

CERTIFICATE OF ANALYSIS

PRODUCT NAME:

Ampicillin Sodium Salt

GRADE:

USP30

CAS NO.

69-52-3

BATCH NO.

18/MFM/2095

MANUFACTURING DATE:

November 2017

EXPIRY DATE (EXTENDED):

October 2019

MOLECULAR FORMULA:

C₁₆H₁₈N₃O₄SNa

MOLECULAR WEIGHT:

371.4

TESTS	SPECS	RESULTS
Description	White or almost white powder	Complies
Identification	A,D OR B,C,D Positive reaction	A,D Positive reaction
Appearance of solution	<= 2	< 0.5
Absorbance	<- 0.15	0.008
рН	8.0 ~ 10.0	8.9
Methylene Chloride	≤0.2%	0.02%
Ampicillin Dimer	≤4.5%	2.6%
Water	≤2.0%	0.7%
Specific optical rotation	+258° ~ +287°	+273°
Bacterial Endotoxins	<0.15 EU/mg	<0.075 EU/mg
Assay (C ₁₆ H ₁₉ N ₃ O ₄ S)	91.0% ~ 102.0%	95.3%
Heavy Metals	≤20ppm	<20ppm .
Sterility	Conforms	Conforms

Conclusion: The product complies with BP2015 standard.

Remark: N,N-Dimethylamine is not used in the manufacturing process of Ampicillin Sodium.

This material is supplied for laboratory use only.

Supplier: Formedium Ltd

Date: 23 MAN 2018

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(Authorised Signature)