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Technical Data Sheet (TDS)

Product Name: PregabalinCAS Number: 148553-50-8Product Number: PREG-20260220Revision Date: 20 FEB 2026

1. Product Overview

Pregabalin is a high-purity chiral pharmaceutical raw material (S-isomer), a gamma-aminobutyric acid (GABA) analog with anticonvulsant, neuropathic analgesic and anxiolytic activities. It acts by binding to the $a_2\delta$ subunit of voltage-gated calcium channels, reducing the release of excitatory neurotransmitters. Produced in accordance with pharmaceutical GMP and chiral synthesis standards, it has high optical purity, excellent water solubility and stable quality, suitable for the production of oral solid preparations (tablets, capsules) and oral solutions.

Key Attributes:

- Formula: C_8 H_{17} NO_2
- Molecular Weight: 159.23 g/mol
- Purity: ≥99.5% (HPLC)
- Optical Rotation: +14.5° to +16.5° ($[a]_{20}$ ^{D})
- Form: White crystalline powder (odorless, highly water-soluble)

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	190-194℃
Loss on Drying	≤0.5%
Residue on Ignition	≤0.1%
Heavy Metals (Pb)	≤5 ppm
Optical Rotation ($[a]_{20}$ ^{D})	+14.5° to +16.5° (1% in water)
Related Substances (Individual)	≤0.05%
Related Substances (Total)	≤0.3%
Solubility	Freely soluble in water/methanol; soluble in ethanol
pH Value (5% in water, 25℃)	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%, low related substances, meeting the strictest international pharmaceutical standards (USP/Ph. Eur.).
2. **High Chiral Purity**: Single S-isomer, no R-isomer impurity, ensuring the best pharmacological activity and minimal side effects.
3. **Excellent Solubility**: Freely soluble in water, suitable for both solid and liquid oral formulations (no solubilizer needed).
4. **Long Shelf Life**: 36 months under normal storage conditions, good stability, no degradation during formulation processing.
5. **Comprehensive Technical Support**: Provide DMF, formulation guidance and process optimization solutions for pharmaceutical production.
6. **Environmentally Friendly**: Non-toxic, fully biodegradable, no environmental pollution during production and use.

4. Application Fields

- **Pharmaceutical Production**: Core raw material for the production of pregabalin tablets, capsules, orally disintegrating tablets and oral syrups. Indicated for the treatment of neuropathic pain, epilepsy (partial seizures), generalized anxiety disorder and fibromyalgia.
- **R&D Application**: Used in pharmaceutical research and development, preclinical trials, biological experiments and drug quality control.
- **Scope of Use**: Only for pharmaceutical manufacturing (human/veterinary medicine); not for direct use or other non-pharmaceutical purposes.

5. Usage & Processing Guidelines

- **Formulation Compatibility**: Highly compatible with all common pharmaceutical excipients (lactose, microcrystalline cellulose, mannitol, magnesium stearate, crospovidone, hydroxypropyl methylcellulose).
- **Processing Conditions**: Process at 20-25℃, relative humidity ≤60%; suitable for direct compression, wet granulation and dry granulation (no special process requirements).
- **Dosage in Formulation**: Adjust according to the drug specification (common specifications: 25mg, 50mg, 75mg, 150mg per tablet/capsule).
- **Dissolution Requirement**: Due to high water 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 available upon request (e.g., 500g/bag for R&D use)

Storage Conditions

- **Temperature**: 15-25℃ (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.

7. Safety & Handling

- The product is a pharmaceutical raw material, **not for direct human/animal consumption**.
- Wear PPE (safety glasses, nitrile gloves, lab coat, 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.
- No fire or explosion risk (non-flammable); no special fire prevention measures required during handling.

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 full test results (including assay, related substances, optical rotation, 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, chiral purity, impurities).