

MSSP Minsheng Group Shaoxing Pharmaceutical Co., Ltd.

Certificate of Analysis

Report No.: C2302090302

Product: Atropine Sulfate
Batch No.: A-APS2301001
Package Size: 1kg/tin
Specification: TS-A-APS-002

Batch Size: 132.805kg
Quantity: 20kg
Manufacturing Date: 2023-01-09
Retest Date: 2026-01-08

Item	Acceptance Criteria	Results
Characters		
Appearance	White or almost white crystalline powder or colourless crystals	White crystalline powder
Solubility	Very soluble in water, freely soluble in ethanol (96 per cent)	Meet the requirement
Identification		
A: Optical rotation(See tests)	Meet the requirement	Meet the requirement
B: Infrared absorption	Conform with the spectrum of RS	Conform with RS
C: Chemical reaction	Meet the requirement	Meet the requirement
D: Chemical reaction	Should be positive	Positive
E: The reactions of sulfates	Should be positive	Positive
F: The reaction of alkaloids	Should be positive	Positive
pH	4.5~6.2	4.9
Optical rotation	-0.50°~+0.05°	0.00°
Related substances	Impurity A≤0.2%	0.03%
	Impurity B≤0.2%	Not detected
	Impurity C≤0.2%	Not detected
	Impurity D≤0.2%	Not detected
	Impurity E≤0.3%	Not detected
	Impurity F≤0.2%	Not detected
	Impurity G≤0.2%	Not detected

Reported by: *[Signature]* 2023.02.09 Reviewed by: *[Signature]* 2023.02.09 Approved by: *[Signature]* 2023.02.10

Address: 315 Tanggong Rd., Paojiang Industrial Zone, Shaoxing, China

Fax/Tel.: 0086-575-88912706

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Ref. No.: COA-A-APS-002

Version: 01

Effective date: 2019-11-19

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Item	Acceptance Criteria	Results
	Impurity $H \leq 0.3\%$	Not detected
	Unspecified impurity $\leq 0.10\%$	Not detected
	Total impurities $\leq 0.5\%$	0.03%
Water	2.0~4.0%	2.7%
Sulfated ash	Not more than 0.1%	0.04%
Assay	99.0%~101.0% (anhydrous basis)	100.2%
Residual solvent		
Acetone	Not more than 2500ppm	Not detected
Ethanol	Not more than 5000 ppm	Not detected
Methanol	Not more than 3000 ppm	Not detected
Chloroform	Not more than 60 ppm	Not detected
Toluene	Not more than 890ppm	Not detected
Benzene	Not more than 2 ppm	Not detected
Microbial Limits		
Total Aerobic Microbial Count	Not more than 1000 cfu/g	Less than 10 cfu/g
Total Combined Yeasts and Moulds Count	Not more than 100 cfu/g	Less than 10 cfu/g
<i>Escherichia coli</i>	Absent	Absent

Selectchemie

Release



acc. AMWHV §25 Nr. 4 Nr. 3-5

Signature QA:

Date: 15.03.2023

Conclusion: Meet requirements of The TS-A-APS-002[EP10.0/CEP(No.R0-CEP2016-11-2-Rev 03)]

Remarks: /

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