



KERALA STATE DRUGS AND PHARMACEUTICALS LTD,

KALAVOOR PO, ALAPPUZHA, KERALA-688522

Raw Material Specification

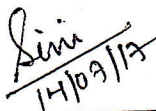


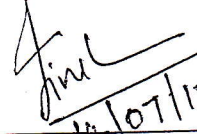
NAME OF THE MATERIAL: AZITHROMYCIN IP

SOP NO: KSDP/SOP/SPEC01

RECORD NO: KSDP/R/SPEC01/10

S.NO	TESTS	SPECIFICATION
1	Description	A white to almost white powder
2	Appearance of solution	Dissolve 0.5g in anhydrous Ethanol and dilute to 50ml with the same solvent. Solution is clear and colourless.
3	Identification	A. By IR B. By HPLC
4	pH	9.0-11.0, determined in a solution prepared by dissolving 0.1g in 25ml of methanol and further diluting to 500ml with water.
5	Heavy Metals	Not more than 25ppm
6	Sulphated Ash	Not more than 0.2%
7	Specific optical rotation	-45.0° to -49.0°
8	Assay*(by HPLC)	NLT 98% and NMT 102.0% on anhydrous basis
9	Water	Between 1.8%-6.5% ,determined on 0.2g
10	Related substances	By HPLC

*IN HOUSE SPECIFICATION

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

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