



PENAM LABORATORIES LTD.

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CERTIFICATE OF ANALYSIS

Product : Ampicillin Trihydrate BP (Compacted)
Lot No. : P/ATH-075/13 **Date** : 15.04.2013
AR No. : FP00400413 **Date of Mfg.** : 04/2013
Quantity : 500kg **Date of Exp.** : 03/2016

TEST	RESULT	SPECIFICATION
Characters	: White powder	: A white or almost white, crystalline powder
Solubility	: Complies	: Slightly soluble in water practically insoluble in alcohol, in ether and in fatty oils. It dissolves in dilute solution of acids and of alkali hydroxides
Identification		
A. By IR	: Complies	: Spectrum of test should be similar to that of working standard
D. Test for Water	: Complies	: It should be 12.0% to 15.0%w/w
Appearance of solution	: Complies	: The solutions are not more opalescent than reference suspension II
pH	: 4.29	: 3.5 to 5.5
Specific Optical Rotation	: +293.5°	: +280° to +305°
Related substances	: Complies	: Any impurity not more than 1.0%
N, N-Dimethylaniline	: Not tested*	: Not more than 20 ppm
Water	: 13.44%w/w	: 12.0% to 15.0%w/w
Sulphated ash	: 0.07%w/w	: Not more than 0.5% w/w
Assay (OAB)	: 98.13%w/w	: 96.0% to 102.0%w/w

Additional Test
Tapped density (g/ml) : 0.82

REMARK : The product complies with BP.
Note : N, N-Dimethylaniline is not used in manufacturing process.


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CERTIFICATE OF ANALYSIS

Product : Ampicillin Trihydrate BP (Powder)
Lot No. : P/ATH-076/13
AR No. : FP00410413
Quantity : 250 kg

Date : 15.04.2013
Date of Mfg. : 04/2013
Date of Exp. : 03/2016

TEST	RESULT	SPECIFICATION
Characters	: White powder	: A white or almost white, crystalline powder
Solubility	: Complies	: Slightly soluble in water practically insoluble in alcohol, in ether and in fatty oils. It dissolves in dilute solution of acids and of alkali hydroxides
Identification		
A. By IR	: Complies	: Spectrum of test should be similar to that of working standard
D. Test for Water	: Complies	: It should be 12.0% to 15.0%w/w
Appearance of solution	: Complies	: The solutions are not more opalescent than reference suspension II
pH	: 4.20	: 3.5 to 5.5
Specific Optical Rotation	: +294.3°	: +280° to +305°
Related substances	: Complies	: Any impurity not more than 1.0%
N, N-Dimethylaniline	: Not tested*	: Not more than 20 ppm
Water	: 13.40%w/w	: 12.0% to 15.0%w/w
Sulphated ash	: 0.08%w/w	: Not more than 0.5% w/w
Assay (OAB)	: 98.19%w/w	: 96.0% to 102.0%w/w

REMARK : The product complies with BP
Note : N, N-Dimethylaniline is not used in manufacturing process.


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