

Technical Data Sheet (TDS)

Product Name: Riluzole CAS Number: 1744-22-5 Product Number: RIL-20260225 Revision Date: 25 FEB 2026

1. Product Overview

Riluzole is a high-purity pharmaceutical raw material, a benzothiazole derivative with neuroprotective and anti-excitotoxic effects. It acts by inhibiting the release of glutamate and blocking sodium channels, reducing neuronal damage. Produced in accordance with pharmaceutical GMP standards, it has high purity, low impurity content, good solubility and stable quality, suitable for the production of oral solid preparations (tablets, capsules) and oral suspensions for the treatment of amyotrophic lateral sclerosis (ALS).

Key Attributes:

- Formula: C₈ H₅ F₃N₂OS
- Molecular Weight: 234.20 g/mol
- Purity: ≥99.5% (HPLC)
- Form: White crystalline powder (slightly characteristic odor)
- Solubility: Freely soluble in ethanol/methanol

2. Technical Specifications (Pharmaceutical Grade, USP 45/Ph. Eur. 10.0)

Item	Specification
Appearance	White to off-white crystalline powder
Assay (HPLC)	≥99.5%
Melting Point	118-122°C
Loss on Drying	≤0.5%
Residue on Ignition	≤0.1%
Heavy Metals (Pb)	≤5 ppm
Optical Rotation	[α] ₂₀ ^D : ±0.5° (1% in CHCl ₃)
Related Substances (Individual)	≤0.05%
Related Substances (Total)	≤0.3%
Solubility	Freely soluble in ethanol/methanol/chloroform; slightly soluble in water
pH Value (1% in water, 25°C)	5.0-7.0
Particle Size	95% passing 120 mesh
Microbial Limit	Total Aerobic Microbial Count ≤100 CFU/g; Yeast & Mold ≤10 CFU/g; Pathogens Negative

3. Product Advantages

1. **Ultra-High Purity:** Pharmaceutical grade with assay ≥99.5%, ultra-low related substances, meets the strictest international pharmaceutical standards (USP/Ph. Eur.).
2. **Good Solubility:** Freely soluble in common organic solvents (ethanol/methanol), suitable for various oral formulation development.
3. **Long Shelf Life:** 36 months under normal storage conditions, excellent stability, no degradation during formulation processing.
4. **Stable Batch Quality:** Strict GMP production and quality control, minimal batch-to-batch variation, ensures formulation consistency.
5. **Environmentally Friendly:** Non-toxic, fully biodegradable, no environmental pollution during production and use.
6. **Comprehensive Technical Support:** Provide DMF, formulation guidance and process optimization solutions for pharmaceutical production.

4. Application Fields



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- **Pharmaceutical Production:** Core raw material for the production of riluzole tablets, capsules and oral suspensions, indicated for the treatment of amyotrophic lateral sclerosis (ALS, Lou Gehrig's disease).
- **R&D Application:** Used in pharmaceutical research and development, neurobiology experiments, preclinical and clinical trial samples for neurodegenerative diseases.
- **Scope of Use:** Only for pharmaceutical manufacturing (human medicine); not for direct use or other non-pharmaceutical purposes.

5. Usage & Processing Guidelines

- **Formulation Compatibility:** Highly compatible with common pharmaceutical excipients (lactose, microcrystalline cellulose, mannitol, magnesium stearate, crospovidone, hydroxypropyl cellulose).
- **Processing Conditions:** Process at 20-25°C, relative humidity ≤60%; suitable for direct compression, wet granulation (no special process requirements).
- **Dosage in Formulation:** Adjust according to drug specifications (standard specification: 50mg per tablet/capsule).
- **Dissolution Requirement:** Due to good solubility, the dissolution rate of the preparation is >90% in 15 minutes (meets USP dissolution standards).
- **Mixing Requirement:** Mix evenly with excipients (mixing time ≥10 minutes) to ensure content uniformity (RSD ≤2%).

6. Packaging & Storage

Packaging Specifications

- 1 kg/bag (food-grade aluminum foil vacuum bag, HDPE drum outer packing)
- 5 kg/drum (HDPE drum with food-grade plastic inner lining, sealed)
- 10 kg/drum (HDPE drum with food-grade plastic inner lining, sealed)
- 25 kg/drum (HDPE drum with food-grade plastic inner lining, sealed) (for large-scale production)
- Custom packaging (500g/bag) available upon request for R&D use.

Storage Conditions

- **Temperature:** 15-25°C (room temperature storage, no refrigeration required)
- **Humidity:** Relative humidity ≤60%
- **Other:** Keep in a cool, dry, dark place; seal tightly to avoid light, moisture and air contact; store separately from strong oxidizing agents and concentrated acids.

Shelf Life

- 36 months (unopened, stored in accordance with the above conditions); 12 months after opening (seal tightly after each use, store at room temperature).

7. Safety & Handling

- The product is a pharmaceutical raw material, **not for direct human/animal consumption.**
- Wear PPE (chemical splash goggles, nitrile gloves, lab coat, N95 dust mask) during handling; avoid dust inhalation and eye contact.
- Operate in a well-ventilated area; do not eat, drink or smoke in the handling area.
- In case of accidental eye contact, rinse with plenty of water and seek medical attention if irritation persists.

8. Quality Assurance

1. Produced in accordance with **GMP**, ISO 9001 quality management system and ISO 14001 environmental management system standards.
2. Each batch is accompanied by a **Certificate of Analysis (COA)** with complete test results (including assay, related substances, melting point, etc.).
3. Provide **DMF (Drug Master File)** (US FDA/EU EDMF), MSDS, TDS and other technical documents as required by customers.
4. Accept third-party inspection (SGS, Intertek, CNAS, FDA) for product quality (purity, impurities, physical and chemical properties).