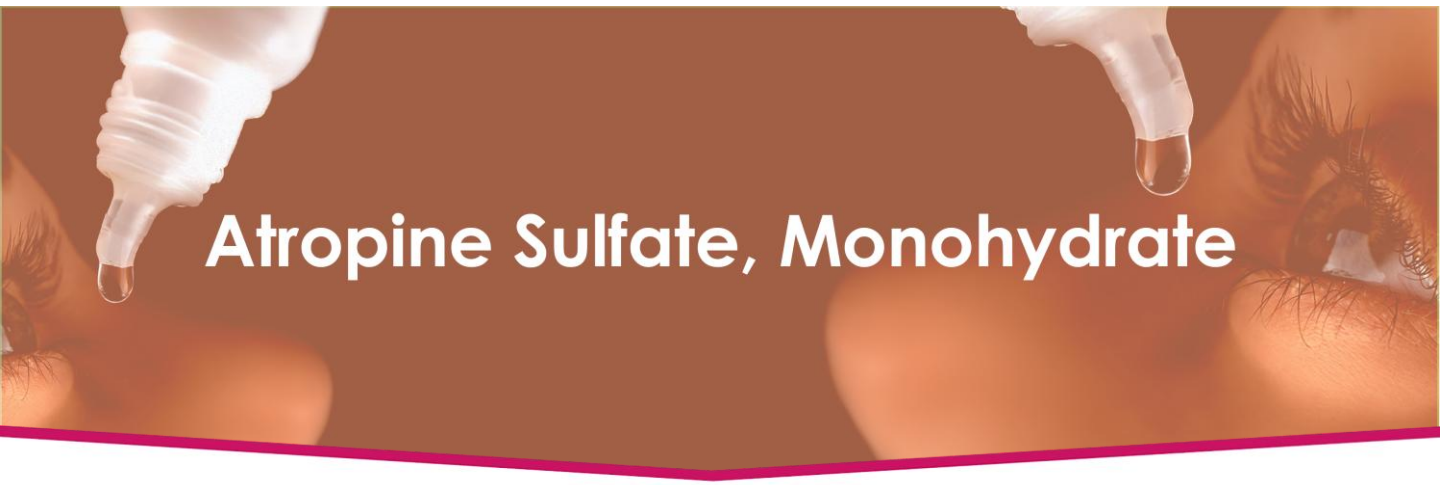


PRODUCT IN FOCUS

EXSYN®
ESSENTIAL CHEMISTRY

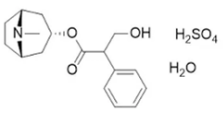
Atropine Sulfate, monohydrate

INTRODUCTION

Atropine sulfate monohydrate is a chemical compound, specifically a salt of atropine and sulfuric acid, with one water molecule (monohydrate) attached. It is commonly used as a medication and in research due to its anticholinergic properties, meaning it blocks the effects of acetylcholine at muscarinic receptors.

MANUFACTURE

The production of Atropine sulfate monohydrate involves several stages — beginning with the extraction of the atropine alkaloid from plants like *Atropa belladonna*, *Datura stramonium*, and *Hyoscyamus niger*, followed by its conversion to atropine sulfate, and finally crystallization into the monohydrate form.

Synonym	(±)-Tropine tropate sulfate monohydrate
CAS no.	5908-99-6
EINECS no.	200-235-0
Molecular formula	$(C_{17}H_{23}NO_3)_2 \cdot H_2SO_4 \cdot H_2O$
Molecular weight	694.84
Structure	

APPLICATIONS

- **Medical Applications:**
  - Ophthalmology
    - ✓ Used as a mydriatic (to dilate pupils) and cycloplegic (paralyze ciliary muscle) in eye examinations.
  - Cardiology
    - ✓ Treats bradycardia (abnormally slow heart rate) by increasing heart rate via vagus nerve inhibition.
  - Pre-anesthetic Agent
    - ✓ Reduces saliva and respiratory secretions before surgery.
  - Poisoning Antidote
    - ✓ Critical antidote for organophosphate and nerve agent poisoning (e.g., pesticides, chemical warfare).
  - GI Disorders
    - ✓ Used to relieve intestinal spasms and hypermotility disorders.
- **Research & Diagnostics:**
  - Utilized in autonomic nervous system studies.
  - Employed in pharmacological tests involving muscarinic receptor activity.

Atropine Sulfate, Monohydrate

PRODUCT IN FOCUS

EXSYN® ESSENTIAL CHEMISTRY

SPECIFICATIONS Ph.Eur

Test	Unit	Specification
Appearance	-	White or almost white, crystalline powder or colorless crystals
Solubility	-	Very soluble in water, freely soluble in ethanol (96%)
Identification		
First Identification a, b and e. OR Second identification c, d, e and f.		
a) Optical rotation	-	Should give positive for optical rotation
b) IR	-	Should conform to Ph.Eur
c) Picrate derivative test	-	Should give positive for derivative test
d) Color test	-	Should give positive for color
e) Sulfates	-	Should give positive for sulfate
f) Alkaloids	-	Should give positive for alkaloids
pH	-	4.5 – 6.2
Optical rotation	°	-0.50 to +0.05
Related substance by HPLC		
a) Impurity A	%	NMT 0.2
b) Impurity B	%	NMT 0.2
c) Impurity C	%	NMT 0.2
d) Impurity D	%	NMT 0.2
e) Impurity E	%	NMT 0.3
f) Impurity F	%	NMT 0.2
g) Impurity G	%	NMT 0.2
h) Impurity H	%	NMT 0.3
i) Unspecified impurities	%	NMT 0.10
j) Specified impurities A	%	NMT 0.15
k) Total impurities	%	NMT 0.5

Atropine Sulfate, Monohydrate

PRODUCT IN FOCUS

EXSYN®
ESSENTIAL CHEMISTRY

SPECIFICATIONS Ph.Eur

Test	Unit	Specification
Water	% w/w	2.0 - 4.0
Sulfated ash	% w/w	Max. 0.1
Assay (by potentiometry) on anhydrous basis	%	99.0 - 101.0
Residual solvents		
a) Methanol	ppm	NMT 3000
b) Acetone	ppm	NMT 5000
c) Isopropanol	ppm	NMT 5000
d) Methylene dichloride	ppm	NMT 600
e) Ethyl acetate	ppm	NMT 5000
f) Tetrahydrofuran	ppm	NMT 720
g) Toluene	ppm	NMT 890

PACKING
25 kg UN approved HDPE drum.

STORAGE
Atropine sulfate is hygroscopic and sensitive to sun light. Store at ambient conditions, well protected from moisture and sun light, away from oxidizing agents.

CERTIFICATION
WHO-GMP, Written Confirmation (WC) and DMF.

ExSyn offers Atropine sulfate on commercial scales and welcomes enquiries. Our exceptional quality and service will make ExSyn your supplier of choice! If you need any additional information or SDS, please contact us.