

Full-Scenario FAQ Compilation for Berberine Hydrochloride (Berberine HCl) from HiSiaddi

Target Audiences: Overseas Purchasers, Health Food OEM Factories, Raw Material Salesmen, QA Quality Control; Covers Five Major Segments: Raw Material Selection, Customs Compliance, Formulation Process, Cost & After-Sales Risks

Part 1: High-Frequency Questions Related to Raw Material Source & Purity

1. What are the core differences between *Coptis chinensis*, *Phellodendron chinensis* and *Berberis* root extract? Can they be mixed for export to Europe & US?
 - *Coptis chinensis*: High purity, low pesticide residues & heavy metals, low impurity palmatine/jatrorrhizine, first choice for FDA & EU dietary supplements, 99% customs clearance pass rate
 - *Phellodendron chinensis*: Price approx. 20% lower, fluctuating impurities, easily trigger customs retest in Europe & US, only suitable for low-end Southeast Asian powder products and external use
 - *Berberis* root: Heavy metals easily exceed standards, direct detention and destruction by European and American customs for oral raw materials, strictly forbidden for oral dietary export
1. How to choose between 97% and 98% specifications, what hidden differences come with price gap?
 - 97% Crude Extract: Single recrystallization, total impurities $\leq 2.0\%$, high impurity content, tablets and capsules turn yellow during long-term storage, large fluctuation of content in overseas retests
 - 98% Refined Extract: Double recrystallization, single palmatine/jatrorrhizine $\leq 0.5\%$, stable content, long shelf life, suitable for European & American capsules and oral liquid
 - On the surface 98% grade costs 6–10USD/kg higher, but eliminates overseas retest, rework and return loss, with lower comprehensive cost
1. Some merchants on the market label "natural berberine", will synthetic berberine be mixed in?

Synthetic Berberine Hydrochloride has extremely low price, no plant traceability and no natural impurity spectra; European and American customs and third-party laboratories can directly identify via infrared and impurity spectra. Raw material suppliers must provide medicinal herb traceability sheets and extraction process records for export dietary raw materials

2. Why does raw material content detection fluctuate greatly?
① Unstable alkaloid content of medicinal herb batches; ② Crude extract without secondary purification; ③ Anhydrous content not converted by moisture loss; ④ Liquid chromatography detection method inconsistent with pharmacopoeia standards. Content RSD of formal 98% refined grade $\leq 0.8\%$

Part 2: Customs Clearance & Compliance Document Questions (Most Frequently Asked by Foreign Customers)

1. What full set of documents are required for export to US/EU? Are Chinese reports accepted by customs?
Mandatory full English documents: COA, TDS, MSDS, Certificate of Origin, CNAS English heavy metal/pesticide residue test reports, plant traceability documents; Pure Chinese reports are not accepted by European and American customs, leading to goods detention and retest requirements
2. What is the HS code, tariff rate and available export tax rebate?
HS Code: 2939999099 Other Vegetable Alkaloids and Their Derivatives
Export Tax Rebate Rate: 13%; US Tariff: 0%; EU Base Tariff: 6.5%; ASEAN achieves 0 tariff with FORM E Certificate of Origin
3. Is REACH registration necessarily provided by the factory? Can goods clear EU customs without registration?
Factories can provide REACH pre-registration notification numbers; Importers shall complete notification independently without pre-registration, generating high allocated fees or even goods detention at port
4. What to do if customs random inspection finds heavy metal/pesticide residue non-compliant?
Berberis root and low-quality Phellodendron chinensis raw materials are high-risk categories; Goods will be directly destroyed together with sea freight, port detention fees and customer order compensation;
Solution: Only select 98% refined Coptis chinensis extract for export,

conduct pre-test by domestic third-party laboratory for each batch before shipment

5. Can dietary supplement labels claim hypoglycemic or gastroenteritis treatment efficacy?

Red line of overseas regulations: US DSHEA and EU food supplement regulations ban any medical efficacy claims; Only nutritional descriptions such as metabolism and intestinal health can be marked, with additional disclaimer statements attached

Part 3: Formulation Production & Dosage Form Process Questions (Pain Points of Health Food Factory Customers)

1. Berberine has extremely bitter taste, how to mask bitterness?
Three Solutions: ① Add Xylitol, Citric Acid and Compound Fruit Powder to formula for taste masking; ② β -Cyclodextrin embedded modified raw material to reduce bitter taste from source; ③ Manufacture sustained-release skeleton tablets to reduce instantaneous stomach irritation
2. Why do capsules and tablets turn yellow and bleed color after storage for a period of time?
Core Causes: ① Excess impurities (palmitine) in raw materials; ② Production under strong light in workshop, finished products without light-proof packaging; ③ Excessive moisture in finished products; ④ Contact with alkaline auxiliary materials. Solutions: Select 98% high-purity grade, adopt brown light-proof packaging, pre-dry auxiliary materials to control moisture $\leq 5\%$
3. Can berberine be compounded with probiotics, calcium/zinc/chromium minerals?
 - Probiotics: Berberine kills live bacteria, separate granulation and layered filling isolation are required
 - Calcium, Iron, Zinc, Chromium: Alkaloids easily chelate to reduce effective content; Intake shall be separated by 2 hours or layered feeding in formula
1. How to solve crystal precipitation in oral liquid?
Crude high-impurity raw materials and system pH < 4.0 cause berberine precipitation; Control pH within 4.5–5.0, select low-impurity 98% refined raw materials and match glycerin buffer system
2. How to optimize formula to avoid nausea, diarrhea and stomach stabbing pain after empty stomach intake?

