



## Data regarding stability, compatibility and disposal of cytostatic solutions as to aseptic preparation

Name of the drug product	Endoxan 200 mg dry substance	Endoxan 500 mg dry substance	Endoxan 1 g dry substance	Endoxan 2 g dry substance
active ingredient (API)	Cyclophosphamide-Monohydrate			
Concentration of active ingredient if necessary in the reconstituted solution	20 mg/ ml (200 mg Cyclo anhydrous + 10 ml NaCl solution 0,9 %)	20 mg/ ml (500 mg Cyclo anhydrous + 25 ml NaCl solution 0,9 %)	20 mg/ ml (1 g Cyclo anhydrous + 50 ml NaCl solution 0,9 %)	20 mg/ ml (2 g Cyclo anhydrous + 100 ml NaCl solution 0,9 %)
storage temperature	< 25 °C			
light protection	no			
shelf life	36 months			
density	2 % solution 1.0110 g/ ml			
pH value	4.0 to 6.0			
carrier solution for infusions	Fructose solution 5 %	Glucose solution 5 %ig	NaCl solution 0,9 %	Ringer's lactate solution
concentration in carrier solution	individual dosing			
physico-chemical stability in carrier solution	increase of degradation resp. decrease of content: 0.3 % per day at < 8°C/ 1.2 % per day at at room temperature			
light protection of prepared solution	<b>recommendation:</b> apply within 24 h, because preparation does not contain any preservative  no			
physico-chemical stability after first opening	reconstituted solution: increase of degradation resp. decrease of content: 0.3 % per day at < 8°C/ 1.2 % per day at at room temperature			
stability of the product after non-proper storage	<b>recommendation:</b> apply within 24 h, because preparation does not contain any preservative  disposal			
applied stopper material	bromobutyl elastomer latex-free			
disposal/combustion/chemical deactivation	disposal according to each current national legal requirement for special waste German disposal code 180105D1			
contact with aluminum-containing materials/ contact with antioxidants	not known			

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