

PRODUCT SPECIFICATION

NICOTINE USP/EP	
TEST ATTRIBUTE	SPECIFICATION
Appearance	<p>A. Appearance: Colourless or brownish viscous liquid</p> <p>B. Colour: Test solution is not more intensely coloured than reference solution Y₅, BY₅ or R₅</p> <p>C. Clarity: Test solution is clear</p>
Identification	<p>A. (HPLC) Retention time of the major peak in the Sample solution corresponds to that of the Standard Solution</p> <p>B. IR Spectrum must be comparable to that of nicotine reference spectrum</p> <p>C. Complies with specific optical rotation test using anhydrous ethanol @ 20° C</p>
Specific Optical Rotation	<p>-130° to -143° @ 25° C</p> <p>-140° to -152° @ 20° C</p>
Water Content	≤ 0.5%
Heavy Metals	Colour not darker than standard (≤ 0.002%)
Chromatographic Purity (HPLC)	<p>Nicotine N'-oxide: ≤ 0.3%</p> <p>Cotinine: ≤ 0.3%</p> <p>Nornicotine: ≤ 0.3%</p> <p>Anatabine: ≤ 0.3%</p> <p>Myosmine: ≤ 0.3%</p> <p>Anabasine: ≤ 0.3%</p> <p>β-Nicotyrine: ≤ 0.3%</p> <p>Any other impurity: ≤ 0.10%</p> <p>Sum of all impurities: ≤ 0.8%</p>
Assay by Non-Aqueous Titration	99.0% to 101.0% (anhydrous substance)
Specific Gravity	Report result

Product	Quality	Batch Quantities	Regulatory
Nicotine USP/EP	USP/Ph Eur	Up to 500kg	USDMF ASMF