

### γ-Cyclodextrin (γ-CD), EP, USP/NF

- CAS No: 17465-86-0
- Empirical formula: C<sub>48</sub>H<sub>80</sub>O<sub>40</sub>
- Molecular weight: 1297.12

TEST	SPECIFICATION
Appearance	white or almost white, amorphous or crystalline, hygroscopic powder
Solubility	freely soluble in water, very slightly soluble in propylene glycol, practically insoluble in anhydrous ethanol and in methylene chloride. When dissolved in water, it forms a colloidal dispersion over time.
Identification	
Specific optical rotation	+174 to +180 (dried substance) (1% w/v in CO <sub>2</sub> -free water)
HPLC	has to confirm with reference material
IR	has to confirm with reference material
Reducing sugars	max. 0.2% (EP)
Reducing substances	max. 0.5% (USP/NF)
pH	5.0 to 8.0
α-CD content	0.5%
β-CD content	0.5%
Sum of impurities other than α-CD and β-CD	0.5 %

TEST	SPECIFICATION
Assay	97.0 - 102.0% dried substance (EP) 98.0 - 102.0% dried substance (USP/NF)
Colour and clarity of solution	clear Abs at 420 nm, NMT 0.20 (10% w/v in CO <sub>2</sub> -free water)
Loss on drying	max. 11.0%
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

Compared with α- and β-Cyclodextrins, γ-Cyclodextrin has a larger internal cavity, which leads to higher water solubility and greater bioavailability of the drug substance.

**Examples of API formulations containing γ-CD, currently on the market\*:** Minoxidil