



## CYCLOLAB

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## PRODUCT SPECIFICATION

Product Name: **Heptakis(2,6-di-O-methyl)- $\beta$ -cyclodextrin (DIMEB-95)**

isomeric purity: > 95 %\*

Quality: pharma grade

Aspects	Method	Specification
Identification	IR, HPLC	conforms to reference
Aqueous solubility $t < +10^{\circ}\text{C}$ $t = +90^{\circ}\text{C}$	Visual inspection	>20 g /100 mL < 5 g /100 mL
Appearance	Visual inspection	white crystalline powder
Assay (methylated $\beta$ -cyclodextrin content)	HPLC	min 99 %
Isomer purity	HPLC	min 95 %
Related $\beta$ -cyclodextrin methylethers	HPLC	max 5%
Unmodified $\beta$ CD	HPLC	max 0.25 %
Degree of substitution	NMR	14 $\pm$ 0.2
Water content	Karl-Fischer titration	$\leq$ 6 %
pH (1 % aqueous solution)	Potentiometry	5.5 – 8.0
Volatile organics	GC	$\leq$ 100 ppm
Heavy metals	USP	$\leq$ 20 ppm
Residue on ignition	USP	$\leq$ 0.1 %
Clarity of a 20 % aqueous solution	Visual inspection	clear solution
UV-active impurities (2 % aqueous solution; 230-400 nm)	UV-VIS	$\leq$ 0.5 AU

\* content of heptakis(2,6-di-O-methyl)- $\beta$ -cyclodextrin species is at least 95 %

Storage: at room temperature, in airtight container