

BGP HEALTHCARE PVT. LTD., ANKLESHWAR

DATA SHEET

Nicotine Polacrilex USP/EP(Contain 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 : Available

Batch Size : 200 Kgs.

Specifications:

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

Nicotine Release : ≥ 70 % release in 10 minutes

Water content : ≤ 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 %