



ASIATIC DRUGS & PHARMACEUTICALS PRIVATE LIMITED

GMP CERTIFIED MANUFACTURER

AMPICILLIN TRIHYDRATE

Test Parameter	Specifications (in house)	Test Result Trend
Appearance	White crystalline powder	Complies
Identification	By IR, HPLC & Chemically	Complies
Crystallinity	Crystalline	Complies
Solubility	Slightly soluble in water,	Complies
pH (0.25% sol. in water, w/v)	4.0 - 5.0	4.3 - 4.7
Clarity of solution HCl 10% sol. in 1.0 M HCl (w/v)	NMT reference suspension II	%T at 650 nm 96 - 98.5% Abs at 430nm 0.02 - 0.045
Clarity of solution NH ₃ 10% sol. in dil. NH ₃ solution (w/v)	NMT reference suspension II	Complies
Water (Karl Fischer, w/w)	NMT 12.0 - 15.0%	13.3 - 13.6%
Sulphated Ash, w/w	NMT 0.5%	0.08 - 0.12%
Specific Optical Rotation (0.25% solution in water)	280° - 305°	289° - 294°
N,N - Dimethyl Aniline	Not Tested	-
Heavy Metals	NMT 20 ppm	Complies
Assay Anhydrous Basis (HPLC %)	NLT 98.5% or NLT 985 µg/mg	98.8 - 99.4%
Any Individual Impurity	NMT 1.0%	0.1 - 0.5%
Total Impurities	NMT 2.0%	0.80 - 1.3%
RESIDUAL SOLVENTS		
Isopropyl alcohol	NMT 2000 ppm	350 - 500 ppm
Methanol	NMT 2000 ppm	200 - 300 ppm

Confirmation:

- We certify that the above mentioned product is in conformity with the specifications of IP, BP, USP & EP.
- N,N'- Dimethylaniline, Triethylamine, Dichloromethane and Pivalic acid are not used in the manufacturing process.
- The product tested according to the IP,BP, USP & EP.

Storage Conditions:

- Preserve in well closed (air tight) containers, in a dry place, at a temperature not exceeding 25°C.

Packing:

- Material packed in double liner poly bags and further packed in HDPE /Fiber board drums.

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