



External Communication 10-089

Drug Loading of DC Bead with Generic Irinotecan Solutions for Infusion (20mg/mL)

Summary

The drug uptake, bead size, pH and in vitro elution of DC Bead loaded with a generic irinotecan solution for infusion (Cell Pharm GmbH) and a proprietary irinotecan solution for infusion (Pfizer) have been compared. Both irinotecan products demonstrate the same physical and chemical characteristics when loaded and are compatible for use with DC Bead.

Manufacturer / Market Authorisation Holder	Product Name	Listed Excipients	Compatible for use with DC Bead
Pfizer Pharma GmbH, Germany	Campto® 20mg/mL	Sorbitol Ph. Eur (E420) Lactic Acid (E270)	YES
Cell Pharm GmbH, Germany	Irinotecan cell pharm® 20mg/mL	Sodium hydroxide (E524) for pH adjustment ¹ Water for Injection	YES

Table 1: Compatibility of Irinotecan Solution for Infusion with DC Bead

Other generic irinotecan solutions for infusion having the same listed excipient(s) in the formulation are expected to be pharmacologically and structurally identical to the irinotecan drug in the Campto® 20mg/mL solution (Pfizer). Given this, the generic drug will bind to the DC Bead in the same manner during the loading process, thus the physical and chemical characteristics of DC Bead when loaded with the generic irinotecan products are expected to be the same as the Pfizer product.

Other generic irinotecan solutions for infusion having the same listed excipient(s) in their formulations that have not been tested, may be considered to be compatible for use with DC Bead.

¹ Campto® 20mg/mL, Pfizer also lists hydrochloric acid as an excipient which is used for pH adjustment as necessary.