

Gojira Fine Chemicals, LLC

Quality Products & Services Meeting Customer Needs
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Specification

Amoxicillin Trihydrate USP

Catalog Number: AT1004 CAS Number: 61336-70-7

Molecular Formula: $C_{16}H_{19}N_3O_5S \cdot 3H_2O$

Molecular Weight: 419.50 Storage: $\leq 0^{\circ}$ C

Retest Period: Three years from the date of manufacture

Test	Specification
Appearance	White crystalline powder
Assay (HPLC, Dry Basis)	95.0 – 100.0%
Identification (IR)	To meet requirements
Optical Rotation	+290° to +315°
Solubility (0.2%)	Clear & colorless
pH (0.2%)	3.5 – 5.5
Bulk Density	0.15 – 0.40g/mL
Moisture (KF)	11.5 – 14.5%
Sulfated Ash	≤ 1.0%
Related Substances	Any peak ≤ 1.0%
Dimethylanilin	≤ 20ppm
Residual Solvents	
Acetone	≤ 800pp
Dichloromethane	≤ 600ppm
N,N-dimethylacetamide	≤ 1090ppm
Pivalic Acid	≤ 1000ppm
Toluene	≤ 600ppm
Triethylamine	≤ 300ppm

Date: September 12, 2018

Approved: John Grubb

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