

PHARMACEUTICAL GRADE NICOTINE

PRODUCT SPECIFICATION

TEST ATTRIBUTE	SPECIFICATION																		
Appearance	Clear and free from suspended matter																		
Identification	A (UV Spectrum) must be comparable to Nicotine reference (i) Maximum at about 259 nm (ii) Minimum at about 225nm B (IR Absorption) Spectrum must be comparable to that of Nicotine reference spectrum																		
Specific Optical Rotation	-130° to -143° @ 25°C																		
Water Content	≤ 0.50%																		
Heavy Metals	Colour Less Intense than Std (≤ 0.002%)																		
Chromatographic Purity (HPLC)	<table> <tr><td>Cotinine:</td><td>≤ 0.3%</td></tr> <tr><td>Myosmine:</td><td>≤ 0.3%</td></tr> <tr><td>Nicotine-1'-N-oxide:</td><td>≤ 0.3%</td></tr> <tr><td>β-Nicotyrine:</td><td>≤ 0.3%</td></tr> <tr><td>Anatabine:</td><td>≤ 0.3%</td></tr> <tr><td>Anabasine:</td><td>≤ 0.3%</td></tr> <tr><td>Nornicotine:</td><td>≤ 0.3%</td></tr> <tr><td>Any other impurity:</td><td>≤ 0.10%</td></tr> <tr><td>Sum of all impurities:</td><td>≤ 0.8%</td></tr> </table>	Cotinine:	≤ 0.3%	Myosmine:	≤ 0.3%	Nicotine-1'-N-oxide:	≤ 0.3%	β-Nicotyrine:	≤ 0.3%	Anatabine:	≤ 0.3%	Anabasine:	≤ 0.3%	Nornicotine:	≤ 0.3%	Any other impurity:	≤ 0.10%	Sum of all impurities:	≤ 0.8%
Cotinine:	≤ 0.3%																		
Myosmine:	≤ 0.3%																		
Nicotine-1'-N-oxide:	≤ 0.3%																		
β-Nicotyrine:	≤ 0.3%																		
Anatabine:	≤ 0.3%																		
Anabasine:	≤ 0.3%																		
Nornicotine:	≤ 0.3%																		
Any other impurity:	≤ 0.10%																		
Sum of all impurities:	≤ 0.8%																		
Chromatographic Purity (GC)	<p>In the test solution the sum of the peak area responses, excluding those of Nicotine and peaks found in the blank, is not more than that of the Nicotine response from Reference solution B, i.e. 1.0%.</p> <p>In the test solution, no single peak area response is greater than that of the Nicotine response from Reference solution A, i.e. 0.5%.</p>																		
Assay by Non-Aqueous Titration	990mg/g – 1010mg/g (99.0% - 101.0%) of C ₁₀ H ₁₄ N ₂ (Nicotine) as calculated on anhydrous basis.																		