

## PRODUCT SPECIFICATION

NICOTINE POLACRILEX 18%	
TEST ATTRIBUTE	SPECIFICATION
Appearance	White or slightly yellowish fine powder, free from contamination
Identification	<p>A. Glycerol colour test must be positive.</p> <p>B. Infrared spectrum of released Nicotine must be comparable to the reference spectrum produced by a similar preparation of nicotine extracted from Nicotine Bitartrate Dihydrate USP Reference standard</p> <p>C. Infrared spectrum of polymer resin must be comparable to a reference spectrum of Polacrilex Resin RS</p> <p>D. Complies with nicotine release test</p> <p>E. The retention time of the major peak of the Sample Solution corresponds to that of the Standard Solution, obtained in the test for Nicotine Content/Chromatographic Purity</p>
Water Content	≤ 5.0%
Nicotine Release	≥ 70.0% Nicotine released in 10 minutes
Nicotine Content	17.10% to 20.70% (95.0% to 115.0% of label claim on anhydrous basis)
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>
Glycerol Content	10.0 ± 1.0%
Loss on drying	≤ 7.0%

Product	Quality	Batch Quantities	Regulatory
Nicotine Polacrilex 18%	USP/Ph Eur	Up to 139kg	USDMF ASMF