



Certificate of Analysis



Amoxicillin Trihydrate(Micronized)

Batch/lot number:	DQ2404069	Manufacturing batch/lot size:	2000.00kg
Manufacturing date:	2024-04-20	Expiry date:	2028-04-19
Test report number:	3-24-04-C-2-352	Batch release date:	2024-04-23

TESTS	SPECIFICATION	UNITS	RESULTS
Appearance	White or almost white crystalline powder		White crystalline powder
Identification	Conforms to standard infra-red (IR) spectrogram HPLC: The retention time of the major peak of the Sample solution corresponds to that of the Standard solution		Complies
Water (by Karl Fischer)	11.5 to 14.5	%w/w	13.0
Specific optical rotation	+290 to +315	degree	+303
pH	3.5 to 5.5		5.0
Related substances:			
A (6-aminopenicillanic acid)	≤ 0.5	%	0.02
B (L-amoxicillin)	≤ 1.0	%	Not detected
C (amoxicillin diketopiperazines)	≤ 1.0	%	0.013
D (penicilloic acids of amoxicillin)	≤ 1.0	%	0.039
E (penilloic acids of amoxicillin)	≤ 1.0	%	Not detected
F (3-(4-hydroxyphenyl)pyrazine-2-ol)	≤ 1.0	%	Not detected
G (D-(4-hydroxyphenyl)glycylamoxicillin)	≤ 1.0	%	Not detected
H ((2R)-2-[(2,2-dimethylpropanoyl)amino]-2-(4-hydroxyphenyl)acetic acid)	≤ 1.0	%	Not detected
I ((2R)-2-amino-2-(4-hydroxyphenyl)acetic acid)	≤ 1.0	%	0.0084
J (co-oligomers of amoxicillin and penicilloic acids of amoxicillin)	≤ 1.0	%	0.034
K (oligomers of penicilloic acids of amoxicillin)	≤ 1.0	%	Not detected
L (6-APA amoxicillin amide)	≤ 1.0	%	Not detected
Unknown single impurities	≤ 1.0	%	0.064
Total impurities	≤ 2.0	%	0.21
Residual Solvents (GC):			
Methanol	3000	ppm	80
Assay (anhydrous)	95.0 to 102.0	%	100.7
Sulfated ash	< 1.0	%	0.035
Crystallinity	Crystallinity		—
Bioburden			
Total aerobic microbial count	≤ 1000	cfu/g	—
Total Yeast/molds count	≤ 100	cfu/g	—
E.coli	Absent		—
Particle size:			
D ₉₀		um	20.1
D ₅₀		um	7.07

Pharmacopoeia quality: Complies with the current editions of USP43, Ph. Eur10.4, &BP2022.

*N,N-Dimethylaniline is not used during the manufacturing process of this product or present in any of the raw materials

#these tests are performed on a rotational frequency. Please contact us should you require these results.

Approved by: 赵亚利

Date: Apr. 23, 2024

Checked by: 李益丹

Date: Apr. 23, 2024

Reported by: 王永

Date: Apr. 23, 2024

Manufactured by SINOPHARM WEIQIDA PHARMACEUTICAL CO., LTD

Address: Economic & Technological Development Zone, Second Medical Zone, Datong, Shanxi, China 037010

