

Technical Data Sheet (TDS)

1. Product Overview

- Product Name: Gabapentin (加巴喷丁)
- English Name: Gabapentin
- CAS Number: 60142-96-3
- Formula: C₉ H₁₇ NO₂
- Molecular Weight: 171.24 g/mol
- Product Characteristics: High-purity crystalline powder; potent anti-epileptic and neuropathic pain relief API; racemic compound with no optical activity; soluble in water, low toxicity; stable under normal storage conditions; meets international pharmacopoeial standards, suitable for various pharmaceutical formulations.

2. Technical Specifications (Complies with EP 10.0, USP 45, CP 2020)

Item	Specification
Appearance	White crystalline powder
Assay (on dry basis)	≥ 98.5%
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 10 ppm
Heavy Metals (As)	≤ 2 ppm
Related Substances	Each impurity ≤ 0.5%; Total ≤ 1.0%
pH Value (1% aqueous solution, 25°C)	5.0-7.0
Solubility	Soluble in water, slightly soluble in ethanol
Optical Rotation	0° ± 1° (1% in water)
Chloride Content	≤ 0.01%
Sulfate Content	≤ 0.03%
Particle Size	90% passing 100 mesh (pharmaceutical grade)
Melting Point	162-166°C (decomposition)

3. Product Advantages

1. **High Purity & Compliance:** Meets EP/USP/CP pharmacopoeial standards; low related substances and heavy metal content; consistent batch-to-batch quality, suitable for GMP pharmaceutical formulation.
2. **Potent Pharmacological Activity:** Selective anti-epileptic effect (against partial seizures, generalized seizures); effective for neuropathic pain (postherpetic neuralgia, diabetic peripheral neuropathy); low side effect profile.
3. **Good Solubility:** Water-soluble (14 g/100 mL at 25°C), suitable for both solid oral dosage forms and oral liquid formulations; no special solubilizers required.
4. **Low Toxicity & Safety:** Low acute toxicity; no skin irritation; only mild eye irritation; no carcinogenic, mutagenic or reproductive toxic effects; high safety for occupational handling and clinical use.
5. **Stable Quality:** 24-month shelf life under ≤25°C storage; no degradation under normal handling and formulation conditions; resistant to light and mild temperature changes.

4. Application Fields

- **Pharmaceutical Formulation:** Production of anti-epileptic drugs (tablets, capsules, oral solutions, dispersible tablets); neuropathic pain relief drug preparation; clinical use for epilepsy, postherpetic neuralgia, diabetic peripheral neuropathy.
- **Pharmaceutical R&D:** Research on new anti-epileptic formulations; preclinical and clinical research on neuropathic pain treatment; drug combination research for central nervous system disorders.
- **Academic Research:** Neuroscience research on epilepsy and pain pathways; development of new GABA receptor modulators.

5. Usage Methods



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- **Formulation Compatibility:** Suitable for all solid oral dosage forms (tablets, capsules, chewable tablets) and oral liquid formulations; compatible with common pharmaceutical excipients (lactose, microcrystalline cellulose, starch).
- **Typical Dosage (Formulated Drug):** Adult oral dosage 900-3600 mg/day (anti-epileptic); 1800-3600 mg/day (neuropathic pain) – **dosage subject to pharmaceutical formulation and clinical prescription.**
- **Processing Precautions:** Process in a dust-free, GMP-compliant workshop; maintain low humidity (<60%) during processing; avoid contact with strong acids/bases/oxidizing agents; use closed handling systems to prevent dust generation.

6. Packaging & Storage

Packaging Specifications

- 100 g/bottle (HDPE bottle with aluminum foil seal, inner plastic liner)
- 500 g/bottle (HDPE bottle with aluminum foil seal)
- 1 kg/drum (HDPE drum with inner plastic bag, sealed)
- 5 kg/drum (fiber drum with HDPE inner liner, sealed)
- Custom GMP-compliant packaging available for industrial bulk orders.

Storage Conditions

- Store in a cool, dry, well-ventilated warehouse at $\leq 25^{\circ}\text{C}$; keep container tightly closed to prevent moisture and dust contamination.
- Avoid direct sunlight, high temperature ($>160^{\circ}\text{C}$), and contact with strong acids, strong bases or oxidizing agents.
- Store separately from food, feed and non-pharmaceutical materials; keep away from children and unauthorized personnel.
- **Shelf Life:** 24 months (unopened, under specified storage conditions); 6 months after opening (if resealed and stored at $\leq 25^{\circ}\text{C}$).

Transportation

- Non-hazardous goods; transport by ordinary vehicles with sealed packaging.
- Avoid direct sunlight, high temperature, moisture and collision during transport; prevent dust leakage from packaging.
- Comply with local road and air transport regulations for non-hazardous pharmaceutical raw materials.

7. Safety & Protection

- The product is low-toxic; only mild eye irritation may occur during handling; no special protective measures for normal small-scale handling.
- Wear **chemical safety glasses** and **nitrile rubber gloves** during large-scale handling or prolonged contact to avoid dust contact with eyes and skin.
- Wear an **N95 dust mask** in high-dust environments (e.g., powder mixing, packaging) to prevent inhalation.
- In case of eye contact, rinse with plenty of water for 5-10 minutes; consult a doctor if irritation persists.
- Do not ingest; if accidentally swallowed, rinse mouth with water and consult a doctor if gastrointestinal discomfort occurs.

8. Quality Assurance

- The product is manufactured in accordance with **ISO 9001** and **GMP** quality management system standards; strict in-process quality control and finished product testing.
- Each batch of product is tested for all quality parameters and accompanied by a **Certificate of Analysis (COA)** with batch-specific test results to ensure compliance with industrial and pharmacopoeial standards.
- Complete raw material traceability; production and quality control records retained for 5 years (in accordance with GMP requirements).
- Professional technical support provided for product application, including formulation optimization, processing parameter adjustment and quality control guidance.