



VAT No. : 03391061164
D.L. No. 1800-OSP, 1804-B

P.S./T.C.S.T. No. 20269913 Dt. 18/8/1980
I.E. Code No. 1293001210

KWALITY PHARMACEUTICALS LTD.
6th Mile Stone, Village Nag Kalan, Majitha Road, Amritsar - 143 601 (INDIA)

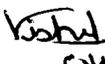
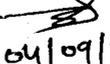
WHO-GMP Certified Co.
ISO 9001:2008 & ISO 14001:2004

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Analytical Retesting Record of Active Pharma Ingredient
(As per Schedule U & G.M.P.)

Certificate of Analysis

C/B	Ampicillin Sodium Sterile USP		
Test Report No: KPL2/QC/AR/RM/25/112			
BR.No: BR25-112	Batch Number: ASS-0624063	Standard : USP	
Mfg. date: 06/2024	Exp. date: 05/2027	Quantity: 30 kg	
Date of receipt of Sample: 20/08/2024	Testing date: 26/08/2024	Retesting date: 25/08/2025	
Sample Drawn by Analyst: Yash			
Analytical Data			
S. No	Tests	Specifications	Observations
01.	Description	White to off-white, odorless or practically odorless, crystalline powder.	Off-white, odorless crystalline powder.
02.	Solubility	Very soluble in water and in isotonic sodium chloride and dextrose solutions.	Complies
03.	Identification A: Infrared absorption spectrophotometry:	A: Compare the spectrum of sample with that obtained with Ampicillin Sodium RS/WS or with the reference spectrum of Ampicillin Sodium.	Complies
	B: Reaction of Sodium	B: A dense precipitate should be formed.	Complies
04.	Crystallinity	The particles show birefringence (interference colors) and extinction positions when the microscope stage is resolved.	Complies
05.	pH	Between 8.0 to 10.0	9.41
06.	Water Determination	Not more than 2.0 percent	0.62 %
07.	Assay By HPLC	Ampicillin Sodium has a potency equivalent to NLT 845 µg and NMT 988 µg of Ampicillin (C ₁₆ H ₁₉ N ₃ O ₄ S) per mg, calculated on the anhydrous	100.3 µg
08.	Organic impurities A. Methylene Chloride:	Not more than 0.2 %.	0.11%
	B. Dimethylaniline	The ratio of the response of any Dimethylaniline peak to the response of the naphthalene peak obtained from the Test Preparation is not greater than that obtained from the Standard Preparation (0.002%).	Complies

 04/09/24	 04/09/24	 04/09/24	 04/09/24
Prepared By (Sign/date) Data Operator	Analyzed By (Sign/date) Analyst QC	Checked By (Sign/date) Reviewer QC	Approved By (Sign/date) Head QC



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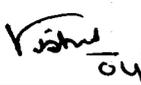
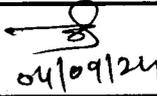
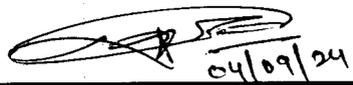
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C/B	Ampicillin Sodium Sterile USP		
Test Report No: KPL2/QC/AR/RM/25/112			
BR.No: BR25-112	Batch Number: ASS-0624063	Standard : USP	
Mfg. date: 06/2024	Exp. date: 05/2027	Quantity: 30 kg	
Date of receipt of Sample:20/08/2024	Testing date:26/08/2024	Retesting date: 25/08/2025	
Sample Drawn by Analyst: Yash			
Analytical Data			
S. No	Tests	Specifications	Observations
09.	Sterility Test	Should be sterile.	Sterile
10.	Bacterial Endotoxins	NMT 0.15 USP EU/mg of Ampicillin.	Less than 0.15 USP EU/mg of Ampicillin.
11.	Particulate matter test Visible Particulate matter Sub-Visible Particulate matter ≥ 10 µm ≥ 25 µm	Free from any Visible particles Not more than 6000 particles Not more than 600 particles	Complies 124 51
Conclusion: The material complies with above specification and is of standard quality as per USP.			

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