

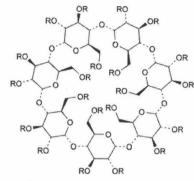
Hydroxypropyl-beta-cyclodextrin EP10.0

Batch no Mf date Expiry HB230607

Jun 23 2023 Jun 22 2026

Batch size

1320. 26 kg



Molecular Structure

 $R = -[CH_2-CH(CH_3)-O]_n-H$ n = 0, 1, 2...

Molecular Formula

 $C_{42}H_{70}O_{35}(C_3H_6O)_x$ with x = 7MS

CAS Registry Number

94035-02-6

Aug 18 2023

<u>Tests</u>	<u>Specifications</u>		Results
Appearance	White or almost white amorphous or crystalline powder		White amorphous powder
Solubility	Freely soluble in water & in propylene glycol		Conforms
Identification	IR		Positive
Appearance of solution	The solution is clear and colorless		Conforms
Conductivity	\leq 200 μ s/cm		61.5 μs/cm
Related substances	Impurity A	≤ 1.5%	0. 33%
	Impurity B (GC)	≤ 2.5%	0. 038%
	Sum of impurities other than A (HPLC)	≤ 1.0%	0.1%
Heavy metals	≤ 20 ppm		< 20 ppm
Loss on drying (120°C, 2hr)	≤ 10.0%		3. 2%
рН	5.0 ~ 7.5		6. 5
Microbiology	Total aerobic microbial count	≤ 1000 cfu/g	10 cfu/g
	Total yeasts and molds count	≤ 100 cfu/g	20 cfu/g
	Escherichia coli	Absent	Absent
	Salmonella	Absent	Absent
Assay	0.4 ~ 1.5		0. 68
(Molar substitution)			
Degree of substitution	2.8 ~ 10.5		4. 75
(7*Molar substitution)			
Dooleaning 0 ata	Preserve in tight and light-resistant containers.		
Packaging & storage	Store at room temperature.		
Conclusion	Material complies with EP10.0		^