



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

Raw Material Specification

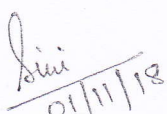
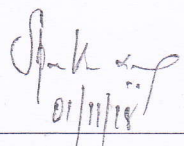

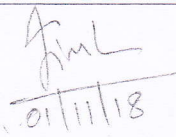
Name of the Material: AMOXYCILLIN TRIHYDRATE IP (COMPACTED)

SOP No: KSDP/SOP/SPEC01 Spec. No: KSDP/R/SPEC01/01

Effective date: 01/11/2018 Revision No: 01

S.NO	TESTS	SPECIFICATION
1.	Description	A white or almost white, practically odorless crystalline powder
2.	Identification	A. By IR absorption spectrophotometry B. By HPLC C. A dark yellow colour develops
3.	Appearance of solution	Dissolve 1.0g in 10 ml of 0.5M HCL and a further 1.0g in a mixture of 3ml of dilute ammonia solution and 7ml water. Both solutions when freshly prepared are not more opalescent than opalescence standard OS2
4.	pH	3.5-5.5, determined in a 0.2%w/v solution
5.	Heavy Metals	Not more than 20ppm
6.	Sulphated Ash	Not more than 1.0%
7.	Specific optical rotation	+290° to +315°, determined in a 0.2% w/v solution in water.
8.	Water	Between 11.5%-14.5% w/w, determined on 0.1g
9.	N,N-Dimethylaniline	Not more than 20ppm
10.	Tapped density *	NLT 0.85 g/ml
11.	Assay *(by HPLC)	NLT 98%w/w and NMT 102%w/w

- 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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CONTROLLED COPY