



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

Raw Material Specification

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

SOP No: KSDP/SOP/SPEC01

Spec. No:

KSDP/R/SPEC01/01

Effective date: 01/12/2022

Revision No:

02

Sl.No.	TESTS	SPECIFICATION
1.	Description	A white or almost white, 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.	Specific optical rotation	+290° to +315°, determined in a 0.2% w/v solution in Carbon dioxide free water.
6.	N,N-Dimethylaniline	Not more than 20ppm
7.	Heavy Metals	Not more than 20ppm
8.	Sulphated Ash	Not more than 1.0%
9.	Water	Between 11.5%-14.5% w/w, determined on 0.1g
10.	Tapped density *	Not less than 0.85 g/mL.
11.	Assay *(by HPLC)	Not less than 98%w/w and not more than 102%w/w

*In house Specification

The product complies to I.P. 2022 with respect to above tests.

Prepared by	Checked by	Reviewed By	Approved By	MASTER COPY UNCONTROLLED COPY
Officer QA	QC Head	Production Head	QA Head	
01/12/22	01/12/22	01/12/22	01/12/22	