



SWAPNROOP DRUGS & PHARMACEUTICALS

Address: Plot No:D-187/16, Five Star Shendra MIDC, Shendra,
Aurangabad-431154, Maharashtra, India.

Call/ WhatsApp: +91-8767062101 Email: enquiry@sdp.org.in
website: www.sdp.org.in

CERTIFICATE OF ANALYSIS

Product Name	Ampicillin Trihydrate BP/EP	CAS No:	7177-48-2
Batch No:	2605001	Manufactured by	-
Date of Mfg.	MAY-2026	Date of Analysis	20/05/2026
Batch Quantity	-	Date of Retest	APR2031

Sr. No	Test	Acceptance Criteria	Results
1.	Description	White or almost white granules	White granules
2.	Solubility	Slightly soluble in water, practically insoluble in ethanol (96%) and in fatty oils. It dissolves in dilute solution of acids and of alkali hydroxide	Slightly soluble in water, practically insoluble in ethanol (96%) and in fatty oils. It dissolves in dilute solution of acids and of alkali hydroxide.
3.	Identification		
	By IR	IR spectra of the sample should be similar to that of working standard.	IR spectra of sample is similar to that of working standard
	Water test	12.0% to 15.0% w/w	Complies
4.	Appearance of solution	The solutions are not more opalescent than reference suspension II	Complies
5.	pH	3.5 to 5.5	4.71
6.	Specific Optical Rotation	+280°-350°	+292.50°
7.	Related Substances	Any impurity not more than 1.0%	0.23%
8.	N, N-Dimethylaniline	Not more than 20 ppm	Not tested
9.	Water	12.0% to 15.0% w/w	13.43% w/w



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10.	Sulphated ash	Not more than 0.5w/w	0.10%w/w
11.	Assay	96.0% to 102.0% w/w of $C_{16}H_{19}N_3O_4S$	98.66w/w
12.	Additional Test Tapped density	Not less than 0.80gm/mL	0.85 gm/mL
13.	Particle Size		
	Pass through 20#	Not less than 95%W/W	95.6%W/W
	Pass through 100#	Not more than 35% w/w	29.4%w/w

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By	Checked by	Approved By
Sonali Nirmal 	Dadarao kakde 	Nayna Nehete 
Date: 23/05/2026	Date: 23/05/2026	Date: 23/05/2026

