism; avoid high-dose mixing with berberine, adopt layered filling
MCC, Silicon Dioxide, Magnesium Stearate	Appropriate amount	Molding excipients

Key Process Points for Capsules

1. Premix berberine powder with silicon dioxide to reduce static electricity and moisture absorption
2. Separately granulate chromium, zinc minerals and fill in layers to prevent chelation and efficacy loss
3. Adopt light-proof brown gelatin capsules or plant HPMC capsules to isolate light and avoid discoloration

Dosage Form 2: Compressed Candy / Health Food Tablets (Two Types: Sustained-Release & Conventional)

Formula 2-1 Conventional Quick-Dissolve Tablet (600mg per tablet)

Berberine Extract 300mg + MCC 220mg + Xylitol 50mg + Magnesium Stearate 3mg + Citric Acid 27mg

Citric acid masks bitter taste, suitable for domestic offline channels; Do not overdose citric acid to prevent berberine precipitation and discoloration

Formula 2-2 Sustained-Release Gentle Gastrointestinal Tablet (Reduces Side Effects of Diarrhea and Nausea)

Sustained-release carriers: HPMC K4M, Sodium Alginate

Formula: Berberine 300mg + HPMC 80mg + Lactose 180mg + Sodium Alginate 40mg

Advantages: Slow release of alkaloids, reduces instantaneous intestinal irritation, suitable for long-term consumption by people with sensitive stomachs

Dosage Form 3: Compound Powder (Strip Sachet Beverage Powder)

Intestinal Conditioning Powder (5g per sachet)

Berberine Extract 500mg, FOS Fructooligosaccharide 2000mg, Inulin 1500mg, Strawberry Fruit Powder 900mg, Erythritol 100mg
Suitable for middle-aged and elderly people who have difficulty swallowing capsules; Note: Mix with warm water only, boiling water will damage partial activity and deepen bitter taste

Dosage Form 4: Oral Liquid (High-End Drops, Bottled Beverages)

1. Solvent System: Glycerin + Purified Water + Sodium Citrate Buffer (Stable pH range: 4.5~5.0)
2. Basic Formula (100mL Finished Product): Berberine Extract 2g, Glycerin 30g, Sodium Citrate 0.5g, Potassium Sorbate 0.1g, Appropriate Edible Flavor
3. Key Control: pH shall not be lower than 4 to avoid berberine crystal precipitation; Full light-proof filling, adopt brown PET bottles

Part 3: Eight Functional Compound Formulas (Differentiated Dietary Supplement Formulas)

Formula 1: Intestinal Flora Balance Formula (Relieves Diarrhea, Improves Chronic Enteritis and Irritable Bowel Syndrome)

Core Compound: Berberine + Probiotics (Bifidobacterium, Lactobacillus acidophilus) + Prebiotic FOS

Logic: Berberine inhibits harmful pathogenic bacteria, probiotics replenish beneficial flora; Probiotics shall be independently embedded and granulated during production to avoid inactivation by berberine

Formula 2: Postprandial Blood Glucose Management Compound (Overseas Best-Selling Blood Sugar Dietary Supplement)

Berberine + Cinnamon Extract + Bitter Melon Polypeptide + Chromium Yeast
Suitable for people with high postprandial blood glucose and excessive carbohydrate intake; Label shall indicate it cannot replace hypoglycemic drugs

Formula 3: Blood Lipid Regulating Formula (Reduces Triglycerides and Cholesterol)

Berberine + Red Yeast Rice Extract (Monacolin K) + Coenzyme Q10

Note: Liver function monitoring is required for simultaneous intake of red yeast rice and berberine; Not recommended for people with abnormal liver function

Formula 4: Weight Loss & Fat Management Formula

Berberine + White Kidney Bean Extract + Green Coffee Extract + CLA
Conjugated Linoleic Acid

Mechanism: Reduces fat accumulation, inhibits sugar absorption, improves metabolic syndrome

Formula 5: Internal Skin Oil Control & Acne Treatment Beauty Supplement

Berberine + Zinc Gluconate + Dandelion Extract

Oral antibacterial effect improves inflammatory acne caused by internal inflammation; Zinc intake shall be separated from berberine by 1 hour

Formula 6: Liver Protection & Anti-Inflammation Formula

Berberine + Silymarin Milk Thistle Extract + Curcumin

Reduces chronic inflammation, assists hepatocyte protection; Suitable for people who stay up late and consume high-fat diets

Formula 7: Middle-Aged and Elderly Cardiovascular Maintenance Formula

Berberine + Omega3 Fish Oil + Hawthorn Extract

Synergistically regulates blood lipid and alleviates chronic vascular inflammation

