



# PENAM LABORATORIES LTD.

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## CERTIFICATE OF ANALYSIS

**Product** : Dicloxacillin Sodium BP (Compacted)  
**Lot No.** : P/DCX-124/13  
**AR No.** : FP00010613  
**Quantity** : 500kg

**Date** : 02.06.2013  
**Date of Mfg.** : 05/2013  
**Date of Exp.** : 04/2016

TEST	RESULTS	SPECIFICATIONS
Characters	: White crystalline powder hygroscopic	: White or almost white crystalline powder hygroscopic
Solubility	: Complies	: Freely soluble in water, soluble in ethanol (95%) and in methanol
Identification		
A. By IR	: Complies	: Spectrum of test should be similar to that of working standard
D. Test for Sodium	: Complies	: Should give reaction A of Sodium
Appearance of solution		
Clarity	: Clear	: Should be clear
Absorbance at 430 nm	: 0.029	: Not more than 0.04
pH (10% w/v solution)	: 6.38	: 5.0 to 7.0
Specific Optical Rotation	: +135.4°	: +128° to +143°
Related Substance		
Single highest impurity	: 0.23%	: Not more than 1.0%
Total impurity	: 0.79%	: Not more than 5.0%
N, N-Dimethylaniline	: Not tested*	: Not more than 20 ppm
2-Ethylhexanoic acid	: 0.24%w/w	: Not more than 0.8% w/w
Water	: 4.06%w/w	: Not more than 4.5%w/w
Assay (OAB)	: 98.11 %w/w	: 95.0 to 102.0%w/w

### Additional Test

Tapped Density : 0.82gm/ml

**REMARKS** : The product complies with BP

\*Note : N, N-Dimethylaniline is not used in manufacturing process

  
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## CERTIFICATE OF ANALYSIS

**Product** : Dicloxacillin Sodium BP (Powder)  
**Lot No.** : P/DCX-097/13  
**AR No.** : FP01300513  
**Quantity** : 250kg

**Date** : 27.05.2013  
**Date of Mfg.** : 05/2013  
**Date of Exp.** : 04/2016

TEST	RESULTS	SPECIFICATIONS
Characters	: White crystalline powder hygroscopic	: White or almost white crystalline powder hygroscopic
Solubility	: Complies	: Freely soluble in water, soluble in ethanol (96%) and in methanol
Identification		
A. By IR	: Complies	: Spectrum of test should be similar to that of working standard
D. Test for Sodium	: Complies	: Should give reaction A of Sodium
Appearance of solution		
Clarity	: Clear	: Should be clear
Absorbance at 430 nm	: 0.027	: Not more than 0.04
pH (10% w/v solution)	: 6.32	: 5.0 to 7.0
Specific Optical Rotation	: +135.4°	: +128° to +143°
Related Substance		
Single highest impurity	: 0.17%	: Not more than 1.0%
Total impurity	: 0.49%	: Not more than 5.0%
N, N-Dimethylaniline	: Not tested*	: Not more than 20 ppm
2-Ethylhexanoic acid	: 0.23%w/w	: Not more than 0.8% w/w
Water	: 4.07%w/w	: Not more than 4.5%w/w
Assay (OAB)	: 98.27 %w/w	: 95.0 to 102.0%w/w

**REMARKS** : **The product complies with BP**

\*Note : N, N-Dimethylaniline is not used in manufacturing process

  
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