Berberine Hydrochloride (Berberine Extract) TDS, COA, MSDS Reference Template from HiSiaddi

CAS No.: 633-65-8 | Source: Natural extraction from Coptis chinensis, Phellodendron chinense, Berberis chinensis | Standards: ChP 2025, USP, General Food & Pharmaceutical Grade

Part 1: TDS (Technical Data Sheet)

1. Basic Product Information

表格

Item	Parameter
Chinese Product Name	Berberine Extract (Berberine Hydrochloride)
English Name	Berberine Hydrochloride Extract
Alias	Berberine Hydrochloride
CAS Number	633-65-8
Molecular Formula	$C_{20}H_{18}ClNO_4 \cdot 2H_2O$ (Dihydrate)
Molecular Weight	407.85
Raw Materials for Extraction	Coptis chinensis, Phellodendron chinense, Berberis root
Specifications of Active Ingredient Content	Natural extract ≥97.0% (HPLC); Refined grade ≥98.0%
Appearance	Bright yellow crystalline fine powder, odorless, extremely bitter taste
Solubility	Soluble in boiling water; slightly soluble in cold water and methanol; insoluble in ethanol, ether, chloroform
Melting Point	204~206℃ (Decomposition)
Bulk Density	≥0.30 g/mL
Particle Size	Fully pass through 80-mesh sieve
Moisture / Loss on Drying	≤12.0%
Residue on Ignition	≤0.20%
Shelf Life	24 months in original unopened packaging
Storage Conditions	Sealed, cool, dry and dark environment, temperature ≤25℃, keep away from oxidants and strong alkalis
Packaging Specifications	25kg fiber drum lined with double PE bags; 1kg aluminum foil bag for samples

2. Application Fields

1. Pharmaceutical API: Intestinal antibacterial agent for bacillary dysentery and gastroenteritis; adjuvant for blood lipid, blood glucose regulation and arrhythmia auxiliary treatment
2. Veterinary Feed Additive: Antibacterial additive against Escherichia coli and yellow-white scour in livestock and poultry
3. Health Food: Dietary supplement for intestinal care and metabolic regulation
4. Cosmetics: Natural antibacterial raw material for oil control and acne treatment

3. Internal Quality Control Standards

- Related Substances: Jatrorrhizine ≤1.0%, Palmatine ≤1.0%, Total Impurities ≤2.0%
- Heavy Metals: Pb ≤10ppm, As ≤2ppm, Cd ≤0.5ppm, Hg ≤0.1ppm
- Microbiological Limits: Total aerobic bacteria ≤1000CFU/g; Molds and yeasts ≤100CFU/g; No Salmonella and Escherichia coli detected
- Residual Solvents: Methanol ≤3000ppm, Dichloromethane ≤600ppm, compliant with ICH Q3C

Image Description

Berberine Powder / High-Purity Berberine Hydrochloride

Part 2: COA (Certificate of Analysis) Standard Template

Product Name: Natural Extracted Berberine Hydrochloride

Batch No.: XXXXXX Production Date: XX.XX.XXXX Test Date: XX.XX.XXXX

Standard Basis: Chinese Pharmacopoeia 2025 Edition Volume I

表格

Test Item	Standard Limit	Actual Test Result	Test Method	Conclusion
Appearance & Properties	Yellow crystalline powder, odorless, extremely bitter taste	Bright yellow fine powder	Visual Inspection	Compliant
Identification 1 (Chloride Reaction)	Positive reaction	Positive	Chemical Color Reaction	Compliant

Test Item	Standard Limit	Actual Test Result	Test Method	Conclusion
Identification 2 (Infrared Spectrum)	Consistent with reference spectrum	Matched	IR	Compliant
Berberine Hydrochloride Content (Anhydrous Basis)	≥97.0%	97.68%	HPLC	Compliant
Loss on Drying	≤12.0%	10.45%	Constant weight at 105℃	Compliant
Residue on Ignition	≤0.20%	0.13%	Ignition at 550℃	Compliant
Related Substance - Jatrorrhizine	≤1.0%	0.42%	HPLC	Compliant
Related Substance - Palmatine	≤1.0%	0.37%	HPLC	Compliant
Other Total Impurities	≤2.0%	1.21%	HPLC	Compliant
Total Heavy Metals	≤20ppm	8ppm	ICP-MS	Compliant
Arsenic Salt	≤2ppm	＜0.5ppm	Ag-DDC Method	Compliant
Total Aerobic Microorganisms	≤1000CFU/g	210CFU/g	Plate Counting	Compliant
Molds & Yeasts	≤100CFU/g	32CFU/g	Plate Counting	Compliant
Salmonella, Escherichia coli	Not detectable	Not Detected	General Microbiological Procedures	Compliant

Test Conclusion: This batch of product complies with the standard for naturally extracted Berberine Hydrochloride specified in Chinese Pharmacopoeia 2025 Edition.

