

Minsheng Group Shaoxing Pharmaceutical Co., Ltd.

Certificate of Analysis

Test No.: C1711220301

| | | | |
|----------------|------------------|-------------------|------------|
| Product: | Atropine Sulfate | Package Size: | 1kg/bag |
| Quantity: | 122.90kg | Date of Analysis: | 2017-11-14 |
| Batch No.: | A-APS1711001 | Date of Report: | 2017-11-22 |
| Re-test Date: | 2019-11-09 | Manufacture Date: | 2017-11-10 |
| Specification: | 02TE0105 | Batch Size: | 126.50kg |

Test results:

| Tests | Acceptance Limits | Test Result |
|------------------------------|--|---------------------------------|
| Characters | | |
| Description | 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 | Meet the requirement | Meet the requirement |
| B: Infrared absorption | Conform with the spectrum of RS | Conform with the spectrum of 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 |
| Inspection | | |
| pH | 4.5~6.2 | 5.5 |
| Optical rotation | -0.50° ~ +0.05° | +0.001° |
| Related substances | Impurity A ≤ 0.2% | 0.02% |
| | Impurity B ≤ 0.2% | Not detected |
| | Impurity C ≤ 0.2% | Not detected |
| | Impurity D ≤ 0.2% | Not detected |

Conclusion: Corresponding to the requirement of 02TE0105 (Current EP)

Remarks: /

Reported by: *[Signature]* 2017.11.22 Reviewed by: *[Signature]* 2017.11.22

QC qualified by: *[Signature]* 2017.11.22 Reviewed by QA: *[Signature]* 2017.11.22

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

TEL: 0575-88912706

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Test results:

| Tests | Acceptance Limits | Test Result |
|-------------------------------|--------------------------------|-------------------|
| | Impurity E≤0.3% | Not detected |
| | Impurity F≤0.2% | Not detected |
| | Impurity G≤0.2% | Not detected |
| | Impurity H≤0.3% | Not detected |
| | Unspecified impurity ≤0.10% | Not detected |
| | Total impurities≤0.5% | 0.02% |
| Water | 2.0~4.0% | 2.8% |
| Sulfated ash | Not more than 0.1% | Less than 0.1% |
| Assay | 99.0%~101.0% (anhydrous basis) | 99.4% |
| 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 10cfu/g |

Conclusion: Corresponding to the requirement of 02TE0105 (Current EP)

Remarks: /

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| Specification: | 02TE0105 | Batch Size: | 126.50kg |

Test results:

| Tests | Acceptance Limits | Test Result |
|--|-------------------------|-------------------|
| Total Combined Yeasts and Moulds Count | Not more than 100 cfu/g | Less than 10cfu/g |
| <i>Escherichia coli</i> | Absent | Absent |

Conclusion: Corresponding to the requirement of 02TE0105 (Current EP)

Remarks: /

Reported by:

[Signature] 2017.11.22

Reviewed by:

[Signature] 2017.11.22

QC qualified by:

[Signature] 2017.11.22

Reviewed by QA:

[Signature] 2017.11.24

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

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