



Selectchemie

ATROPINE SULFATE



**CEP & EU GMP
approved**

Atropine Sulfate



PRODUCT DESCRIPTION

- **Atropine sulfate monohydrate**, $C_{34}H_{48}N_2O_{10}S \cdot H_2O$, CAS 5908-99-6
- Anticholinergic agent
- White crystalline powder
- **CEP available (RO-CEP 2016-112-REV 00)**

KEY CHARACTERISTICS

- Made by Minsheng Group Shaoxing Pharmaceutical Co., Ltd.
- **With 7 t/y largest manufacturer of Atropine sulfate worldwide**
- **Completely synthetic product** → steady supply independent from harvest
- **Fully backwards integrated synthesis process** → full control of product flow and quality
- **Dedicated production line** → no risk of cross-contamination
- Workshop renovated in 2014 **and EU GMP approved in 2018**
- **Batch size >120 kg**; production capacity 10 t/y
- Classified as dangerous goods
- **Exclusive distribution by Selectchemie AG**

APPLICATIONS

- **Well established use in human and veterinary medicine**
- Indications in ophthalmology, bradycardia, diseases of the digestive tract, preanesthetic, detox in case of poisoning with organophosphates, a.o.
- Approved for adult and paediatric uses
- Used mainly as mono-therapy; some combination products
- Sold in form of eye drops (0.1-1%), tablets (0.6 mg), solutions for injection (0.25-1 mg/ml), and auto-injectors for detox (0.25-2 mg per dose)

MARKET SITUATION

- Old niche product experiencing increased pressure to meet latest regulatory requirements
- Repeated shortages in supply → **a sustainable source is key** for market success
- **Potential for new indication** in treatment of childhood myopia could boost use of API

Minsheng Group

MINSHENG GROUP SHAOXING PHARMACEUTICAL CO., LTD.

315 Tanggong Rd, Paojiang Industrial Zone, Shaoxing, China

- Well established API manufacturer for more than 80 years
- New plant in Shaoxing, GMP approved and operational since 2003
 - Validated QA- and EHS-systems
 - Production of >20 kinds of APIs and intermediates
 - 6 products approved by US-FDA, 2 products by EMA
 - 60% of APIs are exported to USA, EU and Japan
- Strategic cooperation with several multinational pharma companies
- **Long history of manufacturing Atropine sulfate and its intermediates**
 - Biggest supplier of intermediates to other Atropine manufacturers

MANUFACTURER



COMPETITIVE EDGE

- State-of-the-art dedicated Atropine plant (since 2015)
- Fully backwards integrated chemical synthesis process
- Largest manufacturer of Atropine and its intermediates worldwide
- Cost leadership due to best Economy of Scale (batch size >120 kg)
- No specific transport conditions required (temperature)
- Exclusive distribution by Selectchemie AG with own warehouses in Europe

AUTHORISED DISTRIBUTOR

Selectchemie AG Switzerland

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P.O. Box 772

CH-8038 Zürich

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PERSONAL NOTES

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SELECTCHEMIE AG

- Established in 1969 in Zurich, Switzerland
- Premier supplier of high quality ingredients for the pharmaceutical and human nutrition industries
- Extensive global network with offices in 14 countries
- Just-in-time deliveries from our local warehouses in Basel, Zurich and Hamburg
- Certificates: ISO 9001 & 22000, GMP & GDP, FDA inspected in 2011, Bio-Inspecta
- EU-registered in Hamburg, Germany (BGV)

Pharma

**ACTIVE PHARMACEUTICAL
INGREDIENTS**

INTERMEDIATES

**PHARMACEUTICAL
EXCIPIENTS**

Nutrition

FOOD INGREDIENTS

HEALTH INGREDIENTS

New Business Develop- ment Pharma

MARKET EVALUATION

PRODUCT DEVELOPMENT

SUPPLY CHAIN MANAGEMENT

PROJECT MANAGEMENT

DOSSIER PROJECTS

Services beyond Sourcing

COMMERCIAL SUPPORT

SCIENTIFIC SUPPORT

**MATERIAL SAFETY DATA
SHEET SERVICES**

REGULATORY SUPPORT

APPLICATION LAB (FOOD)

YOUR CHOICE FOR QUALITY ALL OVER THE WORLD