Tester: XXX Reviewer: XXX QA Approver: XXX

Part 3: MSDS / SDS (Material Safety Data Sheet) GB/T 16483-2008

Section 1: Chemical and Enterprise Identification

1.1 Product Name: Berberine Hydrochloride (Berberine Extract)

1.2 CAS No.: 633-65-8

1.3 Manufacturer Information (Replaceable): XX Biotechnology Co., Ltd., Emergency Contact Number: XXX
1.4 Recommended Use: Pharmaceutical raw material, health food, plant extract; Forbidden to take undiluted orally or apply high-concentration directly on skin
Section 2: Hazard Identification

- GHS Classification: Non-hazardous chemical, no mandatory hazard pictograms
- Hazard Description: Dust irritates eyes and respiratory tract; large oral intake may cause gastrointestinal discomfort and nausea
- Precautionary Statements: Avoid dust generation; wear dust mask and safety goggles

Section 3: Composition Information
Pure product: Berberine Hydrochloride ≥97%, trace alkaloid impurities from plant extraction (jatrorrhizine, palmatine)
Section 4: First-Aid Measures

- Inhalation: Remove victim to well-ventilated area, rinse mouth with clean water; seek medical attention if persistent coughing occurs
- Skin Contact: Rinse contaminated skin with plenty of running water for 10 minutes, remove contaminated clothing
- Eye Contact: Hold eyelids open, continuously flush eyes with clean water for 15 minutes, then seek medical treatment
- Ingestion: Drink warm water to induce vomiting; do not take neutralizing agents without professional guidance, visit hospital promptly

Section 5: Fire-Fighting Measures

- Suitable Extinguishing Media: Dry powder, carbon dioxide, water mist; Do not spray direct water jet on dust
- Combustion Products: Toxic flue gas containing nitrogen oxides and chlorides; Firefighters shall wear gas masks
- Incompatible Materials: Mixing with strong oxidants at high temperature may cause heat release

Section 6: Accidental Release Measures

1. Small Spill: Collect materials with dry sand or dust-free paper into sealed barrels, prevent dust dispersion; do not discharge into sewer
2. Large Spill: Isolate the contaminated area, ensure ventilation, wear dust-proof protective clothing and contain the spill for collection

3. Environmental Protection: Strictly prevent leakage into rivers and groundwater

Section 7: Handling and Storage

- Handling: Closed feeding with local exhaust ventilation; No eating, drinking or smoking during operation; thoroughly wash hands after work
- Storage: Sealed warehouse with cool and dry environment; store separately from oxidants, strong alkalis and food raw materials; avoid light exposure

Section 8: Exposure Controls / Personal Protection

- Ventilation: Workshop dust removal and exhaust system
- Respiratory Protection: KN95 dust mask in dusty environment
- Eye Protection: Chemical safety goggles
- Hand Protection: Nitrile rubber chemical-resistant gloves
- Body Protection: Dust-proof work clothes

Section 9: Physical and Chemical Properties

Appearance: Yellow crystalline powder; Odor: Odorless; pH of saturated aqueous solution: 4.0~6.0; Decomposition temperature: 204℃; Non-flammable; No flash point; No explosion limit

Section 10: Stability and Reactivity

- Stable Conditions: Stable under normal temperature and sealed storage
- Incompatible Substances: Strong oxidants, concentrated strong alkalis
- Conditions to Avoid: Long-term strong light irradiation, high temperature and high humidity

Section 11: Toxicological Information

- Acute Oral LD50 (Mice): ＞1000mg/kg, low acute toxicity
- Slight irritation to skin and eyes; No skin sensitization; No clear evidence of reproductive or mutagenic toxicity

Section 12: Ecological Information

Not prone to bioaccumulation; Avoid mass discharge into water bodies; can be slowly degraded by microorganisms

Section 13: Disposal Considerations

1. Product Waste: Incinerate through qualified hazardous waste or plant extract waste recycling institutions
2. Packaging: Clean PE bags for recycling; Crush fiber drums for recovery

Section 14: Transport Information

UN Number: None (Non-dangerous goods); Packaging Category: General Class III Packaging; General sea and land freight, protected from light and moisture

Section 15: Regulatory Information

Compliant with Chinese Pharmacopoeia and relevant food additive specifications; Eligible for EU REACH registration; Not regulated as precursor chemicals or hazardous chemicals

Section 16: Other Information

Revision Date: June 25, 2026; Version V1.0; Only for reference in trade and production safety; Batch-specific documents from manufacturers shall prevail

Supplementary Notes

1. Complete printable PDF original documents shall be obtained from manufacturers with batch-specific exclusive files; Templates are for general reference only
2. English versions of TDS/COA/MSDS can be provided for European and American overseas customers
3. If you need documents for 98% pharmaceutical refined grade or 90% low-purity crude extract, I can adjust indicators and rework the full set of documents for you