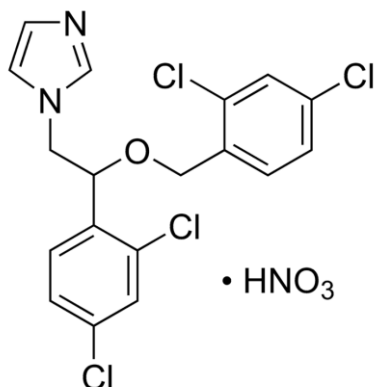


MICONAZOLE NITRATE USP-43 (MICRONIZED)**PRODUCT DATA SHEET**

Product Name: Miconazole Nitrate Micronized USP
Synonyms / INCI Name: Miconazole Nitrate
Molecular Formula: C₁₈H₁₄Cl₄N₂O·HNO₃
Molecular Weight: 479.14 g/mol
Manufacturer: GUANGZHOU HANUP PHARMACEUTICAL CO. LTD.
Distributor: Chemical Store Inc., Clifton, New Jersey
Pack Sizes: 5g, 25g, 1kg, 10kg, 25kg
CAS Number: 22832-87-7
EC Number: 245-256-6
CAS Name: Miconazole Nitrate
Product Code: MICONAZOL

1. PRODUCT IDENTIFICATION

Product Name: Miconazole Nitrate USP-43 (Micronized)

CAS Number: 22832-87-7

Chemical Class: Imidazole Antifungal

Molecular Formula: C₁₈H₁₄Cl₄N₂O·HNO₃

Grade: USP-43 (pharmaceutical grade)

Appearance: White to off-white crystalline powder

2. PRODUCT DESCRIPTION

Miconazole Nitrate USP-43 is a pharmaceutical-grade antifungal active ingredient (API) belonging to the imidazole class.

The micronized grade offers improved dispersion, enhanced uniformity, and better performance in topical and semi-solid formulations.

It exhibits broad-spectrum antifungal activity and is widely used in dermatological and mucosal antifungal products.

3. MECHANISM OF ACTION

Miconazole inhibits the biosynthesis of ergosterol, an essential component of fungal cell membranes.

This disruption leads to increased membrane permeability and ultimately fungal cell death.

4. KEY FEATURES

- Micronized particle size for improved dispersion
- Suitable for multiple dosage forms
- Broad-spectrum antifungal activity
- Consistent batch-to-batch quality

5. TYPICAL APPLICATIONS

Pharmaceutical:

- Topical antifungal creams (2%)
- Vaginal creams (2% and 4%)
- Powder sprays and dermatological formulations

Compounding:

- Custom antifungal creams, gels, and solutions

Personal Care / Cosmeceutical:

- Antimicrobial and medicated skincare products

Veterinary:

- Treatment of fungal infections in animals

Research & Development:

- Formulation development and antifungal testing

6. FORMULATION GUIDANCE

Miconazole Nitrate is poorly soluble in water and should be properly dispersed before use.

Typical incorporation methods:

- Pre-dispersion in propylene glycol or PEG systems
- Incorporation into oil phase for emulsions
- Use of micronized grade for improved uniformity

Typical use levels:

- 2% for topical creams and sprays
- 2% to 4% for vaginal creams
- Up to 8–10% in specialized nail formulations (with penetration enhancers)

Note: Miconazole is an antifungal active ingredient and not a stand-alone preservative system.

7. TYPICAL PROPERTIES

Assay: 98.0% – 102.0%

Solubility: Slightly soluble in water; soluble in organic solvents

Melting Point: ~178–182°C

Particle Size: D90: 10 µm

Molecular weight: 479.1 g/mol

Broad-Spectrum Antifungal activity

8. QUALITY & COMPLIANCE

- Manufactured in accordance with USP-43 specifications
- Packaged for pharmaceutical, compounding and research applications
- Documentation available: CoA, SDS, TDS

9. PACKAGING

Available packaging:

- 5 g, 25 g, 1 kg (R&D quantities)
- 10 kg, 10 kg (pilot scale research)
- 25 kg drums (bulk supply for manufacturing)

Custom packaging and private labeling available upon request for R&D suppliers.

10. STORAGE AND HANDLING

Store in a cool, dry, well-ventilated area.

Keep container tightly closed.

Protect from moisture and direct sunlight.

Use appropriate PPE and avoid inhalation of dust.

Refer to SDS for complete safety information.

11. REGULATORY NOTICE

This product is intended for pharmaceutical manufacturing, compounding, and research laboratory use only.

Not intended for direct consumer use.

Users are responsible for compliance with applicable regulations in their jurisdiction.

12. DISCLAIMER

The information provided in this document is believed to be accurate and reliable.

However, it is the responsibility of the user to determine the suitability of this product for their specific application.

Supplier makes no warranties, express or implied, regarding the use of this product.

Read SDS (Safety Data Sheet) before use or handling.

Date: 4/1/2026

Revision: 1.0