

FICHE TECHNIQUE

(2-hydroxypropyl)- β -cyclodextrine
Ph. Eur., USP, pour usage parentéral

Ref : 37501

CAS [128446-35-5]

Formule : $C_{42}H_{70}O_{35}(C_3H_6O)_7$

P.M. : 1396

	<u>Spécifications</u>	<u>Méthode</u>
Identity	conforms	Ph. Eur., USP
Appearance		
-white or almost white	conforms	Ph. Eur., USP
Solubility		
-freely sol. H ₂ O and propylene glycol	conforms	Ph. Eur., USP
Molar substitution (MS)	0,40 - 1,50	Ph. Eur., USP
Appearance of solution	conforms	Ph. Eur., USP
Conductivity 10% solution	$\leq 200,0 \mu S/cm$	Ph. Eur., USP
Heavy metals (as Pb)	$\leq 20 ppm$	Ph. Eur., USP
Related substances		
- Impurity B	$\leq 2,5 \%$	Ph. Eur., USP
- Impurity A	$\leq 1,5 \%$	Ph. Eur., USP
- sum of all other impurities	$\leq 1,00 \%$	Ph. Eur., USP
- Any other single impurity	$\leq 0,25 \%$	Ph. Eur., USP
Loss on drying	$\leq 10,0 \%$	Ph. Eur., USP
Total aerobic count	$\leq 100 cfu/g$	Ph. Eur., USP
Moulds and yeasts	$\leq 100 cfu/g$	Ph. Eur., USP
Salmonella		
- Ausencia	conforms	Ph. Eur., USP
E. Coli		
- Ausencia	conforms	Ph. Eur., USP
Bacterial endotoxins	$\leq 10 IU/g$	Ph. Eur., USP
Propylene oxide	$\leq 1 ppm$	Ph. Eur., USP