



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


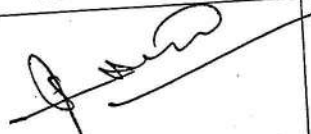
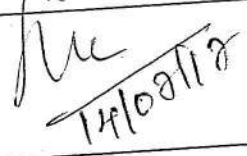

Raw Material Specification

NAME OF THE MATERIAL: SULPHAMETHOXAZOLE IP

SOP NO: KSDP/SOP/SPEC01

RECORD NO: KSDP/R/SPEC01/20

S.NO	TESTS	SPECIFICATION
1	Description	A white or almost white crystalline powder, almost odourless
2	Solubility	Practically insoluble in water, freely soluble in acetone, sparingly soluble in ethanol (96%). It dissolves in dilute solutions of sodium hydroxides and acids.
3	Identification	A. By IR B. By TLC C. Acidification D. Melting Point 169°C-172°C
4	Appearance of solution	Dissolve 0.8g in 10ml of 1 M NaOH. The solution is not more intensely coloured than reference solution YS5, BYS5 and GYS5
5	Related substance	By HPLC
6	Acidity	Not more than 0.3ml of 0.1M NaOH is required to change the colour of solution.
7	Heavy Metals	Not more than 20ppm
8	Loss on drying	Not more than 0.5%, determined on 1.0g
9	Sulphated ash	Not more than 0.1%
10	Assay	NLT 99% to NMT 101%

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

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