

## 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

CEP

Batch size: 300 Kgs.

#### Specifications:

Appearance: 1) Colourless to brownish viscous liquid  
2) The solution should be clear and not more intensely colored than reference solution Y<sub>5</sub>, BY<sub>5</sub>, or R<sub>5</sub>

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 metal: 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 Impurities: Not more than 0.80 %