3. Mark post-meal consumption only on product specification; 2. Adopt sustained-release process; 3. Compound with prebiotics and licorice extract to relieve irritation; 4. Reduce single capsule dosage
4. Is yellow urine after consumption a sign of product deterioration or side effects?

Normal phenomenon: Yellow berberine alkaloid is excreted via kidney metabolism with no toxic side effects; Mark reminder in specification in advance for consumers

Part 4: Procurement Cost & Supply Chain Order Questions

1. Why does berberine raw material price fluctuate sharply periodically?
Coptis chinensis has a 4–5 year planting cycle; Production reduction in producing areas, extreme weather, environmental protection production restrictions and stockpiling in Chinese medicinal herb market will push up prices directly; Price fluctuation range of Phellodendron chinensis and Berberis root is relatively smaller
2. Small-batch procurement has high unit cost, how to lower unit price?
Combine orders to reach over 500kg bulk shipment, sign annual price lock framework, full container sea freight to evenly allocate logistics and testing unit costs, cancel 1kg small package procurement
3. Is a middleman quotation much lower than factory price reliable?
Most low quotations from middlemen are crude extracts of Phellodendron chinensis/Berberis root with unstable batches and incomplete documents; Once overseas customs detain goods, middlemen cannot bear cargo loss compensation; Source GMP factories provide more stable after-sales guarantee
4. What are the main hidden costs for overseas procurement?
International sea/air freight, destination port tariff & VAT, local third-party retest fees, allocated REACH compliance cost, detention risk loss, finished product return & rework cost
5. How to stock up to hedge shortage risks during factory peak seasons?
Dual supplier reserve, stock 3-month safety inventory at low price off-season, prioritize cooperation with source factories with self-owned medicinal herb planting bases

Part 5: Safety, Toxicology & Population Contraindication Consultations

1. What is the safe upper limit of daily added dosage?
General standard for dietary supplements: Total daily berberine extract intake shall not exceed 1000mg; Recommend stop consumption for 7

days after 3 consecutive months of intake; Single dose within 500mg split into two post-meal servings

2. Which populations are forbidden to consume dietary supplements containing berberine?

Pregnant women, lactating women, adolescents under 18 years old, hypoglycemic patients, people taking hypoglycemic/anticoagulant drugs, severe gastric ulcer patients, liver function damaged patients

3. Is berberine highly acutely toxic?

Mouse oral LD₅₀ > 1000mg/kg, low acute toxicity; Only high-dose empty stomach intake causes gastrointestinal irritation, no clear carcinogenic or mutagenic data

4. Mandatory storage requirements?

Raw materials and finished products must be stored in cool environment ≤25°C, dry, light-proof and sealed; Keep away from strong alkalis and oxidants; Do not refrigerate liquid formulations to avoid crystallization

Part 6: Quality After-Sales & Common Quality Complaints of QC

1. Why does powder agglomerate upon arrival?

Transportation moisture absorption, damaged packaging, excessive raw material moisture during workshop production; Moisture of qualified raw materials ≤12%, packaging equipped with double PE bags and desiccants inside

2. Is inconsistent color difference between batches normal?

Obvious color difference exists in crude extracts of Berberis root and Phellodendron chinensis; 98% refined Coptis chinensis extract has uniform batch color with minimal chromatic aberration, suitable for overseas brands with strict appearance requirements

3. Why is there inconsistency between COA measured value and finished product test result?

① Raw material loss on drying not converted; ② Different chromatographic conditions adopted by factory and overseas laboratory; ③ Uneven sample sampling; Confirm unified adoption of ChP/USP liquid chromatography testing method before order placement

4. How to prevent microbial exceeding standard?

Control total bacteria ≤1000CFU/g and no pathogenic bacteria before raw material delivery; Ten-thousand-grade purification workshop for production, full sealed and moisture-proof packaging process

Part 7: Exclusive Questions for Export Target Markets

1. Are there special berberine raw material requirements for US Amazon shelf listing?

Must be 98% refined grade extracted from *Coptis chinensis* with full set of English test reports and complete plant traceability; *Phellodendron chinensis*/Berberis root raw materials are not accepted, platform conducts irregular third-party laboratory random inspection

2. Have import rules changed after UK Brexit?

UK implements independent food regulations requiring separate submission of safety assessment documents; VAT declaration rules differ from EU, REACH notification needs separate confirmation

3. Can 97% *Phellodendron chinensis* extract replace *Coptis chinensis* in Southeast Asian market?

Feasible for offline low-price powder products with FORM E tariff exemption; High-end online capsules and cross-border e-commerce platforms still recommend 98% *Coptis chinensis* grade to reduce customer complaints and product removal risks