Paclimed 300 mg
Paclitaxel injection USP 300mg/50ml



Module-V Clinical Study

COMMON TECHNICAL DOSSIER

Module 5- Clinical study report			
5.0	Clinical Study Report		
5.1	Table of content		
5.2	Tabular Listing of All Clinical Studies		
5.3	Clinical Study Reports		
	5.3.1	Reports of Biopharmaceutics Studies	
	5.3.1.1	Bioavailability (BA) Study Reports	
	5.3.1.2	Comparative Bioavailability (BA) and Bioequivalence	
		(BE) Study Reports	
	5.3.1.3	In vitro-In vivo Correlation Study Reports	
	5.3.1.4	Reports of Bioanalytical and Analytical Methods for	
		Human Studies	
	5.3.2	Reports of Studies Pertinent to Pharmacokinetics using	
		Human Biomaterials	
	5.3.3	Reports of Human Pharmacokinetic Studies	
	5.3.4	Reports of Human Pharmacodynamic Studies	
	5.3.5	Reports of Efficacy and Safety Studies	<u> </u>
	5.3.6	Reports of Post-marketing Experience	
	5.3.7	Case Report Forms and Individual Patient Listings	
5.4	Literature References		

Not applicable (not for generic products)