

**CERTIFICATE OF ANALYSIS**

**LOPERAMIDE USP31**

TEST	RESULT	SPECIFICATION
DESCRIPTION	WHITE POWDER	WHITE TO SLIGHTLY YELLOW POWDER
SOLUBILITY	COMPLIES	FREELY SOLUBLE IN METHANOL, IN ISOPROPYL ACOHOL AND IN CHLOROFORM. SLIGHTLY SOLUBLE IN WATER AND IN DILUTE ACIDS
IDENTIFICATION A. IR	COMPLIES	THE IR ABSORTION SPECTRUM OF THE PREPARATION OF THE SPECIMEN, EXHIBITS MAXIMA ONLY AT THE SAME WAVELENGTH AS THAT OF A SIMILAR PREPARATION OF THE CORRESPONDING LOPERAMIDE HYDROCHLORIDE REFERENCE STANDARD
UV	COMPLIES	BETWEEN 250 AND 300NM OF THIS SOLUTION EXHIBITS MAXIMA AND MINIMA AT THE SAME WAVELENGTH
LOSS ON DRYING	0.25	NOT MORE THAN 0.5
RESIDUE ON IGNITION (% W/W)	0.03	NOT MORE THAN 0.2
HEAVY METALS (%)	<0.002	NOT MORE THAN 0.002
CHROMATOGRAPHIC PURITY (BT TLC,%)	COMPLIES	NO SECONDARY SPOTS ARE OBSERVED
CHLORIDE CONTENT (% W/W)	13.96	BETWEEN 13.52 AND 14.20
ASSAY (BY TITRIMETRY, ON DRIED BASIS, % W/W)	99.60	NOT LESS THAN 98.0 AND NOT MORE THAN 102.0
ADDITIONAL TEST		
RESIDUAL SOLVENTS		
ACETONA	291	NOT MORE THAN 5000
METHANOL	139	NOT MORE THAN 3000
TOLUENE	NOT DETECTED	NOT MORE THAN 890
CHLOROFORM	NOT DETECTED	NOT MORE THAN 60
METHYLENE DICHLORIDE	NOT DETECTED	NOT MORE THAN 600

REMARK: THE PRODUCT COMPLIES AS PER USP SPECIFICATION