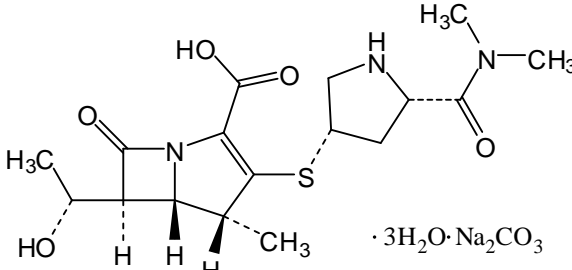


SPECIFICATIONS

Product Name	<p>Meropenem for Injection (with Sodium Carbonate Buffer)</p> 		
Molecular Formula	-	Molecular Weight	-
No.	Items	Specifications	
1	Description	A white or light yellow crystalline powder	
2	Constituted solution	Meets the requirements	
3	Identification 1) HPLC retention time	The RT for the Meropenem peak corresponds to that of the Standard.	
4	Bacterial endotoxins	Not more than 0.125 EU/mg of Meropenem	
5	pH	7.3 ~ 8.3 in a solution (1 in 20)	
6	Loss on drying	9.0 ~ 12.0%	
7	Particulate Matter 1) Particles: $\geq 10\mu\text{m}$ 2) Particles: $\geq 25\mu\text{m}$	Not more than 6,000 pc/g Not more than 600 pc/g	
8	Sterility	Sterile	
9	Chromatographic purity 1) Impurity (RRT 0.45) 2) Impurity (RRT 1.9)	Not more than 0.8% Not more than 0.6%	
10	Content of sodium	80 ~ 120% (labeled amount of Sodium) 5.2 ~ 7.8 % (Content of Sodium)	
11	Assay	90.0 ~ 120.0% [labeled amount of Meropenem($\text{C}_{17}\text{H}_{25}\text{N}_3\text{O}_5\text{S}$)] Not less than 77.0 % (As dried basis)	