

### β-Cyclodextrin 2-hydroxypropyl ether (HP-β-CD), EP, USP/NF

Synonyms: 2-Hydroxypropyl-β-cyclodextrin, Hydroxypropylbetadex

- CAS No: 128446-35-5, 940035-02-6, 136019-12-0
- Average molecular formula:  $C_{42}H_{70}O_{35} (C_3H_6O)_x, x=7 \cdot MS$
- Average formula weight: -

TEST	SPECIFICATION
Appearance	white or almost white, amorphous or crystalline powder
Solubility	freely soluble in water and in propylene glycol
Identification	
IR	has to confirm with reference material
Clarity of solution	Clear and colourless
Conductivity	max. $200 \mu S \cdot cm^{-1}$ (10% w/v in CO <sub>2</sub> -free water)
β-CD content	max. 1.5%
Propylene glycol	max. 2.5%
Propylene oxide	NMT 0.0001% (USP/NF)
Other single impurity	max. 0.25% (USP/NF)
Sum of other impurities	max. 1%

TEST	SPECIFICATION
Assay—Molar substitution (MS)	0.40 - 1.50
Loss on drying	max. 10.0%
Residual solvents	limits according to EP, USP/NF, ICH Q3C
Microbiological analysis: TAMC, TYMC, specific microorganisms, BET, sterility (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 HP-β-CD, currently on the market\*:** Aripiprazole, Cisapride, Hydrocortisone, Indomethacin, Levosimendan, Mitomycin, Posaconazole (POS) and Florfenicol (veterinary drug)