

# BGP HEALTHCARE PRIVATE LIMITED

## DATA SHEET

### Nicotine Polacrilex USP/EP (Contains 15 % Nicotine)

Nicotine Polacrilex is an Active Pharmaceutical Ingredient used mostly in smoking cessation therapies. Nicotine Polacrilex allows for sustained release of Nicotine.

#### Identification:

Molecular Formula :  $(C_{10}H_{14}N_2) [(C_{10}H_{10}) X (C_4H_6O_2) y]$

CAS No. : 96055-45-7

**Pharmacopoeial Compliance:** USP, EP

#### Regulatory Documents

USDMF : Under preparation

EDMF : Under preparation

CEP : Applied

Batch Size : 200 Kgs.

#### Specifications:

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

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

Water content :  $\leq 5.0$  %

Glycerol : 22 to 26 %

#### Assay

Nicotine content : 95 %- 115 % of labeled claim on anhydrous basis  
(i.e. 14.25 % to 17.25 % Nicotine content)

#### Chromatographic purity:

By HPLC

Largest identified impurity: Not more than 0.30 %

Largest Unidentified impurity: Not more than 0.10 %

Total impurity: Less than 0.80 %