

Nicotine Bitartrate Dihydrate is a salt of nicotine and is an extremely pure and stable source of nicotine.

Molecular Formula: $C_{10}H_{14}N_2(C_4H_6O_6) \cdot 2H_2O$
Molecular Weight: 498.44
CAS: 65-31-6
Physical state: Crystalline powder

Pharmacopoeia Compliance:

A proposed monograph for Nicotine Bitartrate Dihydrate has been submitted to the European Pharmacopoeia. USP submission under consideration

Nicobrand Specification:

Appearance: White, lustrous crystalline powder

Solubility:

- In water: ≥ 10 % to give clear solution
- In Methanol: ≥ 5 % to give clear solution

PH of 10% Aq. Soln: 3.0 to 3.4

Specific Optical Rotation: +20.0 to +22.0 at 20°C

Melting Point: 87.0°C to 91.0°C

Particle Size: ≤ 1.0 % greater than 250µm

Water Content: 6.9 % to 7.6 %

Sulphated Ash: ≤ 0.1 %

Heavy Metals: ≤ 10 ppm

Residual Solvents:

- Ethanol: ≤ 100 ppm
- Acetone: ≤ 100 ppm

Drug Master Files/Common Technical Document

US: Yes
EU: Yes

Quantities:

Batch Size: 12kg upwards
Samples: On request
 (Shipping costs excluded)

Application:

Nicotine Bitartrate Dihydrate finds application as the nicotine active in a wide range of smoking cessation products such as nicotine lozenges and nicotine sub-lingual tablets.

Assay:

Nicotine content by non-aqueous titration: 32.1% to 33.0%

Chromatographic Purity:

By HPLC:

Largest identified impurity: ≤ 0.30 %

Largest unidentified impurity: ≤ 0.10 %

Total impurities: ≤ 0.50 %

Ref FP Protocol # : FP0002