



**CERTIFICATE OF ANALYSIS**

<b>Product</b>	: <b>Flucloxacillin Sodium BP2018/EP9.0 (Compacted)</b>	<b>Date</b>	:	12/01/2019
<b>Lot No.</b>	: P/FCX-0010/19	<b>Date of Mfg.</b>	:	01/2019
<b>AR No.</b>	: FP002480119	<b>Date of Exp.</b>	:	12/2021
<b>Lot size</b>	: 1000 kg			

TEST	RESULT	SPECIFICATION
Appearance	: White hygroscopic, granules	: White or almost white, hygroscopic, granules
Solubility	: Freely soluble in water and in methanol, soluble in ethanol (96%)	: Freely soluble in water and in methanol, soluble in ethanol (96%)
Identification		
A. By IR	: IR spectra of sample is similar to that of working standard	: IR spectra of the sample should be similar to that of working standard.
D. Reaction of sodium	: Gives reaction (a) of sodium	: Should give reaction (a) of sodium
Appearance of solution		
Clarity	: Clear	: Should be clear
Absorbance at 430 nm	: 0.022	: Not more than 0.040
pH	: 5.93	: 5.0 to 7.0
Specific Optical Rotation	: +162.6°	: +158° to +168°
Related Substance		
Single highest impurity	: 0.22%	: Not more than 1.0%
Total impurity	: 0.35%	: Not more than 5.0%
N, N-Dimethylaniline	: Not tested*	: Not more than 20 ppm
2-Ethylhexanoic acid	: 0.18%	: Not more than 0.80% w/w
Water	: 4.02% w/w	: 3.0 to 4.5% w/w
Assay	: 98.62% w/w	: 95.0% to 102.0% w/w of C <sub>19</sub> H <sub>16</sub> ClFN <sub>3</sub> NaO <sub>5</sub> S (On anhydrous basis)

**Additional Tests**

Tapped density	: 0.87gm/ml	: Not less than 0.80gm/ml
Particle size		
Pass through 20#	: 92.1%	: Not less than 90%w/w
Pass through 100#	: 34.3%	: Not more than 35%w/w

**REMARK** : The product complies with BP2018/EP9.0

Note \*1- N, N-Dimethylaniline is not used in manufacturing process  
2- Material shall comply with current editions of IP, BP and USP if tested, wherever applicable.

Sign with date

*Akmal*  
14/01/19

*[Signature]*  
14/01/19

*[Signature]*  
14/01/19

Designation

**Analysed by**  
**(QC- Chemist)**

**Checked by**  
**(QC- In-charge)**

**Approved by**  
**(QA- Head)**