



# PENAM LABORATORIES LTD.

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## CERTIFICATE OF ANALYSIS

**Product** : Dicloxacillin Sodium BP2018/EP9.0 (Compacted)  
**Lot No.** : P/DCX-0022/19 **Date** : 12/01/2019  
**AR No.** : FP01720119 **Date of Mfg.** : 01/2019  
**Lot size** : 1000 kg **Date of Exp.** : 12/2021

TEST	RESULT	SPECIFICATION
Appearance	: White granules.	: White or almost white granules.
Solubility	: Freely soluble in water; soluble in ethanol (96%) and in methanol.	: Freely soluble in water; soluble in ethanol (96%) and in methanol.
Identification		
A. 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.
D. 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	: 0.017	: Not more than 0.040
pH	: 6.30	: 5.0 to 7.0
Specific Optical Rotation	: +137.9°	: +128° to +143°
Related Substance		
Single highest impurity	: 0.17%	: Not more than 1.0%
Total impurity	: 0.40%	: Not more than 5.0%
N, N-Dimethylaniline	: Not tested*	: Not more than 20 ppm
2-Ethylhexanoic acid	: 0.34%	: Not more than 0.80% w/w
Water	: 3.90% w/w	: 3.0 %to 4.5% w/w
Assay	: 98.28% w/w	: 95.0% to 102.0% w/w of C <sub>19</sub> H <sub>16</sub> Cl <sub>2</sub> N <sub>3</sub> NaO <sub>5</sub> 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 is not used in manufacturing process  
2- Material shall comply with current editions of IP, BP and USP if tested, wherever applicable.

Sign with date

Designation

*Arjun*  
14/01/19

Analysed by  
(QC- Chemist)

*Arjun*  
14/01/19

Checked by  
(QC- In-charge)

*Arjun*  
14/01/19

Approved by  
(QA- Head)