纳维盈医化科技
NEWAY SINOPHC TECH

NEWAY SINOPHC TECH. LIMITED

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Technical Data Sheet (TDS)

1. Product Overview

- Product Name: 扑热息痛 / 对乙酰氨基酚
- English Name: Paracetamol / Acetaminophen
- CAS Number: 103-90-2
- Molecular Formula: $C_8H_9NO_2$
- Molecular Weight: 151.16 Da
- **Product Characteristics**: High-purity pharmaceutical grade paracetamol, a classic antipyretic analgesic with mild anti-inflammatory effects; white odorless free-flowing crystalline powder, slightly soluble in water and soluble in hot water/organic solvents; exerts antipyretic and analgesic effects by inhibiting prostaglandin synthesis in the central nervous system; mild side effects, good patient tolerance, suitable for all age groups; stable under recommended storage conditions; compatible with most pharmaceutical excipients; meets USP/EP/BP pharmaceutical grade standards; suitable for the preparation of oral, rectal and topical antipyretic analgesic pharmaceutical formulations.

2. Technical Specifications (Complies with USP/EP/BP & Pharmaceutical Industrial Standards)

Item	Specification
Appearance	White to off-white free-flowing crystalline powder
Assay (HPLC, dry basis)	≥ 99.0%
Melting Point	168-172℃ (Capillary Method)
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
pH Value (5% aq. solution,25℃)	5.5-6.5
Heavy Metals (Pb)	≤ 10 ppm
Heavy Metals (As)	≤ 2 ppm
Chloride (Cl^-)	≤ 0.01%
Sulfate (SO_4^{2-})	≤ 0.01%
Related Substances	≤ 0.5% (HPLC)
Total Aerobic Microorganisms	≤ 100 CFU/g
E. coli	Negative
Particle Size	≥95% passing 100 mesh
Water Solubility	Slightly soluble (1.4 g/100 mL, 25℃); soluble in hot water
Organic Solubility	Soluble in ethanol/methanol/acetone
Bulk Density	1.29-1.32 g/cm³
Hygroscopy	Slightly hygroscopic
Temperature Stability	Stable at 0-30℃ (assay retention ≥98% for 36 months)
Light Stability	Stable under dark storage (assay retention ≥98% for 36 months)

3. Product Advantages

1. **High Purity & Pharmaceutical Grade**: Assay ≥99.0%, low related substances (≤0.5%), excellent batch-to-batch consistency; complies with USP/EP/BP global pharmacopoeia standards; meets GMP production requirements for pharmaceutical raw materials, ensuring high product quality and clinical application safety.
2. **Mild & Effective**: Potent antipyretic and analgesic effects with mild anti-inflammatory activity; mild gastrointestinal side effects, no obvious irritation to the digestive tract; good tolerance for children, the elderly and patients with weak gastrointestinal function.
3. **Broad Applicability**: Suitable for relieving various mild to moderate pains (headache, toothache, muscle pain, joint pain, menstrual pain) and reducing fever caused by various reasons; applicable to all age groups including infants and the elderly (adjust dosage according to age/weight).

4. **Good Formulability**: Soluble in hot water and common organic solvents; compatible with most pharmaceutical excipients (starch, lactose, microcrystalline cellulose, mannitol); easy to process into various dosage forms with good formulation stability.
5. **Stable Quality & Long Shelf Life**: Slightly hygroscopic, no degradation under recommended storage conditions (≤25℃, dry, dark); 36-month long shelf life for unopened products; easy to store and transport for industrial pharmaceutical production.
6. **Mature Clinical Application**: A classic clinical antipyretic analgesic with decades of application experience; complete research data on pharmacology, toxicology and formulation; low research and development risk for pharmaceutical formulation development.

4. Application Fields

- **Pharmaceutical Preparations**: Oral formulations (tablets, capsules, granules, oral suspensions, syrups) for antipyretic and analgesic; rectal suppositories for children and patients with poor oral tolerance; topical formulations (gels, creams) for local pain relief.
- **Pharmaceutical Research**: Research reagent for antipyretic analgesic drug development, pharmaceutical formulation optimization and prostaglandin synthesis inhibition mechanism studies.

5. Usage Methods

5.1 Formulation Compatibility

- **Oral Tablets/Capsules**: Mix with lactose/microcrystalline cellulose/starch at a ratio of 1:4-1:8; add disintegrant (croscarmellose sodium) and lubricant (magnesium stearate); compress into tablets or fill into hard capsules; control processing temperature below 60℃ to prevent active ingredient degradation.
- **Oral Granules/Syrups**: Dissolve in hot purified water (80-90℃) first, then mix with mannitol/sucrose (sweetener) and dextrin (binder); granulate and dry for granules, or add flavoring agent for syrups; adjust pH to 5.5-6.5 to improve stability.
- **Rectal Suppositories**: Mix with suppository bases (polyethylene glycol, cocoa butter) at a ratio of 1:8-1:12 under water bath heating (≤50℃); stir evenly and pour into molds for cooling and shaping.
- **Key Note**: Do not mix with strong acids, strong bases, oxidizing agents or heavy metal salts; use deionized water for aqueous formulations; avoid high-temperature processing (>60℃) for solid formulations.

6. Packaging & Storage

6.1 Packaging Specifications

- 100 g/bottle (pharmaceutical grade brown glass bottle, aluminum foil sealed, light-proof and moisture-proof)
- 1 kg/bag (pharmaceutical grade aluminum foil bag, vacuum sealed, light-proof)
- 5 kg/10 kg/drum (sealed HDPE drum with inner pharmaceutical grade aluminum foil bag, light-proof)
- 25 kg/drum (pharmaceutical grade fiber drum with inner vacuum-sealed aluminum foil bag, light -proof)
- **Custom Packaging**: 500 g/2 kg packaging is available for pharmaceutical customers (MOQ applicable) according to production needs.

7. Safety & Protection

- The product is a pharmaceutical grade hazardous chemical; **only for use by trained professional personnel** (pharmaceutical production, formulation development and scientific research staff) with relevant operating qualifications.
- Wear **mandatory full personal protective equipment** during all handling, processing and preparation operations (chemical-resistant goggles + face shield, nitrile rubber gloves ≥0.18mm thick, N95 respirator, chemical-resistant lab coat, protective shoes).
- Avoid direct skin contact, eye exposure and dust inhalation; in case of accidental contact, follow the first aid measures in the MSDS (Section 4) and seek medical attention **immediately** (especially for eye contact).