



PRODUCT NAME : AZITHROMYCIN DIHYDRATE USP 31
MFG DATE : OCT 2009
EXP DATE : SEPT 2012
BATCH NO. 11/09/AZI

TEST	RESULTS	STANDARD VALUE
DESCRIPTION	WHITE CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER
IDENTIFICATION BY	PASSES	PASSES
A. HPLC	PASSES	PASSES
B. IR		
CRYSTALLINITY	PASSES	PASSES
MOISTURE	4.41%	MAX. 5.0%
HEAVY METAL	PASSES	NOT>0.0025% (25 PPM)
RESIDUE ON IGNITION	0.05%	MAX. 0.3%
ASSAY (HPLC) ON DRY BASIS	98.21%	NOT<94.5% TO 103.00%
SPECIFIC ROTATION (ON DRY BASIS)	-46.53°	BETWEEN -45° TO 49°
PH	9.86	BETWEEN 9 TO 11