

CERTIFICATE OF ANALYSES
NAME OF THE PRODUCT: AMITRIPTYLINE HYDROCHLORIDE USP 31

TEST	RESULT	SPECIFICATION	
CHARACTERS	A WHITE POWDER	A WHITE OR ALMOST WHITE POWDER OR COLOURLESS CRYSTALS	
SOLUBILITY	COMPLIES	FREELY SOLUBLE IN WATER, IN ALCOHOL AND IN METHYLENE CHLORIDE	
IDENTIFICATION			
FIRST IDENTIFICATION			
C	INFRARED SPECTRUM(AS KBr disc)	COMPLIES	THE SPECTRUM OBTAINED WITH THE SUBSTANCES TO BE EXAMINED CORESPONDANCE IN POSITION AND RELATIVE SIZE TO THOSE IN THE SPECTRUM OBTAINED WITH THE AMITRIPTILINE HCI REFERENCE STANDARD (WORKING STANDARD)
	TEST FOR CHLORIDES	COMPLIES	THE PAPER TURNS VIOLET-RED
E	SECOND IDENTIFICATION		
A	MELTING POINT(°C)	195.9- 197.7	195 TO 199
B	SPECIFIC ABSORBANCE BETWEEN 230NM AND 350NM(0.0125 MG/ML SOLN IN METHANOL) SPECIFIC ABSORBANCE AT 239NM	COMPLIES	435TO 475
D	COLORIMETRIC REACTION		A VIOLET RED COLOUR SHOULD PRODUCE IN THE LOWER LAYER
E	TEST FOR CHLORIDES	COMPLIES	THE PAPER TURNS VIOLET-RED
TESTS			
	APPEARANCE OF SOLUTION (10% W/V, AQUEOUS SOLN)	COMPLIES	THE SOLUTION SHOULD BE CLEAR AND NOT MORE INTENSELY COLOURED THAN REFERENCE SOLUTION B7
	ACIDITY(OR) ALKALANITY	COMPLIES	THE SOLN SHOULD BE YELLOW THE SOLUTION SHOULD BE RED
RELATED SUBSTANCE BY TLC (%)			
	DIBENZOSUBERONE	< 0.05	NOT MORE THAN 0.05
	CYCLOBENZAPRINE	< 0.2	NOT MORE THAN 0.2
	ANY INDIVIDUAL IMPURITY (OTHER THAN CYCLOBENZAPRINE)	< 0.2	NOT MORE THAN 0.2
	HEAVY METALS(PPM)	< 20	NOT MORE THAN 20
	LOSS ON DRYING (% W/W)	0.22	NOT MORE THAN 0.5
	SULPHATED ASH(% W/W)	0.03	NOT MORE THAN 0.1
	ASSAY(BY TITRIMETRY,% W/W, ON DRIED SUBSTANCE)	99.67	NOT LESS THAN 99.0 AND NOT MORE THAN THE EQUIVALENT OF 101.0

REMARKS: THE MATERIAL COMPLIES THE USP31 SPECIFICATION