# Physical and Chemical Stability

**of DC Bead loaded with Doxorubicin (Adriblastin ® / Adriamycin® Pfizer), Epirubicin (Farmorubicin® Pfizer) and Irinotecan (Campto® Pfizer)**

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## Doxorubicin (Adriblastin® 50mg and Adriamycin® RDF powder)

Each 50mg vial of doxorubicin was reconstituted with 2mL of water for injection (25mg/mL, doxorubicin). The packing solution was removed from the contents of one DC Bead vial before a total of 3mL of reconstituted doxorubicin was added to the vial to obtain a target dose of 75mg doxorubicin/2mL DC Bead.

The table shows the physical and chemical stability (>95% doxorubicin purity) of the doxorubicin loaded DC Bead stored at 2-8°C. Microbiological stability is the responsibility of the user. DC Bead should be prepared under aseptic conditions.

| Physical and Chemical Stability | DC Bead * 100-700µm |
|---|---|
| Doxorubicin loaded DC Bead (75mg/2mL) | 14 days |
| Doxorubicin loaded DC Bead (75mg/2mL) mixed with 6 mL (Omnipaque 350/NaCl 0.9% - 50/50) | 7 days |

Stability of doxorubicin loaded DC Bead stored at 2-8°C

## Epirubicin (Farmorubicin® 50mg powder)

Each 50mg vial of Epirubicin was reconstituted with 2mL of water for injection (25mg/mL epirubicin).

The packing solution was removed from the contents of one DC Bead vial before a total of 3mL of reconstituted epirubicin was added to the vial to obtain a target dose of 75mg Epirubicin/2mL DC Bead.

The table shows the physical and chemical stability (>95% epirubicin purity) of the epirubicin loaded DC Bead stored at 2-8°C. Microbiological stability is the responsibility of the user. DC Bead should be prepared under aseptic conditions.

| Physical and Chemical Stability | DC Bead* 100-700µm |
|---|---|
| Epirubicin loaded DC Bead ( 75mg / 2mL) | 14 days |
| Epirubicin loaded DC Bead (75mg/2mL) mixed with 6mL(Omnipaque 350/NaCl 0.9% - 50/50) | 7 days |

Stability of epirubicin loaded DC Bead stored at 2-8°C

**Irinotecan (Campto® injection solution (100mg / 5mL))**

The packing solution was removed from the contents of one DC Bead vial before the contents of 1 vial of irinotecan 100mg/5mL (Campto®) was added to the vial to obtain a target dose of 100mg irinotecan/2mL DC Bead.

The table shows the physical and chemical stability (>95% irinotecan purity) of the irinotecan loaded DC Bead stored at 2-8°C. Microbiological stability is the responsibility of the user. DC Bead should be prepared under aseptic conditions.

| Physical and Chemical Stability | DC Bead*<br>100-700µm |
|---|---|
| Irinotecan loaded DC Bead ( 100mg / 2mL) | 14 days |
| Irinotecan loaded DC Bead mixed with<br>non- ionic contrast media | USE<br>IMMEDIATELY |

Stability of irinotecan loaded DC Bead stored at 2-8°C

Due to the tendency of contrast media to extract small amounts of irinotecan from DC Bead **we do not recommend the storage of DC Bead loaded with irinotecan and mixed with contrast**. This does not apply to doxorubicin or epirubicin.

**References**


847BB / 158 Chromatographic purity of Adriblastin
856BB / 074 Drug Uptake using Adriblastin®
863BB / 028 Drug uptake using Campto®
863BB / 039 Drug uptake using Farmorubicin®
863BB / 069 Drug Uptake using Adriamycin® RDF
864BB / 013 Chromatographic purity of in-vitro sample


* 100-300, 300-500, 500-700micron DC Bead was tested .Stability time lines were limited by the test duration and may not be indicative of instability after this period.