

**CYCLOLAB**

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**PRODUCT SPECIFICATION**

Product name: **(2-hydroxy)propyl- $\beta$ -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 $\beta$ CD	HPLC	$\leq 1.0$ %
Degree of substitution*	NMR	2 - 4
Water content	Karl-Fischer titration	$\leq 6.5$ %
pH (2% aqueous solution)	Potentiometry	5.0 – 9.0
Volatile organics	GC	$\leq 50$ ppm
Heavy metals	USP	$\leq 20$ ppm
Residue on ignition	USP	$\leq 0.1$ %
Propylenglycol	GC	$\leq 0.5$ %
Clarity of solution (1.0g in 2.0mL water)	USP	clear solution
UV-active impurities (2% aqueous solution, 230-400nm)	UV	$\leq 0.5$ AU
Reducing substances	Ph.Eur.	$\leq 1$ %
Microorganism	Ph.Eur.	$\leq 1000$ CFU/g

\* Number of hydroxypropyl substituents/cyclodextrin ring

Storage: at room temperature, in airtight container