
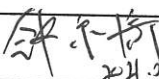



## Certificate of Analysis

Report No.: C2106010302

Product: Atropine Sulfate	Batch Size: 132.565kg
Batch No.: A-APS2104001	Quantity: 20kg
Package Size: 1kg/tin	Manufacturing Date: 2021-04-19
Specification: TS-A-APS-001	Retest Date: 2024-04-18

Item	Acceptance Criteria	Results
Description	Colorless crystals or white crystalline powder, odorless	White crystalline powder, odorless
Identification		
Infrared absorption	The Sample spectrum agrees with the reference standard spectrum	The sample spectrum agrees with the reference standard spectrum
Sulfates	Should be positive	Positive
HPLC	The retention time of the atropine peak in the Sample solution corresponds to that of the system suitability solution, as obtained in the Assay	The retention time of the atropine peak in the Sample solution corresponds to that of the system suitability solution, as obtained in the assay
Assay(HPLC)	98.0~102.0%( anhydrous basis)	99.8%
Residue on ignition	Not more than 0.2%	Less than 0.2%
Organic Impurities(HPLC)		
Tropic acid	Not more than 0.2%	Not detected
7- Hydroxyhyoscyamine	Not more than 0.2%	Not detected
Scopolamine	Not more than 0.2%	Not detected
6- Hydroxyhyoscyamine	Not more than 0.2%	Not detected
Hyoscyamine related compound A	Not more than 0.3%	Not detected
Littorine	Not more than 0.2%	Not detected
Apoatropine	Not more than 0.2%	0.03%
Any individual unspecified impurity	Not more than 0.1%	Not detected

Reported by:  / Reviewed by:  Approved by:  2024.06.02

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

Fax/Tel.: 0086-575-88912706

Email: mssxyy@mspharm.com

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Batch No.: A-APS2104001	Quantity: 20kg
Package Size: 1kg/tin	Manufacturing Date: 2021-04-19
Specification: TS-A-APS-001	Retest Date: 2024-04-18

Item	Acceptance Criteria	Results
Total impurities	Not more than 0.5%	0.03%
Specific Rotation	-0.50°to +0.05°(20°C, anhydrous basis)	-0.02°
Water	Not more than 4.0%	2.7%
Residual solvent		
Acetone	Not more than 2500 ppm	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
<i>Escherichia coli</i>	Absent	Absent

Comment footnote: The impurities 7- Hydroxyhyoscyamine, 6- Hydroxyhyoscyamine, Hyoscyamine related compound A, and Littorine are listed per USP monograph but not produced in current synthetic process.

Conclusion: Corresponding to the requirement of TS-A-APS-001(USP)

Remarks: /

Reported by: [Signature] 2021.06.01 / Reviewed by: [Signature] 2021.06.02 / Approved by: [Signature] 2021.06.02

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Email: mssxyy@mspharm.com