

**CYCLOLAB**

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**PRODUCT SPECIFICATION**

Product name: **(2-hydroxy)propyl- β -cyclodextrin (DS=2 - 4)**

Quality: pharma grade

Aspects	Method	Specification
Identification	HPLC	conforms to Reference
Appearance	Visual inspection	white or off-white powder
Assay	HPLC	min 97 %
Unmodified β CD	HPLC	≤ 1.0 %
Degree of substitution*	NMR	2 - 4
Water content	Karl-Fischer titration	≤ 6.5 %
pH (2% aqueous solution)	Potentiometry	5.0 – 9.0
Volatile organics	GC	≤ 50 ppm
Heavy metals	USP	≤ 20 ppm
Residue on ignition	USP	≤ 0.1 %
Propylenglycol	GC	≤ 0.5 %
Clarity of solution (1.0g in 2.0mL water)	USP	clear solution
UV-active impurities (2% aqueous solution, 230-400nm)	UV	≤ 0.5 AU
Reducing substances	Ph.Eur.	≤ 1 %
Microorganism	Ph.Eur.	≤ 1000 CFU/g

* Number of hydroxypropyl substituents/cyclodextrin ring

Storage: at room temperature, in airtight container