



KERALA STATE DRUGS AND PHARMACEUTICALS LTD,
KALAVOOR PO, ALAPPUZHA, KERALA-688522

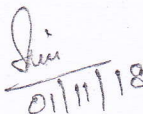
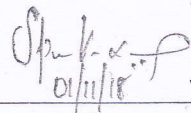

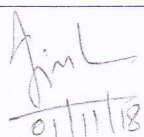
Raw Material Specification

Name of the Material: AMPICILLIN TRIHYDRATE I.P (COMPACTED)

SOP No:	KSDP/SOP/SPEC01	Spec. No:	KSDP/R/SPEC01/02
Effective date:	01/11/2018	Revision No:	01

S.NO	TESTS	SPECIFICATION
1	Description	A white crystalline powder
2	Identification	A. By IR Absorption spectrophotometry B. By HPLC
3	Appearance of solution	Dissolve 1.0g in 10ml of 1M HCL and a further 1.0g in a mixture of 3ml of dilute ammonia solution and 7ml of water. Both solutions when freshly prepared are not more opalescent than opalescence standard OS2
4	PH	3.5-5.5, determined in a 0.25%w/v solution
5	Heavy Metals	Not more than 20ppm
6	Sulphated Ash	Not more than 0.5%
7	Specific optical rotation	+280° to +305° determined in a 0.25%w/v solution
8	N, N-Dimethylaniline	Not more than 20ppm
9	Water	Not more than 2% determined on 0.3g
10	Tapped density*	NLT 0.85 g/ml
11	Related substances	By HPLC
12	Assay*(by HPLC)	NLT 98% and NMT 100.5% (on anhydrous basis)

*IN HOUSE SPECIFICATION

Prepared by	Checked by	Reviewed By	Approved By
Junior Manager QA	QC Head	Production Head	QA Head
 01/11/18	 01/11/18	 11/11/18	 01/11/18

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