



PENAM LABORATORIES LTD.

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CERTIFICATE OF ANALYSIS

Product : Oxacillin Sodium BP (Compacted)
Lot No : P/OXC-009/13
AR No. : FP00330413
Quantity : 500 kg

Date : 09.04.2013
Date of Mfg. : 03/2013
Date of Exp. : 02/2016

TEST	RESULT	SPECIFICATION
Appearance	: White powder	: White to almost white powder
Solubility	: Complies	: Freely soluble in water soluble in methanol practically insoluble in methylene chloride
Identification		
A. By IR	: Complies	: Spectrum of test should be similar to that of working standard
B. Test for Sodium	: Complies	: Should give reaction- A of Sodium
Appearance of solution		
Clarity	: Clear	: Should be clear
Absorbance at 430 nm	: 0.034	: Not more than 0.10
pH	: 5.83	: 4.5 to 7.5
Specific Optical Rotation	: +202.7°	: +196° to +212°
Related Substances		
Impurity B	: 0.27%	: Not more than 1.5%
Impurity E	: 0.36%	: Not more than 1.0%
Any other impurity	: 0.18%	: Not more than 0.5%
Total Impurities	: 1.31%	: Not more than 3.0%
Ethyl acetate	: 0.43%	: 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	: 0.27 %w/w	: Not more than 0.8% w/w
Water	: 4.16 % w/w	: 3.5 to 5.0% w/w
Assay (OAB)	: 98.23 %w/w	: 95.0% to 102.0%w/w

Additional Test

Tapped density : 0.81 gm/ml

REMARKS : The product complies with BP.

*Note : Not used in manufacturing process


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CERTIFICATE OF ANALYSIS

Product : Oxacillin Sodium BP (Powder)
Lot No : P/OXC-004/13
AR No. : FP00260213
Quantity : 250 kg

Date : 07.02.2013
Date of Mfg. : 01/2013
Date of Exp. : 12/2015

TEST	RESULT	SPECIFICATION
Appearance	: White powder	: White to almost white powder
Solubility	: Complies	: Freely soluble in water soluble in methanol practically insoluble in methylene chloride
Identification		
A. By IR	: Complies	: Spectrum of test should be similar to that of working standard
B. 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 0.10
pH	: 5.89	: 4.5 to 7.5
Specific Optical Rotation	: +202.8°	: +196° to +212°
Related Substances		
Impurity B	: 0.31%	: Not more than 1.5%
Impurity E	: 0.33%	: Not more than 1.0%
Any other impurity	: 0.14%	: Not more than 0.5%
Total Impurities	: 1.37%	: Not more than 3.0%
Ethyl acetate	: 0.45%	: 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	: 0.28 %w/w	: Not more than 0.8% w/w
Water	: 4.10 % w/w	: 3.5 to 5.0% w/w
Assay (OAB)	: 98.13 %w/w	: 95.0% to 102.0%w/w

REMARKS : The product complies with BP

*Note : Not used in manufacturing process


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