

BGP HEALTHCARE PVT. LTD., ANKLESHWAR

DATA SHEET

NICOTINE FREE BASE USP/EP

Nicotine free base is an Active Pharmaceutical Ingredient used mostly in smoking cessation therapies. Nicotine free base offered by BGP is isolated from tobacco leaves by a series of extraction and purification stages ultimately producing a very high purity product.

Identification :

Molecular Formula : $C_{10}H_{14}N_2$
Molecular Weight : 162.23 KG/ Kg mole
CAS No. : 54-11-5

Pharmacopoeial Compliance: USP, EP

Regulatory Documents

USDMF

EDMF

Batch Size : 450 Kgs.

Specifications:

Appearance :
1) Colourless viscous liquid
2) The solution should be clear and not more intensely coloured than reference solution Y_s, BY_s, or R_s

Specific Optical Rotation: (A) Between - 130° and - 143° at 25° C using 96% ethanol
(B) Between - 140° and - 152° at 20° C using anhydrous ethanol

Water content : Not more than 0.5% w/w

Heavy Metals: Not more than 0.002%

Assay

By potentiometer on anhydrous basis: Not less than 99.0% and not more than 101.0%

Chromatographic purity:

By HPLC

Largest identified impurity: Not more than 0.30 %

Largest Unidentified impurity: Not more than 0.10 %

Total impurity: Not more than 0.80 %