



PENAM LABORATORIES LTD.

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CERTIFICATE OF ANALYSIS

Product : Cloxacillin Sodium BP (Compacted)
Lot No. : P/CLX-216/13
AR No. : FP01040313
Quantity : 500 kg

Date : 22.03.2013
Date of Mfg. : 03/2013
Date of Exp. : 02/2016

TEST	RESULTS	SPECIFICATIONS
Characters	: White crystalline powder hygroscopic	: White or almost white crystalline powder hygroscopic
Solubility	: Complies	: Freely soluble in water and in methanol soluble in alcohol
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	: 0.030	: Not more than 0.04
pH (10% w/v solution)	: 6.11	: 5.0 to 7.0
Specific Optical Rotation	: +165.5°	: +160° to +169°
Related Substance		
Single highest impurity	: 0.24%	: Not more than 1.0%
Total impurity	: 0.56%	: Not more than 5.0%
N, N-Dimethylaniline	: Not tested*	: Not more than 20 ppm
2-Ethylhexanoic acid	: 0.28%w/w	: Not more than 0.8% w/w
Water	: 4.15%w/w	: 3.0% to 4.5% w/w
Assay (OAB)	: 98.13%w/w	: 95.0 to 102.0%w/w

Additional Test

Tapped Density (gm/ml) : 0.83

REMARKS : **The product complies with BP**

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


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CERTIFICATE OF ANALYSIS

Product : Cloxacillin Sodium BP (Powder)
Lot No. : P/CLX-301/13
AR No. : FP00500413
Quantity : 250 kg

Date : 16.04.2013
Date of Mfg. : 04/2013
Date of Exp. : 03/2016

TEST	RESULTS	SPECIFICATIONS
Characters	: White crystalline powder hygroscopic	: White or almost white crystalline powder hygroscopic
Solubility	: Complies	: Freely soluble in water and in methanol soluble in alcohol
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	: 0.023	: Not more than 0.04
pH (10% w/v solution)	: 5.97	: 5.0 to 7.0
Specific Optical Rotation	: +164.9°	: +160° to +169°
Related Substance		
Single highest impurity	: 0.26%	: Not more than 1.0%
Total impurity	: 0.43%	: Not more than 5.0%
N, N-Dimethylaniline	: Not tested*	: Not more than 20 ppm
2-Ethylhexanoic acid	: 0.26%w/w	: Not more than 0.8% w/w
Water	: 4.04%w/w	: 3.0% to 4.5% w/w
Assay (OAB)	: 98.26%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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