



KERALA STATE DRUGS AND PHARMACEUTICALS LTD,

KALAVOOR PO, ALAPPUZHA, KERALA-688522

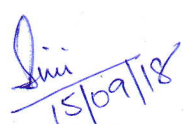

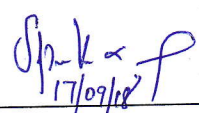
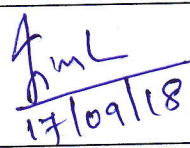
**Raw Material Specification**

NAME OF THE MATERIAL: METFORMIN DIRECTLY COMPRESSIBLE GRANULES 95 %

SOP NO: KSDP/SOP/SPEC01

RECORD NO: KSDP/R/SPEC01/100

S.NO	TESTS	SPECIFICATION
1	Description	A white free flowing granules
2	Identification	a. Metformin reaction with sodium hypochlorite solution-shall develop an orange-red colour, which darkens on standing. b. by infrared absorption spectrum- the IR spectrum of test sample shall be concordant with that of Reference spectrum.
3	Moisture content	0.9%-1.8%w/w
4	Related substances	By HPLC Method
5	Metformin HCL Content ( by UV Method)IP Method	91.5% to 96.5%
6	Bulk density	0.75-0.9 gm/ml

Prepared by	Checked by	Reviewed By	Approved By
Junior Manager QA	Production Head	QC Head	QA Head
 15/09/18		 17/09/18	 17/09/18

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