



ASIATIC DRUGS & PHARMACEUTICALS PRIVATE LIMITED

GMP CERTIFIED MANUFACTURER

AMOXICILLIN TRIHYDRATE

Test Parameter	Specifications(in house)	Test Result Trend
Appearance	White or almost white crystalline powder	Complies
Identification	By IR, HPLC & Chemically	Complies
Crystallinity	Crystalline	Complies
Solubility	Slightly soluble in water,	Complies
pH (0.2% sol. in water, w/v)	4.0 - 5.0	4.3 - 4.6
Clarity of solution HCl 10% sol. in 0.5 M HCl (w/v)	NMT reference suspension II	%T at 650 nm 96 - 98% Abs at 430nm 0.035 - 0.070
Clarity of solution NH ₃ 10% sol. in dil. NH ₃ solution (w/v)	NMT reference suspension II	Complies
Water (Karl Fischer, w/w)	11.5 - 14.5%	13.4 - 13.6%
Sulphated Ash, w/w	NMT 1.0%	0.09 - 0.14%
Specific Optical Rotation 0.2% solution in water	290° - 315°	298° - 305°
N,N-Dimethyl Aniline	Not Tested	-
Heavy Metals	NMT 20 ppm	Complies
Assay Anhydrous Basis (HPLC %)	NLT 98% or NLT 980 µg/mg	98.6 - 99.2%
Any Individual Impurity	NMT 1.0%	0.2 - 0.6%
Total Impurities	NMT 2.0%	1.1 - 1.5%
RESIDUAL SOLVENTS		
Isopropyl Alcohol	NMT 2000 ppm	250 - 400 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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