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Technical Data Sheet (TDS)

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1. Product Overview

- **Product Name**: Naltrexone
- **CAS Number**: 16590-41-3
- **Molecular Formula**: $C_{20}H_{23}NO_4$
- **Molecular Weight**: 337.40 g/mol
- **Chemical Source**: Synthetic pharmaceutical raw material (synthesized from noroxymorphone via cyclopropylmethylation and oxidation; purified by recrystallization and column chromatography to ensure high purity and low impurity content; optimized synthetic process for good formulation compatibility for oral pharmaceutical preparations).
- **Product Trait**: White to off-white crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; freely soluble in ethanol/methanol/chloroform, slightly soluble in water; stable in dry, dark and neutral/weakly acidic environment, mild hydrolysis in strong alkaline environment; good stability in pharmaceutical processing with light protection and low temperature (≤80℃).
- **Core Properties**: **Selective non-opioid competitive opioid receptor antagonist**; binds strongly to μ, δ and κ opioid receptors without agonist activity; blocks the euphoric and reinforcing effects of opioids and alcohol; no tolerance or physical dependence with long-term use; the classic pharmaceutical raw material for clinical treatment of alcohol and opioid addiction; low systemic side effects at clinical doses.
- **Main Application**: Pharmaceutical raw material for human oral solid formulations (tablets, capsules); treatment of alcohol dependence and opioid addiction; pharmaceutical R&D reference reagent for neuroscience, addiction pharmacology and opioid receptor research; analytical standard for pharmaceutical quality inspection and clinical testing.

2. Technical Specifications (Pharmaceutical Grade, Complies with USP/EP/CP)

Item	Specification
Appearance	White to off-white crystalline powder
Odor	Practically odorless
Assay (Naltrexone)	98.5-101.5%
Melting Point	169-173℃
Loss on Drying	≤ 0.5%
Residue on Ignition	≤ 0.1%
Heavy Metals (Pb)	≤ 2 ppm
Heavy Metals (As)	≤ 1 ppm
Related Substances	≤ 0.5%
Optical Rotation ($[\alpha]_{20}^{D}$)	+205° to +215°
pH Value (1% aqueous suspension,25℃)	6.0-8.0
Solubility	Freely soluble in ethanol; slightly soluble in water
Total Bacterial Count	≤ 10 CFU/g
E. coli	Negative
Yeast & Mold	≤ 10 CFU/g
Particle Size	95% passing 100 mesh
Bulk Density	1.32-1.36 g/cm³
Photostability	≤ 0.3% related substances after 7 days (25℃, light exposure)
Water Solubility	≥ 1.0 g/L (25℃)

3. Product Advantages

1. **Selective Opioid Receptor Antagonism**: Binds selectively to μ, δ and κ opioid receptors with high affinity, blocks the central effects of opioids and alcohol without agonist activity; no euphoria or dependence, high safety for long-term clinical use.
2. **Broad Anti-Addiction Efficacy**: Effective for both alcohol dependence and opioid addiction treatment; reduces alcohol craving and opioid withdrawal symptoms; significantly improves abstinence rate in clinical applications (≥70% for alcohol addiction, ≥85% for opioid addiction).
3. **Good Formulation Compatibility**: Suitable for **oral solid pharmaceutical formulations** (tablets/capsules); good compatibility with common pharmaceutical excipients; slightly water-soluble but can be formulated into high-bioavailability oral preparations via solubilization technology; stable in granulation and tableting processes.
4. **Pharmaceutical Grade High Purity**: Meets USP/EP/CP international pharmacopoeia standards; ultralow heavy metal, microbial and related substance limits; high assay (98.5-101.5%); suitable for GMP production of clinical oral anti-addiction pharmaceutical formulations.

4. Application Fields

4.1 Pharmaceutical Industry (Oral Anti-Addiction Formulations)

- **Oral Tablets/Capsules**: Core raw material for 50mg naltrexone tablets/capsules (clinical standard dose); first-line treatment for alcohol dependence and opioid addiction maintenance treatment; 50mg once daily for alcohol dependence, 50-100mg once daily for opioid addiction, taken with water after meals.
- **Combination Formulations**: Adjuvant raw material for anti-addiction combination formulations (with acamprosate, disulfiram); simultaneous blocking of opioid receptors and regulation of glutamate/GABA system; enhanced anti-alcohol addiction efficacy, reduced relapse rate.
- **Pediatric/Geriatric Formulations**: Low-dose formulations (10mg/25mg) for special populations with professional dosage adjustment; used for adolescent opioid addiction intervention under medical supervision.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Oral Tablets (Adult Standard Dose)**: 50mg per tablet (pure naltrexone); 1 tablet once daily, taken with water after meals, for alcohol/opioid dependence treatment.
- **High-Dose Formulation (Opioid Addiction)**: 100mg per tablet (pure naltrexone); 1 tablet once daily, for severe opioid addiction maintenance treatment.
- **Low-Dose Formulation (Adolescent/Geriatric)**: 10mg/25mg per tablet (pure naltrexone); dosage adjusted according to body weight and clinical condition by a physician.

6. Packaging & Storage

6.1 Packaging Specifications (Pharmaceutical Grade, Light Protection & Anti-Hygroscopic)

- 100 g/bottle: Amber glass pharmaceutical bottle with aluminum foil seal and plastic inner cap (R&D/analytical use, light protection + moisture-proof).
- 1 kg/bag: Aluminum foil vacuum bag with PE inner lining (small-batch pharmaceutical production use, light protection + moisture-proof).
- 5 kg/25 kg/drum: HDPE brown pharmaceutical drum with aluminum foil inner lining and sealed plastic cover (bulk pharmaceutical production use, light protection + moisture-proof).
- Custom packaging (500 g/2 kg) available for R&D and custom formulation production needs (all **light-proof + moisture-proof**).

7. Safety & Protection

- The product is a Class 6.1 toxic pharmaceutical raw material with mild gastrointestinal/nervous system toxicity and irritant effects; **all operations must be conducted by trained professional personnel** with full specified PPE (N95 dust mask, chemical-resistant safety goggles, nitrile rubber gloves ≥0.20 mm, impermeable lab coat, chemical apron).
- Avoid direct contact with eyes, skin, mucous membranes and respiratory tract; avoid inhaling dust and accidental swallowing; operate in a well-ventilated dust-free fume hood with **light protection measures** (blackout curtain, amber equipment).
- Monitor gastrointestinal and nervous system function (nausea, dizziness) for personnel with prolonged handling exposure; take regular rest and medical check-ups.