

KERALA STATE DRUGS AND PHARMACEUTICALS LTD.

KALAVOOR PO, ALAPPUZHA, KERALA-688522

RAW MATERIAL SPECIFICATION



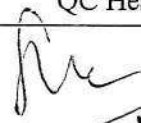
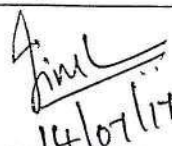
NAME OF THE MATERIAL: CLOXACILLIN SODIUM IP (Compacted)

SOP NO: KSDP/SOP/SPEC01

RECORD NO: KSDP/R/SPEC01/03

S.NO	TESTS	SPECIFICATION
1	Description	A white or almost white, crystalline powder, hygroscopic
2	Solubility	Slightly soluble in water, in methanol, soluble in ethanol (95%), slightly soluble in chloroform.
3	Identification	A. By IR B. By HPLC C. Gives reaction of sodium salts
4	Appearance of solution	Clarity –should be clear at 10%w/v solution Absorbance at 430 nm- Not more than 0.04
5	Related substances	By HPLC
6	pH	5.0-7.0, determined in a 10.0%w/v solution
7	Specific optical rotation	+160° to +169°, determined at 20° in a 1.0%w/v solution
8	N,N-Dimethylaniline	Not more than 20ppm
9	Water	Not more than 4.5%, determined on 0.3g
10	Tapped density*	Not less than 0.85gm/ml
11	Assay*	NLT 97.0% to NMT 101.0% on the anhydrous basis

*IN HOUSE SPECIFICATION

Prepared by	Checked by	Reviewed By	Approved By
Junior Manager QA	Production Head	QC Head	QA Head
 14/09/17		 14/08/17	 14/07/17

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