

## **PRODUCT SPECIFICATION**

Product : **Amoxicillin Trihydrate Powder**

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Appearance	:	A white or almost white crystalline powder
Identification	:	Examine by IR absorption spectrophotometry comparing with the spectrum obtained with Amoxicillin Trihydrate CRS.
Ph (acidity)	:	3.5 to 5.5
Specific optical rotation	:	+290 to +315
Any specified impurity	:	NMT 1.0 %
Any unspecified impurity	:	NMT 0.10 %
Total impurities	:	NMT 3.0 %
N,N-Dimethylaniline	:	NMT 20 ppm (not used in process)
Water	:	11,5 % to 14.5 %
Sulphated ash	:	NMT 1.0%
Assay	:	95.0 % to 102,0 % ,C <sub>16</sub> H <sub>19</sub> O <sub>5</sub> S, calculated on anhydrous basis
Residual solvents		
a) Acetone	:	NMT 800 ppm
b) Dichloromethane	:	NMT 600 ppm
c) Triethylamine	:	NMT 300 ppm
d) N,N-dimethylacetamide	:	NMT 1090 ppm
e) Toluene	:	NMT 600 ppm
f) Pivalic acid	:	NMT 1000 ppm
Bulk density	:	0.15 - 0.23 g/ml
Microbial Limit	:	NMT 1000 bacteria per gram NMT 80 molds and yeasts per gram  E. coli should be undetectable in 1 gram
MSDS	:	available upon request