

CERTIFICATE OF ANALYSIS

NAME OF THE PRODUCT: AMLODIPINE BESILATE USP 31

TEST	SPECIFICATION	RESULTS
APPERANCE	WHITE OR ALMOST WHITE POWDER	ALMOST WHITE POWDER
SOLUBILITY	SLIGHTLY SOLUBLE IN WATER,FREELY SOLUBLE IN METHANOL,SPARINGLY SOLUBLE IN ETHANOL,SLIGHTLY SOLUBLE IN 2-PROPANOL	SLIGHTLY SOLUBLE IN WATER,FREELY SOLUBLE IN METHANOL,SPARINGLY SOLUBLE IN ETHANOL,SLIGHTLY SOLUBLE IN 2-PROPANOL
IDENTIFICATION	A)INFRARED ABSOPRTION SPECTROPHOTOMETRY	COMPLIES
	B)TLC	COMPLIES
	C)SPECIFIC ABSORBANCE MAX 360 NM 113-121	116
OPTICAL ROTATION	- 0.10° TO + 0.10°	0°
RELATED SUBSTANCES BY		
1.TLC	IT SHOULD COMPLIES AS PESCRIBED TEST	COMPLIES
2.LIQUID CHROMATOGRAPHY		
a. IMPURITY D	NMT 0.3%	a. 0.09%
b. OTHER IMPURITIES	NMT 0.3%	b. 0.2%
WATER	NMT 0.5%	0.19%
SULPHATED ASH	NMT 0.2%	0.049
ASSAY (ANHYDROUS BASIS)	97.0% - 102%	99.3%