

KERALA STATE DRUGS AND PHARMACEUTICALS LTD.

KALAVOOR PO, ALAPPUZHA, KERALA-688522


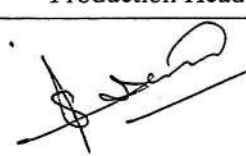
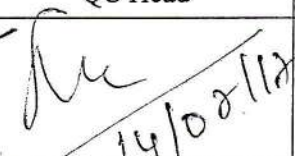
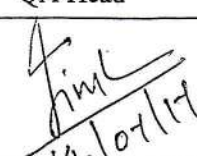
RAW MATERIAL SPECIFICATION

NAME OF THE MATERIAL: TRIMETHOPRIM IP

SOP NO: KSDP/SOP/SPEC01

RECORD NO: KSDP/R/SPEC01/21

S.NO	TESTS	SPECIFICATION
1.	Description	A white or yellowish white powder, odorless or almost odorless
2.	Identification	A. By IR Absorption spectrophotometry B. Dissolve 25mg in 25ml of ethanol(95%) and dilute 2.0ml to 100ml with 0.1M NaOH, absorbance at about 287nm, about 0.49 C. The chloroform layer exhibits a green fluorescence when examined under ultraviolet light at 365nm.
3.	Appearance of solution	A 5% w/v solution in a mixture of 10 volumes of chloroform , 9volumes of methanol and 2 volumes of water is not more intensely coloured than reference solution BYS7.
4.	Related substances	By HPLC
5.	Heavy metals	Not more than 20ppm
6.	Sulphated ash	Not more than 0.1%
7.	Loss on drying	Not more than 1.0%, determined on 1.0g
8.	Assay	NLT 98.5%w/w to NMT 101.0% on the dried basis

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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