

LORATADINE USP31 CERTIFICATE OF ANALYSES

TEST SPECIFICATION RESULT

DESCRIPTION	A WHITE TO ALMOST	COMPLIES
	WHITE CRYSTALLINE	
	POWDER	
SOLUBILITY	SOLUBLE IN	COMPLIES
	METHANOL FREELY	
	SOLUBLE IN	
	CHLOROFORM AND	
	SLIGHTLY SOLUBLE	
	IN WATER	
IDENTIFICATION	IR- SPECTRUM UV –	COMPLIES
	ABS SPECTRUM	
MELTING RANGE	132° C – 137° C	134° C – 136° C
LOSS ON DRYING	NMT 1.0 %	0.14%
CLARITY OF SOLN.	10% OF SOLN. IN	COMPLIES
	METHANOL IS CLEAR	
RELATED SUBSTANCE	TOTAL: NMT 1.0%	COMPLIES
	INDIVIDUAL: NMT	
	0.5%	
ASSAY BY HPLC	98.0% 102%	99.49%

REMARK: PRODUCT COMPLIES WITH USP 31 STANDARD

SPECIFICATION