

## Technical Data Sheet (TDS)

### 1. Product Overview

- Product Name: 苦杏仁提取物
- English Name: Bitter Almond Extract
- CAS Number: 29883-15-6 (Amygdalin)
- Formula: C<sub>20</sub> H<sub>27</sub> NO<sub>11</sub>
- Molecular Weight: 457.40 Da
- Product Characteristics: High-purity natural plant extract derived from *Prunus armeniaca* L. var. *ansu* Maxim. seed via low-temperature water-ethanol extraction; standardized amygdalin content ≥98%; white to off-white crystalline fine powder with faint almond-like fragrance; soluble in water and ethanol, slightly soluble in ether; pharmaceutical-grade purity with low heavy metal and microbial impurities; stable under recommended sealed storage conditions; compatible with common pharmaceutical/health care excipients; **for professional formulation use only** (hazardous if ingested in bulk).

### 2. Technical Specifications (Complies with USP/EP/CP 2020 Standards)

Item	Specification
Appearance	White to off-white crystalline fine powder
Amygdalin Content (dry basis)	≥ 98.0%
Loss on Drying	≤ 3.0%
Residue on Ignition	≤ 0.5%
pH Value (1% aq. solution, 25°C)	5.0-6.5
Heavy Metals (Pb)	≤ 5 ppm
Heavy Metals (As)	≤ 1 ppm
Total Aerobic Microorganisms	≤ 1000 CFU/g
Molds & Yeasts	≤ 100 CFU/g
E. coli / Salmonella	Negative
Particle Size	≥95% passing 100 mesh
Water Solubility	Soluble (20 g/100 mL, 25°C)
Bulk Density	1.60-1.70 g/cm <sup>3</sup>
Temperature Stability	Stable at 0-30°C (amygdalin retention ≥ 95%)
Storage Stability	24 months (unopened, ≤25°C, dry & sealed)
Odor	Faint natural almond-like fragrance

### 3. Product Advantages

1. **High Purity Standard:** Amygdalin content ≥98% with batch-to-batch consistency; complies with USP/EP/CP pharmaceutical-grade plant extract standards; low impurity and microbial load.
2. **Green Extraction Process:** Low-temperature water-ethanol extraction (no organic solvent residue); no artificial additives, preservatives or colorants; raw material undergoes strict heavy metal/pesticide residue detection.
3. **Excellent Formulability:** Soluble in water and ethanol; compatible with common pharmaceutical/health care excipients (mannitol, lactose, starch, glycerin); no precipitation in formulated aqueous/organic systems.
4. **Stable Quality:** Good chemical stability under recommended storage conditions; no active ingredient degradation within shelf life; low hygroscopy with vacuum-sealed packaging.
5. **Compliant with International Norms:** Meets GHS, REACH and TSCA regulatory requirements; complete test data and COA provided for each batch.

### 4. Application Fields

- **Pharmaceutical Intermediates:** Raw material for cough/expectorant pharmaceutical formulations; research and development of targeted pharmaceutical preparations (for professional pharmaceutical production only).



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- **Health Care Products:** Raw material for professional formulated health care products (respiratory system conditioning, controlled dosage only); no direct oral use.
- **Scientific Research Reagents:** Raw material for pharmaceutical and biological research on amygdalin's biological activity; laboratory R&D use.

## 5. Usage Methods

### 5.1 Formulation Compatibility

- **Pharmaceutical Formulations:** Dissolve in deionized water/ethanol first (1:10 ratio) then mix with pharmaceutical excipients; avoid adding to strong acidic systems (pH < 3) or high-temperature formulations ( $\geq 70^{\circ}\text{C}$ ).
- **Health Care Products:** Mix with maltodextrin/starch for solid dosage forms (capsules/tablets) under low-dust closed operation; strictly control the addition ratio to ensure controlled daily dosage.
- **Research Use:** Dissolve in DMSO/water mixed solvent to prepare standard solution; store the prepared solution at 2-8 $^{\circ}\text{C}$  for short-term use.

### 5.2 Recommended Dosage (Professional personnel operation only)

- **Pharmaceutical Intermediates:** 5.0-20.0% (w/w) of the total formulation (follow pharmaceutical GMP formulation requirements).
- **Health Care Products:** 2.0-8.0% (w/w) of the total formulation; adult daily dosage of pure amygdalin  $\leq 50$  mg (strictly controlled).
- **Scientific Research:** 0.1-1.0 mg/mL (solution concentration, adjust according to experimental needs).

### 5.3 Processing Precautions

- Operate in a **closed, low-dust, well-ventilated** workshop by trained professional personnel only; avoid powder dispersion and inhalation.
- Do not mix with strong mineral acids, high-temperature catalysts or digestive enzymes (amylase/pepsin) to prevent active ingredient degradation and hazardous by-product release.
- Seal the product container immediately after sampling/use; control workshop humidity  $\leq 60\%$  to prevent product hygroscopy and caking.

## 6. Packaging & Storage

### 6.1 Packaging Specifications

- 1 kg/bag (pharmaceutical-grade aluminum foil bag, vacuum sealed)
- 5 kg/10 kg/drum (sealed HDPE drum with inner pharmaceutical-grade aluminum foil bag)
- 25 kg/drum (food/pharmaceutical-grade fiber drum with inner vacuum-sealed aluminum foil bag)
- Custom small packaging (100g/500g) available for scientific research use (MOQ applicable)

## 7. Safety & Protection

- **Professional operation only:** No unauthorized handling, use or storage; the product is harmful if swallowed in bulk, and untrained personnel are prohibited from contacting it.
- **Mandatory PPE:** Wear full personal protective equipment during all operations: safety goggles + face shield (100% eye coverage), nitrile rubber gloves ( $\geq 0.1$  mm), N95 respirator, impermeable lab coat and protective shoes.
- **Strict hygiene measures:** Prohibit eating, drinking, smoking or touching the mouth/nose/eyes in the operation area; wash hands and face thoroughly with soap and water after operation, and change contaminated clothing immediately.

## 8. Quality Assurance

- The product is manufactured in accordance with **ISO 9001 quality management system** and **pharmaceutical GMP standards**; the entire production process is under closed and sterile operation to ensure product purity and quality.
- Each batch of product is tested by an independent third-party professional testing institution; a complete **Certificate of Analysis (COA)** with full test results is attached to each batch, and the test data is traceable.