Physical and Chemical Stability of DC Bead® loaded with Doxorubicin Adriblastin®/Adriamycin® Pfizer) Epirubicin (Farmorubicin® Pfizer)

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.

<table>
<thead>
<tr>
<th>Physical and Chemical Stability</th>
<th>DC Bead® 100-700μm</th>
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</thead>
<tbody>
<tr>
<td>Doxorubicin-loaded DC Bead® (75mg/2ml)</td>
<td>14 days</td>
</tr>
<tr>
<td>Doxorubicin-loaded DC Bead® (75mg/2ml) mixed with 6ml (Omnipaque 350/NaCl 0.9% - 50/50)§</td>
<td>7 days</td>
</tr>
</tbody>
</table>

Stability of doxorubicin-loaded DC Bead® stored at 2-8 °C.
*100-300, 300-500, 500-700μm DC Bead® was tested. Stability time lines were limited by the test duration and may not be indicative of instability after this period.

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.

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References:
847BB/158 Chromatographic purity of Adriblastin,
856BB/074 Drug uptake using Adriblastin®
863BB/039 Drug uptake using Farorubicin®
863BB/069 Drug uptake using Adriamycin® RDF
864BB/013 Chromatographic purity of in-vitro sample

DC Bead® is manufactured by Biocompatibles UK Ltd,
Chapman House, Farmham Business Park, Weydon Lane,
Farnham, Surrey, GU9 8QL, UK. Biocompatibles UK Ltd is an BTG International group company. DC Bead is a registered trademark of Biocompatibles UK Ltd.
BTG and the BTG roundel logo are registered trademarks of BTG International Ltd. Adriblastin, Adriamycin and Farmorubicin are registered trademarks of Pfizer Inc.
DC Bead is not currently cleared by the FDA for sale or distribution in the USA.
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DC Bead®: Important information

DC Bead® Indications:
- DC Bead is CE marked and is indicated for the treatment of malignant hypervascular tumours and loading with doxorubicin drug
- DC Bead is also indicated for loading with irinotecan for the treatment of metastatic colorectal cancer (mCRC).
- Both indications may not be available in your territory

Cautions: Doxorubicin-loaded DC Bead®
- Embolisation with DC Bead should only be performed by a physician with appropriate interventional occlusion training in the region intended to be embolised
- Exceeding a loading dose of 37.5mg doxorubicin per 1ml DC Bead may lead to some systemic distribution of doxorubicin and related side effect

For instructions for use, please refer to
www.biocompatibles.com/dcbead.info

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Potential Complications:
1. Undesirable reflux or passage of DC Bead into normal arteries adjacent to the targeted lesion or through the lesion into other arteries or arterial beds
2. Non-target embolisation
3. Pulmonary embolisation
4. Ischaemia at an undesirable location
5. Capillary bed saturation and tissue damage
6. Ischemic stroke or ischemic infarction
7. Vessel or lesion rupture and haemorrhage
8. Neurological deficits including cranial nerve palsies
9. Vasospasm
10. Death
11. Recanalization
12. Foreign body reactions necessitating medical intervention
13. Infection necessitating medical intervention
14. Detachment at the tip of the catheter and subsequent dislodgement causing arterial thromboembolic sequelae