

Nicotine Polacrilex Resin is a white powder with a fine particle size, it allows for a sustained release of nicotine.

**Molecular Formula:**  $[(C_4H_6O_2)_x(C_{10}H_{10})_y](C_{10}H_4N_2)$

Physical state: Fine white powder

**Pharmacopoeia Compliance:** EP, USP

**Nicobrand Specification:**

Appearance: Fine powder with off-white colour, free from contamination

Nicotine Release:  $\geq 70$  % released in 10 minutes

Water Content:  $\leq 5.0$  %

Glycerol Content: Dependent on final nicotine content required

**Assay:**

Nicotine Content: 95% - 115% of labelled claim on anhydrous basis

**Chromatographic Purity:**

By HPLC:

Cotinine:  $\leq 0.30$ %

Myosmine:  $\leq 0.30$ %

Nicotine -1'-N- oxide:  $\leq 0.30$ %

$\beta$ -Nicotyrine:  $\leq 0.30$ %

Anatabine:  $\leq 0.30$ %

Anabasine:  $\leq 0.30$ %

Nornicotine:  $\leq 0.30$ %

Any other impurity:  $\leq 0.10$ %

Total impurities:  $\leq 0.8$ %

**Drug Master Files/Common Technical Document:**

US: Yes

EU: Yes

**Quantities:**

Batch Size: 139kg  
(smaller commercial quantities available)

Samples: On request  
(Shipping costs excluded)

**Application:**

Nicotine Polacrilex Resin finds wide application as the nicotine active in nicotine gums and in some nicotine lozenge products.

Ref FP Protocol # : FP0003