



KERALA STATE DRUGS AND PHARMACEUTICALS LTD.

KALAVOOR PO, ALAPPUZHA, KERALA-688522

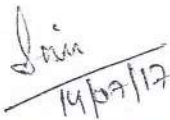
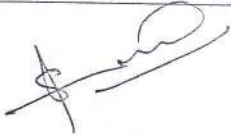
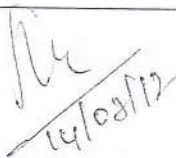
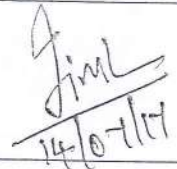
## RAW MATERIAL SPECIFICATION

NAME OF THE MATERIAL: OMEPRAZOLE 10%W/W E.C PELLETT

SOP NO: KSDP/SOP/SPEC01

RECORD NO: KSDP/R/SPEC01/66

S.NO	TESTS	SPECIFICATION
1	Description	White to off white spherical pellets
2	Solubility	Freely soluble in chloroform , soluble in ethanol (95%) and very slightly soluble in water
3	Identification	A. To a quantity of the contents of the capsules containing 50mg of Omeprazole in an 100ml volumetric flask and add about 70ml of 0.1M NaOH. Mix in an ultrasonic bath for about 5 minutes and heat on a water bath for 10 minutes. Cool, make up to volume with 0.1M NaOH and filter. Dilute 2ml of the filtrate to 100ml with 0.1M NaOH. When examined in the range 230nm to 360nm, the resulting solution shows absorption maximum at about 276nm and 305nm. B. By HPLC
4	Loss on drying	Not more than 3.0%, determined on 0.5g of the contents of the capsules by drying in an oven at 60 at a pressure not exceeding 0.7kPa for 4 hours.
5	Gastric resistance (in 0.1 N HCL)	Not less than 85% should retain in 0.1N HCL for 2 hrs
6	Dissolution in phosphate buffer (PH -6.8)	not less than 70% should dissolve in 45 minutes at 100 RPM
7	Assay ( R.M. Omeprazole use as per IP)	9.50% to 10.50%
8	Bulk density	0.70 to 0.95 g/ml

Prepared by	Checked by	Reviewed By	Approved By
Junior Manager QA	Production Head	QC Head	QA Head
 14/07/17		 14/08/17	 14/07/17

MASTER COPY