

### β-Cyclodextrin (β-CD), EP, USP/NF

- CAS No: 7585-39-9
- Empirical formula: C<sub>42</sub>H<sub>70</sub>O<sub>35</sub>
- Molecular weight: 1134.98

TEST	SPECIFICATION
Appearance	white or almost white, amorphous or crystalline powder
Solubility	sparingly soluble in water and in propylene glycol, practically insoluble in anhydrous ethanol and in methylene chloride
Identification	
Specific optical rotation	+160 to +164 (dried substance) (1% w/v in CO <sub>2</sub> -free water)
HPLC	has to confirm with reference material
Reaction with Iodine solution	positive
IR (USP/NF)	has to confirm with reference material
Reducing sugars	max. 0.2%
pH	5.0 to 8.0
α-CD content	max. 0.25%
γ-CD content	max. 0.25%
Sum of impurities other than α- CD and γ-CD	max. 0.5%
Light absorbing impurities	NMT 0.10 between 230-350 nm NMT 0.05 between 350-750nm (1% w/v in CO <sub>2</sub> -free water)

TEST	SPECIFICATION
Assay	98.0 - 101.0% dried substance (EP) 98.0 - 102.0% on anhydrous basis (USP/NF)
Colour and clarity of solution	clear and colourless
Loss on drying Water	max. 16% (EP) max. 14% (USP/NF)
Sulfated ash	max. 0.1%
Residual solvents	limits according to EP, USP/NF, ICH Q3C
Microbiological analysis: TAMC, TYMC, specific microorganisms (USP/NF)	tests and limits may vary depending on the use of the material
Storage conditions	in an airtight container

**Examples of API formulations containing β-CD, currently on the market\*:** Benexate, Cetirizine, Iodine, Nicotine, Nimesulde, Omeprazole, Piroxicam, Tiaprofenic acid