



**CERTIFICATE OF ANALYSIS**

**MEROPENEM-R/SODIO CARBONATO**

<b>TEST</b>	<b>RESULTS</b>	<b>UNITS</b>
APPEARANCE	WHITE TO LIGHT YELLOW POWDER	
IDENTIFICATION (HPLC,SODIUM)	POSITIVE	-
APPEARANCE	COMPLIES	-
CLARITY (5% SOLN)	<=SUSPENSION I	FNU
COLOR (5% SOLN)	<=Y3	-
POTENCY	70.5 TO 76.4	% W/W
PH (5% SOLN)	7.3 TO 8.3	PH UNITS
RELATED SUBSTANCES		
- UK-1	<=0.5	% W/W
- UK-2	<=0.5	% W/W
LOSS ON DRYING	9.0 TO 12.0	%
SODIUM CARBONATE (HCL 0.2N)	14.7 TO 16.1	%
FOREIGN INSOLUBLE MATTER (DISSOLUTION TIME)	<=10	MINUTES
BULK DENSITY	0.2 TO 0.5	G/ML
TAP DENSITY	0.4 TO 0.7	G/ML
COMPRESSIBILITY	27 TO 50	%
FOREIGN PARTICLES		
- PARTICLES $\geq$ 10 MICRON	<=400	PARTICLES/G
- PARTICLES $\geq$ 25 MICRON	<=40	PARTICLES/G
STERILITY	COMPLIES	-
BACTERIAL ENDOTOXINS (LAL TEST)	<=0.125	EU/MG