



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

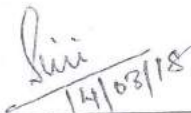
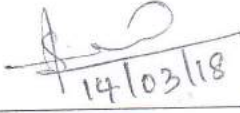
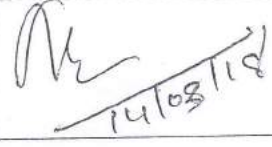
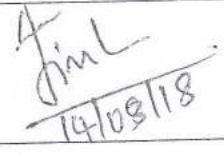
Raw Material Specification

NAME OF THE MATERIAL: CEFIXIME TRIHYDRATE IP (compact)

SOP NO: KSDP/SOP/SPEC01

RECORD NO: KSDP/R/SPEC01/78

S.NO	TESTS	SPECIFICATION
1	Description	A white to light yellow, crystalline powder.
2	Solubility	Soluble in methanol, sparingly soluble in ethanol (95%), practically insoluble in ethyl acetate and in water.
3	Identification By I R absorption Spectrophotometry	Compare the spectrum with that obtained with Cefixime RS working standard.
4	pH	Between 2.6 to 4.1, determined in a 5.0% w/v suspension in carbon dioxide free water.
5	Related substance (by HPLC ) a. Individual impurity	Not more than 0.5%
	b. Total impurity	Not more than 3.0%
6	Water content	9.0 % to 12.0%, determined on 0.20g.
7	Sulphated Ash	Not more than 0.2%
8	Assay by HPLC	Not less than 97.0 % and not more than 101.0%, calculated on the anhydrous basis.

Prepared by	Checked by	Reviewed By	Approved By
Junior Manager QA	Production Head	QC Head	QA Head
 14/03/18	 14/03/18	 14/03/18	 14/03/18

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