



PENAM LABORATORIES LTD.

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CERTIFICATE OF ANALYSIS

Product : Flucloxacillin Sodium BP (Compacted)
Lot No. : P/FCX-107/13
AR No. : FP00060613
Quantity : 500 kg

Date : 04.06.2013
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 and in methanol Soluble in ethanol (96%) |
| 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 | : 0.031 | : Not more than 0.04 |
| pH (10% w/v solution) | : 6.31 | : 5.0 to 7.0 |
| Specific Optical Rotation | : +164.7° | : +158° to +168° |
| Related Substance | | |
| Single highest impurity | : 0.29% | : Not more than 1.0% |
| Total impurity | : 0.73% | : Not more than 5.0% |
| 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 | : 4.02%w/w | : 3.0% to 4.5% w/w |
| Assay (OAB) | : 98.23%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 not used in manufacturing process


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CERTIFICATE OF ANALYSIS

Product : Flucloxacillin Sodium BP (Powder)
Lot No. : P/FCX-105/13 **Date** : 16.05.2013
AR No. : FP00490513 **Date of Mfg.** : 05/2013
Quantity : 250 kg **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 and in methanol Soluble in ethanol (96%) |
| 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) | : 6.19 | : 5.0 to 7.0 |
| Specific Optical Rotation | : +164.4 ^o | : +158 ^o to +168 ^o |
| Related Substance | | |
| Single highest impurity | : 0.26% | : Not more than 1.0% |
| Total impurity | : 0.67% | : 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 | : 4.05%w/w | : 3.0% to 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 not used in manufacturing process


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