

CERTIFICATE OF ANALYSIS

PRODUCT NAME:	AMPHOTERICIN B (NON-STERILE)(INJ.)	CAS NO.:	139	.397-89-3	
ITEM	SPECIFICATION		RESULTS		
DESCRIPTION	YELLOW OR ORANGE POWDER.		CONFORMS		
SOLUBILITY	INSOLUBLE IN WATER, IN ANHYDROUS ALCOHOL, IN ETHER, IN BENZENE, AND IN TOLUENE; SOLUBLE IN DIMETHYLFORMAMIDE, IN DIMETHYL SULFOXIDE, AND IN PROPYLENE GLYCOL; SLIGHTLY SOLUBLE IN METHANOL.			CONFORMS	
IDENTIFICATION	UV: CONFORMS TO STANDARD; ABSORBANCE IN THE RANGE OF 240NM TO 320NM UV/VIS: CONFORMS TO STANDARD; ABSORBANCE IN THE RANGE OF 320NM TO 400NM			CONFORMS	
LOSS ON DRYING	NOT MORE THAN 5.0%		1.10%		
RESIDUE ON IGNITION	NOT MORE THAN 0.5%		0.20%		
LIMIT OF AMPHOTERICIN A	NOT MORE THAN 5% CALCULATED ON THE DRIED BASIS		NOT DETECTED		
BACTERIAL ENDOTOXIN	NOT MORE THAN 5EU/MG		CONFORMS		
MICROBIAL LIMIT	BACTERIAL COUNT: NOT MORE THAN 1000UFC/G FUNGUS COUNT: NOT MORE THAN 100CFU/G		CONFORMS		
ASSAY (MICROBIAL)	NOT LESS THAN 750UG/MG (ON DRIED BASIS)(C ₄₇ H ₇₃ NO ₁₇)			1094UG/MG	
CONCLUSION:	THE RESULTS CONFORM TO THE STANDARD OF USP30.				

STORAGE: PRESERVE IN WELL-CLOSED, LIGHT-RESISTANT AND TIGHT CONTAINERS.

STORE IN COOL & DRY PLACE.