



**CERTIFICATE OF ANALYSIS**  
**NAME OF THE PRODUCT: EZETIMIBE**  
**MFG DT: MAY 2010 EXP DT :APRIL 2012**  
**BATCH NUMBER :EM006F09**

TEST	RESULTS	SPECIFICATION
DESCRIPTION	A WHITE POWDER	AWHITE TO OFF WHITE POWDER
SOLUBILITY	COMPLIES	FREELY SOLUBLE IN METHANOL,ETHANOL AND ACETONE
IDENTIFICATION BY IR	COMPLIES	IR ABSORPTION SPECTRUM OF THE SAMPLE IN KBr DISPERSION SHOULD CONCORDANT WITH EZETIMIBE WORKING STANDARD
LOSS ON DRYING	0.2% W/W	NOT MORE THAN 0.5% W/W
SULPHATED ASH	0.05% W/W	NOT MORE THAN 0.2% W/W
HEAVY METALS	COMPLIES	NOT MORE THAN 20 PPM
SPECIFIC OPTICAL ROTATION(C=3,IN METHANOL)	-27.1°	BETWEEN -25.0° AND -34.0°
CHROMATOGRAPHIC PURITY BY HPLC		
a) EZB -1 IMPURITY	NOT DETECTED	NOT MORE THAN 0.30%
b)DESFLUORO IMPURITY	0.22%	NOT MORE THAN 0.505
c)ANY OTHER IMPURITY	0.04%	NOT MORE THAN 0.30%
d)TOTAL IMPURITIES	0.26%	NOT MORE THAN 1.0%
ASSAY BY HPLC (ON DRIED BASIS)	99.4% W/W	BETWEEN 98.0% W/W AND 102.0% W/W