

Hydroxypropyl- β -Cyclodextrin (HP- β -CD), EP, USP/NF

- CAS No: 94035-02-6
- Average molecular formula: C₄₂H₇₀O₃₅ (C₃H₆O)_x, x=7·MS
- Average formula weight: -

TEST	SPECIFICATION	TEST	SPECIFICATION
Appearance	white or almost white, amorphous or crystalline powder	Assay—Molar substitution (MS)	0.40 - 1.50
Solubility	freely soluble in water and in propylene glycol	Loss on drying	max. 10.0%
Identification IR	has to confirm with reference material	Residual solvents	limits according to EP, USP/NF, ICH Q3C
Clarity of solution	Clear and colourless	Microbiological analysis: TAMC, TYMC, specific microorganisms, BET, sterility (USP/NF)	tests and limits may vary depending on the use of the material
Conductivity	max. 200 μ S·cm ⁻¹ (10% w/v in CO ₂ –free water)	Storage conditions	in an airtight container
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%		

Examples of API formulations containing HP- β -CD, currently on the market*: Aripiprazole, Cisapride, Hydrocortisone, Indomethacin, Levosimendan, Mitomycin, Posaconazole (POS) and Florfenicol (veterinary drug)