纳维盈医化科技
NEWAY SINOPHC TECH

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Technical Data Sheet (TDS)

1. Product Overview

- **Product Name**: Buspirone Hydrochloride (盐酸布斯庇酮)
- **CAS Number**: 33386-08-2
- **Formula**: $C_{21}H_{31}N_5 \cdot O_2 \cdot HCl$
- **Formula Weight**: 421.97 g/mol
- **Molecular Form**: Anxiolytic pharmaceutical active ingredient (API) (5-HT1A receptor partial agonist)
- **Product Characteristics**: High-purity GMP grade Buspirone Hydrochloride is a white to off-white crystalline powder, a non-benzodiazepine anxiolytic with selective partial agonist activity at 5-HT1A receptors. Soluble in water and polar organic solvents, slightly hygroscopic, stable at room temperature sealed storage. Clinically used for the treatment of generalized anxiety disorder (GAD); no sedative, hypnotic or muscle relaxant effects, low risk of dependence and withdrawal; meets USP/EP/CP pharmacopoeial standards for pharmaceutical formulation.

2. Technical Specifications (USP/EP/CP Compliant, GMP Grade)

Item	Specification (Pharmaceutical API Grade)
Appearance	White to off-white crystalline powder
Assay (On Anhydrous Basis)	98.0-102.0% (HPLC)
Water Content	≤ 1.0% (Karl Fischer)
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 10 ppm (AAS)
Heavy Metals (As)	≤ 2 ppm (AFS)
Related Substances (Individual)	≤ 0.5% (HPLC)
Related Substances (Total)	≤ 1.0% (HPLC)
Melting Point	190-195℃ (Capillary Method)
pH Value (1% aqueous, 25℃)	4.0-5.0
Chloride Content	8.0-8.8% (w/w, Volumetric Titration)
Solubility	Soluble in water, methanol, ethanol; slightly soluble in acetone
Particle Size (D90)	≤ 80 μm (Pharmaceutical grade)
Hygroscopy	Slight (stable at RH ≤65%)
Storage Stability	36 months (unopened, 25℃±5℃); 6 months (after opening)

3. Product Advantages

1. **Unique Mechanism**: Selective 5-HT1A receptor partial agonist; no benzodiazepine binding, avoids sedation/hypnosis/muscle relaxation side effects.
2. **Low Dependence Risk**: No tolerance or physical dependence with long-term use; minimal withdrawal symptoms after discontinuation.
3. **High Purity & Quality**: ≥98.0% HPLC assay, low related substances; meets global pharmacopoeia (USP/EP/CP) standards; GMP compliant production.
4. **Favorable Physicochemical Properties**: Soluble in water (suitable for oral/parenteral formulation); slightly hygroscopic, stable at room temperature; low batch-to-batch variation.
5. **Clinically Proven Efficacy**: First-line anxiolytic for generalized anxiety disorder (GAD); effective for mild to moderate anxiety without impairing cognitive function.
6. **Versatile Formulability**: Compatible with various pharmaceutical excipients; suitable for tablets, capsules, oral solutions and injectable formulations.

4. Application Fields

- **Pharmaceutical Formulation**: Production of anxiolytic oral formulations (tablets, capsules, oral suspensions); research for injectable formulation development for acute anxiety.
- **Biomedical Research**: Neuroscience research (5-HT1A receptor system study); psychopharmacology research (anxiolytic drug screening); in vitro/vivo anxiety model research.

- **Pharmaceutical R&D**: Reference standard for non-benzodiazepine anxiolytic drug development; formulation optimization research; drug stability/bioavailability study.

5. Usage Methods

- **Pharmaceutical Formulation (Oral Tablets/Capsules)**: Mix with pharmaceutical excipients (lactose, microcrystalline cellulose, magnesium stearate) at 5-30 mg per unit dose; wet/dry granulation process; compress into tablets or fill into hard gelatin capsules; adjust pH to 4.0-5.0 for oral solutions to ensure stability.
- **Research Use (In Vitro)**: Prepare 10 mM stock solution with deionized water/methanol; dilute to 1-100 μM working concentration for in vitro cell experiments (5-HT1A receptor binding assay); store stock solution at 4℃ for 1 month (sealed).
- **Research Use (In Vivo)**: Dissolve in normal saline/5% glucose solution to prepare 0.1-5 mg/mL formulation; administer via oral/gastric gavage injection at 1-20 mg/kg body weight for animal anxiety models; adjust dosage according to animal species/strain.
- **Critical Notes**:

1. **Pharmaceutical GMP conditions only**: For formulated pharmaceutical products only; no direct human use (unformulated API).
2. Avoid high humidity (RH >65%) during formulation; use moisture-proof excipients for solid formulations.
3. Do not mix with strong acids/bases/oxidizing agents; use stainless steel/plastic equipment for formulation processing.
4. Strict dosage control in clinical use; gradual dose titration to achieve optimal anxiolytic effect.

6. Packaging & Storage

Packaging Specifications (GMP Compliant, Moisture-Proof)

- 100 g/bottle (GMP grade, HDPE plastic bottle with moisture-proof cap + aluminum foil liner)
- 500 g/bottle (GMP grade, HDPE plastic bottle with moisture-proof cap + aluminum foil liner)
- 1 kg/drum (GMP grade, HDPE plastic drum with inner aluminum foil bag)
- 5 kg/drum (Bulk GMP grade, HDPE plastic drum with inner aluminum foil bag)
- Custom packaging (10 g/50 g) for research/small-batch orders available on request.

Storage Conditions (Room Temperature Mandatory)

- **Long-term Storage**: 25℃±5℃, dry, dark, **sealed**; store in original GMP packaging; avoid temperature fluctuation (>5℃) and high humidity (RH >65%).
- **Short-term Storage**: 25℃, sealed, up to 6 months after opening; place in a desiccator with anhydrous silica gel if needed.
- **Avoid**: High temperature (>60℃), direct sunlight, high humidity, strong acids/bases, oxidizing/reducing agents, heavy metal ions.
- **Segregation**: Store in **locked dedicated GMP pharmaceutical API storage area**; separate from food/feed/cosmetics/other hazardous chemicals; no co-storage with strong acids/bases.

7. Safety & Protection

- The product is **harmful if swallowed**, causes **serious eye irritation** and may damage the nervous system via prolonged exposure; no skin irritation/sensitization.
- **Mandatory PPE** for handling: chemical safety goggles, N95/P95 dust mask, powder-free nitrile gloves (≥0.18mm), disposable clean lab coat.
- Operate in well-ventilated area; avoid dust generation/inhalation, skin/eye contact and accidental ingestion; wash hands thoroughly after handling.
- In case of eye contact, **immediately rinse with sterile water for 15-20 mins and consult an ophthalmologist**.

8. Quality Assurance

- Manufactured in accordance with **GMP (Good Manufacturing Practice)** , **ISO 9001 (Quality)** and **ISO 14001 (Environment)** standards; full traceability of production process.
- Each batch is tested by an independent third-party GMP laboratory and accompanied by a **Certificate of Analysis (COA)** with full pharmacopoeial test data.
- Provide **USP/EP/CP compliance documents**, GMP certification and hazardous chemical safety certificates for pharmaceutical grade products.