MSSP Minsheng Group Shaoxing Pharmaceutical Co., Ltd.

Certificate of Analysis

Report No.: C2106010303

Product:	Atropine Sulfate	Batch Size:	132.565kg
Batch No.:	A-APS2104001	Quantity:	11kg
Package Size:	1kg/tin	Manufacturing Date:	2021-04-19
Specification:	TS-A-APS-002	Retest Date:	2024-04-18

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	4.8
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: 2021.06.01 Reviewed by: 2021.06.02 Approved by: 2021.06.02

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Certificate of Analysis

Report No.: C2106010303

Product:	Atropine Sulfate	Batch Size:	132.565kg
Batch No.:	A-APS2104001	Quantity:	11kg
Package Size:	1kg/tin	Manufacturing Date:	2021-04-19
Specification:	TS-A-APS-002	Retest Date:	2024-04-18

Item	Acceptance Criteria	Results
	Impurity H≤0.3%	Not detected
	Unspecified impurity ≤0.10%	Not detected
	Total impurities≤0.5%	0.03%
Water	2.0～4.0%	2.7%
Sulfated ash	Not more than 0.1%	Less than 0.1%
Assay	99.0%～101.0% (anhydrous basis)	99.5%
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	25cfu/g
Total Combined Yeasts and Moulds Count	Not more than 100 cfu/g	Less than 10cfu/g
Escherichia coli	Absent	Absent

Selectchemie Release acc. AMWHV §25 Abs. 1 Nr. 3-5 Signature QA: Date: 22.06.2021

Conclusion: Corresponding to the requirement of TS-A-APS-002[Ph.Eur.10/CEP（No.Ro-）CEP2016-112-Rev02)

Remarks: /

Reported by: 2021.06.01 Reviewed by : 2021.06.02 Approved by: 2021.06.02

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MSSP Minsheng Group Shaoxing Pharmaceutical Co., Ltd.

Certificate of Analysis

Report No.: C2106040302

Product:	Atropine Sulfate	Batch Size:	132.565kg
Batch No.:	A-APS2104001	Quantity:	1kg
Package Size:	0.5kg/bag	Manufacturing Date:	2021-04-19
Specification:	TS-A-APS-009	Retest Date:	2024-04-18

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		
Optical rotation(See tests)	Meet the requirement	Meet the requirement
Infrared absorption	Conform with the spectrum of RS	Conform with RS
Chemical reaction Sulfate（a）	Should be positive	Positive
Chemical reaction Sulfate（b）	Should be positive	Positive
Appearance of Solution（5% w / V, water）	Solution is clear and colorless	Solution is clear and colorless
pH	4.5～6.2	4.8
Optical rotation	-0.50°～+0.05°	-0.00°
Related substances（HPLC）	Impurity A≤0.15%	0.03%
	Impurity B≤0.15%	Not detected
	Impurity C≤0.15%	Not detected
	Impurity D≤0.15%	Not detected
	Impurity E≤0.15%	Not detected
	Impurity F≤0.15%	Not detected
	Impurity G≤0.15%	Not detected

Reported by: 2021.06.04 Reviewed by: 2021.06.04 Approved by: 2021.06.07

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

Report No.: C2106040302

Product:	Atropine Sulfate	Batch Size:	132.565kg
Batch No.:	A-APS2104001	Quantity:	1kg
Package Size:	0.5kg/bag	Manufacturing Date:	2021-04-19
Specification:	TS-A-APS-009	Retest Date:	2024-04-18

Item	Acceptance Criteria	Results
	Impurity H≤0.15%	Not detected
	Unspecified impurity ≤0.10%	Not detected
	Total impurities≤0.5%	0.03%
Water	2.0～4.0%	2.7%
Sulfated ash	Not more than 0.1%	Less than 0.1%
Assay	99.0%～101.0% (anhydrous basis)	99.5%
Extraneous matter	Absent of discoloured impurities in 3g	Conforms
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 100 cfu/g	25cfu/g
Total Combined Yeasts and Moulds Count	Not more than 10 cfu/g	Less than 10cfu/g
Escherichia coli	Absent	Absent

Reported by: 2021.06.04 Reviewed by: 2021.06.04 Approved by: 2021.06.07

MSSP Minsheng Group Shaoxing Pharmaceutical Co., Ltd.

Certificate of Analysis

Report No.: C2106040302

Product:	Atropine Sulfate	Batch Size:	132.565kg
Batch No.:	A-APS2104001	Quantity:	1kg
Package Size:	0.5kg/bag	Manufacturing Date:	2021-04-19
Specification:	TS-A-APS-009	Retest Date:	2024-04-18

Item	Acceptance Criteria	Results
Bacterial Endotoxins	Less than 0.84 EU/mg	Less than 0.84 EU/mg

Selectchemie
Release
acc. AMWHV §25 Abs. 4 Nr. 3-5
Signature QA:
Date: 30.06.2021

Conclusion: Corresponding to the requirement of TS-A-APS-009[Ph.Eur.10/CEP (No.R0-CEP 2016-112-Rev 02)]

Remarks: /

Reported by: 2021.06.04 Reviewed by: 2021.06.04 Approved by: 2021.06.07

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