

DATA SHEET

NICOTINE POLACRILEX 20 % USP/EP

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

EDMF

CEP

Batch size: 200 Kgs.

Specifications:

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

Nicotine Release ≥ 70 % released in 10 minutes

Water content: ≤ 5.0 %

Assay

Nicotine content: 95 % - 115 % of labeled claim on anhydrous basis
(i.e. 19.0 % to 23.0 % 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 %