Formula 8: Oral Mucosa Maintenance Powder (Dual Use for Gargling & Oral Administration)

Berberine + Dipotassium Glycyrrhizate + Xylitol, Targets Recurrent Oral Ulcers and Periodontal Inflammation

Part 4: Production Process Control Manual for Formulation

4.1 Core Process for Bitterness Masking

1. Excipient Masking: Xylitol, Erythritol, Citric Acid, Fruit Juice Powder
2. Embedding Process (High-End Products): β -CD Cyclodextrin inclusion of berberine powder, greatly reduces bitter taste and gastrointestinal irritation
3. Sustained-release skeleton tableting to delay instantaneous release of alkaloids in stomach

4.2 Stability Control (Solve Yellowing, Precipitation and Content Decline Problems)

1. Full light-proof production with yellow light workshop lighting
2. Finished product moisture controlled $\leq 5\%$, excipients pre-dried
3. Forbid strong alkaline excipients (such as sodium bicarbonate), which cause berberine decomposition and efficacy loss
4. Standard packaging: Aluminum foil composite film, brown bottles, desiccants, light-proof sealed package

4.3 Incompatible Ingredients (Strictly Forbidden to Mix in Formula)

1. High-concentration calcium, iron, zinc minerals (chelation reduces effective content)
2. Strong alkaline raw materials
3. High tannin plant extracts (Galla Chinensis, Pomegranate Peel, causing precipitation)
4. Unembedded live probiotics (directly killed upon contact)

Part 5: Population Adaptation, Consumption Suggestions and Safety Warnings (Mandatory Label Content)

5.1 Suitable Populations

- People with greasy diet, frequent takeout and prone to intestinal diarrhea
- Sub-health groups with high postprandial blood glucose and blood lipid
- People with chronic internal inflammation and recurrent inflammatory acne
- Adults with slow metabolism and weight management demands

5.2 Unsuitable Populations (Must Be Printed on Outer Packaging)

1. Pregnant and lactating women
2. Children and adolescents under 18 years old (Not recommended)
3. Hypoglycemic patients and people taking oral hypoglycemic western medicines
4. People with liver damage and jaundice
5. People with abnormal coagulation function and taking anticoagulant drugs
6. Patients with severe gastric ulcer

5.3 Standard Consumption Suggestion Copy (Universal for Cross-border & Domestic Market)

1-2 times daily, 1 capsule/tablet each time, take with warm water after meals; Stop consumption for 7 days after 3 consecutive months of intake; Forbid empty stomach administration

5.4 Common Adverse Reactions & Formula Mitigation Solutions

1. Nausea, stomach dull pain: Adopt sustained-release formula or β -cyclodextrin embedding
2. Alternating constipation and diarrhea: Reduce single dosage, compound with prebiotics
3. Yellow urine: Normal pigment metabolism, no need to stop consumption; Mark reminder in specification

Part 6: Domestic & Foreign Compliance Label & Regulation Explanation

6.1 China Health Food Specifications

1. Berberine (Berberine Hydrochloride) shall be declared as plant extract raw material; Medical treatment efficacy claims are prohibited
2. Permitted claims: Regulate intestinal flora, assist blood lipid regulation, assist metabolism improvement; Strictly ban medical terms such as hypoglycemic, gastroenteritis treatment, hypotensive

6.2 US FDA DSHEA Dietary Supplement (Export to North America)

1. Classified as Berberine HCl plant extract dietary raw material
2. Disclaimer Statement: This product is not intended to diagnose, treat, cure or prevent any disease

6.3 EU Food Supplements

Daily total berberine dosage complies with EU plant raw material limits ($\leq 1000\text{mg}$); COA, TDS and MSDS clearance documents are required for products

Part 7: Finished Product Shelf Life & Storage Specifications

1. Unopened original packaging: Cool, dry environment below 25°C , protected from light, shelf life 24 months
2. After opening: Consume within 3 months, place desiccant, avoid high temperature and humid kitchen environment
3. Forbid refrigeration or freezing: Low temperature causes crystallization of liquid products and moisture softening of tablets

Part 8: Quality Acceptance Standards (Finished Product Factory Inspection Items)

1. Berberine Hydrochloride Content Uniformity ($\text{RSD} \leq 5\%$ for tablets/capsules)
2. Dissolution Rate: Conventional preparations $\geq 80\%$ dissolved within 45min; Sustained-release preparations $\leq 30\%$ released within 2h
3. Microbiological Limits, Heavy Metals, Color Stability Accelerated Test (No obvious yellowing after 30 days at $40^{\circ}\text{C}/\text{RH}75\%$, content decline $< 5\%$ is qualified)