



CERTIFICATE OF ANALYSIS

Product	: Oxacillin Sodium Monohydrate BP2018/EP9.0 (Compacted)	Date	:	12/01/2019
Lot No.	: P/OXC-0004/19	Date of Mfg.	:	01/2019
AR No.	: FP03020119	Date of Exp.	:	12/2021
Lot size	: 1000 kg			

TEST	RESULT	SPECIFICATION
Description	: White granules	: White or almost white, granules
Solubility	: Freely soluble in water, soluble in methanol practically insoluble in methylene chloride.	: Freely soluble in water, soluble in methanol practically insoluble in methylene chloride.
Identification By IR	: IR spectra of sample is similar to that of working standard	: IR spectra of the sample should be similar to that of working standard.
Reaction of sodium	: Gives reaction (a) of sodium	: Should give reaction (a) of sodium
Appearance of solution Clarity	: Clear	: Should be clear
Absorbance at 430 nm	: 0.023	: Not more than 0.10
pH	: 5.52	: 4.5 to 7.5
Specific Optical Rotation	: +205.3°	: +196° to +212°
Related Substance		
Impurity B	: Not detected	: Not more than 1.5%
Impurity E	: 0.17%	: Not more than 1.0%
Any highest impurity	: 0.12%	: Not more than 0.5%
Total impurities	: 0.39%	: Not more than 3.0%
Ethyl acetate	: 0.33% w/w	: Not more than 1.0% w/w
Butyl acetate	: Not tested*	: Not more than 1.0% w/w
N, N-Dimethylaniline	: Not tested*	: Not more than 20 ppm
2-Ethylhexanoic acid	: 0.21%	: Not more than 0.80% w/w
Water	: 4.36% w/w	: 3.5% to 5.0% w/w
Assay	: 98.76% w/w	: 95.0% to 102.0% w/w of C ₁₉ H ₁₈ N ₃ NaO ₅ S (On anhydrous basis)

Additional Tests

Tapped density	: 0.87gm/ml	: Not less than 0.80gm/ml
Particle size		
Pass through 20#	: 92.1%	: Not less than 90%w/w
Pass through 100#	: 34.3%	: Not more than 35%w/w

REMARK : The product complies with BP2018/EP9.0

Note *1- N, N-Dimethylaniline and Butyl acetate are not used in manufacturing process
2- Material shall comply with current editions of IP, BP and USP if tested, wherever applicable.

Sign with date

Sumit
14/01/19

[Signature]
14/01/19

[Signature]
14/01/19

Designation

Analysed by
(QC- Chemist)

Checked by
(QC- In-charge)

Approved by
(QA- Head)