

PRODUCT SPECIFICATION

Product : **Ampicillin Trihydrate Powder**

Appearance	:	A white or almost white crystalline powder
Identification	:	A. The IR spectrum obtained with the substance to be examined. Corresponds with that obtained with reference standard. B. Should meet the requirement under water.
Appearance solution	:	Not more opalescent than reference suspension II (1 mol/L HCL solution) ≤ reference suspension II (2 mol/L ammonia)
PH	:	3.5 ~ 5.5
Specific optical rotation	:	+ 280 ~ + 305 (calculated on the anhydrous basis)
Related substances	:	Any specified impurity ≤ 1.0 % Any unspecified impurity ≤ 0.2 % Total impurities ≤ 3.0 %
N,N-Dimethylaniline	:	NMT 20 ppm (not used in process)
Water	:	12.0 % ~ 15.0 %
Sulphated ash	:	≤ 0.5 %
Assay	:	96.0 % ~ 102.0 % C ₁₆ H ₁₉ N ₃ O ₄ S (calculated on anhydrous basis)
Residual solvents		
a) Methylene Chloride	:	NMT 600 ppm
b) Triethylamine	:	NMT 300 ppm
c) Pivalic Acid	:	NMT 1000 ppm
d) Acetone	:	NMT 800 ppm
Bulk density	:	0.15 ~ 0.40 g/ml
MSDS	:	available upon request