

Holding Times

Temperature 2-8 °C. Room temperature.

	Jan 01	Jan 02	Jan 03	Jan 04	Jan 05	Jan 06	Jan 07	Jan 08	Jan 09	Jan 10
^ Collapse All	Janu	Jan UZ	Jan US	Jan U 4	Jan UJ	Jan oo	Jan U <i>i</i>	Jan oo	Jan US	Jan 10
- Transport Time										
С	Removal of bags from deep freezer. → Start of thawing.									
Drug Substance										
М	Removal of vessel from deep freezer. → Removal of bag from thawer / 2-8 °C storage.									
Thawed Drug Substances in Closed Ba										
С	End of thawing. → Removal of bag from thawer / 2-8 °C storage.									
С	End of thawing. → Removal of bag from thawer / 2-8 °C storage.									
Bulk Drug Product Solution										
С	Start of compounding. → End of sterile filtration / filling.									
Compounding										
М	Removal of thawed drug substance from 2-8 °C. → End of microbial filtration.									
Prefiltered Bulk Drug Product Solution										
С	End of microbial filtration. → End of sterile filtration / filling.									
Sterile Filtration										
M	Start of microbial filtration. → End of sterile filtration / filling.									
Prefilled Syringe										
С				Start of filling	$oldsymbol{.} ightarrow Final$ storage at	2-8 °C.				
- Filling										

Start of filling. → End of sterile filtration / filling.