PRODUCT: CAPECITABINE

ITEMS	SPECIFICATIONS
IDENTIFICATION	a) Infrared Absorption b) The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the assay
CHARACTERISTICS	White or almost white powder
WATER	NMT 0.3%
SPECIFIC ROTATION	96.0º~100.0º
HEAVY METALS	NMT 20 ppm
RELATED COMPOUNDS ➢ **Capecitabine related compound A** ➢ **Capecitabine related compound B** ➢ **2´, 3´-Di-O-acetyl-5´-deoxy-5-fluorocytidine** ➢ **5´-Deoxy-5-fluoro-N4-(2-methyl-1-butyloxycarbonyl) cytidine+5´-Deoxy-5-fluoro-N4-(3-methyl-1-butyloxy carbonyl) cytidine** ➢ **[1-[5-Deoxy-3-O-(5-β-D-ribofuranosyl)- β-D- ribofuranosyl] -5-fluoro-2-oxo-1,2-dihydropyrimidin-4-yl]-carbamic acid pentyl ester**	 ≤ 0.3% ≤ 0.3% ≤ 0.1% ≤ 0.5% ≤0.3 %

➢ **[1-[5-Deoxy-2-O-(5-β-D-ribofuranosyl)- β-D- ribofuranosyl] -5-fluoro-2-oxo-1,2-dihydropyrimidin-4-yl]-carbamic acid pentyl ester** ➢ **Capecitabine related compound C** ➢ **[1-[5-Deoxy-2-O-(5-α-D-ribofuranosyl)- β-D- ribofuranosyl] -5-fluoro-2-oxo-1,2-dihydropyrimidin-4-yl]-carbamic acid pentyl ester** ➢ **2´, 3´-Di-O-acetyl-5´-deoxy-5-fluoro-N4-(pentyloxycarbonyl) Cytidine** ➢ **Individual unspecified impurity** ➢ **Total unspecified impurities** ➢ **Total impurities**	≤ 0.2 % ≤ 0.2% ≤0.3% ≤0.1% ≤0.1% ≤0.5% ≤1.5%
RESIDUAL SOLVENTS **a) Ethyl Acetate** **b) Methanol** **c) Isopropanol** **d) Chloromethane** **e) Toluene**	≤ 5000 ppm ≤ 3000 ppm ≤ 5000 ppm ≤ 600 ppm ≤ 890 ppm
PURITY	≥98.5%