



CERTIFICATE OF ANALYSIS
NAME OF THE PRODUCT: PANTOPRAZOLE SODIUM

TEST	RESULT	SPECIFICATION
DESCRIPTION	OFF WHITE POWDER	A WHITE TO OFF WHITE POWDER
SOLUBILITY	COMPLIES	FREELY SOLUBLE IN METHANOL AND WATER, SOLUBLE IN ETHANOL
IDENTIFICATION		
HPLC	COMPLIES	THE RETENTION TIME OF SAMPLE SHOULD CONCORDANT WITH THE RETENTION TIME OF THE STANDARD
UV ABSORTPION (0.01% W/V IN METHANOL)	COMPLIES	EXHIBITS MAXIMUM AT ABOUT 289NM
COLOUR OF SOLN	0.03	ABSORBANCE AT 420NM IS NOT MORE THAN 0.125
CLARITY OF SOLN	COMPLIES	SOLN SHOULD BE CLEAR
WATER (% W/W)	6.27	NOT LESS THAN 4.0 AND NOT MORE THAN 8.0
HEAVY METALS (PPM)	<10	NOT MORE THAN 10
RELATED SUBSTANCE (BY HPLC, %)		
ANY OTHER INDIVIDUAL SPECIFIED & IDENTIFIED IMPURITY	0.14	NOT MORE THAN 0.5
UNIDENDIFIED IMPURITY	0.11	NOT MORE THAN 0.3
TOTAL IMPURITIES	0.29	NOT MORE THAN 1.0
ASSAY BY HPLC (% ON ANHYDROUS BASIS W/W)	99.52	NOT LESS THAN 98.0 AND NOT MORE THAN 101.0
ASSAY (BY TITRIMETRY, % W/W)	99.72	NOT LESS THAN 98.0 AND NOT MORE THAN 101.0

ON ANHYDROUS BASIS)		
ADDITIONAL TEST		
I.R. (KBR DISC)	COMPLIES	THE IR ABSORPTION SPECTRUM OF THE PREPARATION OF THE TESTSPECIMEN ,EXHIBITS MAXIMA ONLY AT THE SAME WAVELENGTH AS THAT OF SIMILAR PREPARATION OF THE CORRESPONDING PANTOPRAZOLE SODIUM SESQUIHYDRATE WORKING STANDARD
TEST FOR SODIUM	COMPLIES	COMPLY WITH THE TEST FOR SODIUM
PH(2% SOLN)	10.24	BETWEEN 10 AND 11