

## INCORPORATED

## Certificate of Analysis NICOTINE

Lot # 8727-15-06-02 Manufactured May 6, 2015

| Parameter                 | Method                 | Acceptance Criteria<br>(Monograph) <sup>1</sup>   | Result  |
|---------------------------|------------------------|---|---|
| Identification            | USP<197U>              | UV absorption spectra of test solution and the standard solution exhibit maxima and minima at the same wavelengths. | UV absorption spectra of test solution and the standard solution exhibit maxima and minima at the same wavelengths. |
| Specific Rotation         | USP <781S>             | -130° to -143°  | -133°   |
| Heavy Metals              | USP <231><br>Method II | NMT 0.002%  | < 0.002%  |
| Water<br>Determination    | USP <921><br>Method I  | NMT 0.5%  | 0.2%  |
| Chromatographic<br>Purity | USP <621>              | No single impurity >0.5%  | Impurities:  RRT 1.07: 0.2%  RRT 1.09: 0.1%  RRT 1.10: 0.1%  RRT 1.15: 0.1%  RRT 1.17: 0.2%                         |
|                           |                        | Total impurities NMT 1.0%   | Total<br>Impurities <sup>2</sup> : 0.6%   |
| Titrimetric Assay         | USP <541>              | 99.0 % -101.0%  | 99.6%   |

Maria Clara U. Smith Quality Control Manager

Comments: <sup>1</sup>Refers to USP 36-NF32s2 (Monograph is Nicotine)

<sup>2</sup>Difference between the sum of listed impurities and 'Total Impurities' is due to rounding and additional minor (0.02-0.05%) impurities

NMT = Not more than

RRT = Relative retention time with respect to Nicotine peak