

Certificate of Analysis

Product: Nicotine EP
Code-Number: 7000136
CAS-Number: 54-11-5
Formula: $C_{10}H_{14}N_2$
Formula weight: 162,23 g/mol
Manufacturing Date: 27/05/2013
Expiry Date: 26/05/2018
Storage: Store under nitrogen in well-closed container below 20 °C, protected from light and moisture

Test	Specifications	Results
Batch		469102405064
Appearance	Colorless or brownish viscous liquid, volatile, hygroscopic	Colorless viscous liquid, volatile, hygroscopic
Solubility	Soluble (1gm in 10 to 30ml) in water, miscible with anhydrous ethanol.	Soluble in water, miscible with anhydrous ethanol.
Identification A.	Specific optical rotation	Complies by specific optical rotation.
Identification B.	Infrared absorption spectrophotometry comparing with Reference spectrum of Nicotine	Infrared absorption Spectrophotometry compared with standard.
Appearance of Solution	The solution is clear and not more intensely colored than reference solution Y ₅ , BY ₅ or R ₅	The solution is clear and not more intensely colored than reference solution Y ₅
Specific optical Rotation (on anhydrous basis)	(-)-140° to (-)-152°	(-)-149.4°
Related substances		
Impurity A	≤ 0.3%	< 0.05%*
Impurity B	≤ 0.3%	< 0.05%*
Impurity C	≤ 0.3%	< 0.05%*
Impurity D	≤ 0.3%	0.14%
Impurity E	≤ 0.3%	< 0.05%*
Impurity F	≤ 0.3%	0.06%
Impurity G	≤ 0.3%	< 0.05%*
Unspecified impurities (for each impurity)	≤ 0.10%	< 0.05%*

Total impurities	≤ 0.8%	0.20%
Water	≤ 0.5	0.14%
Assay (on anhydrous substance)	99.0% - 101.0%	100.3%

*Disregard limit of impurity is 0.05%.

On the basis of above tests the material is found to Conform / ~~does not Conform~~ with the specification as per European Pharmacopoeia.

Data as received from supplier

Date of issue: 06/06/2013



i. A. [redacted]
Quality Control

