

HepaSphere™

Microspheres

Loading **HepaSphere Microspheres** with
Lyophilized Doxorubicin - 50 mg, 75 mg and 150 mg



A Step-by-Step Reference for Clinicians

HepaSphere™

Microspheres

50 mg
IN 1 VIAL

PREPARE IN BIOHAZARD HOOD

Supplies:

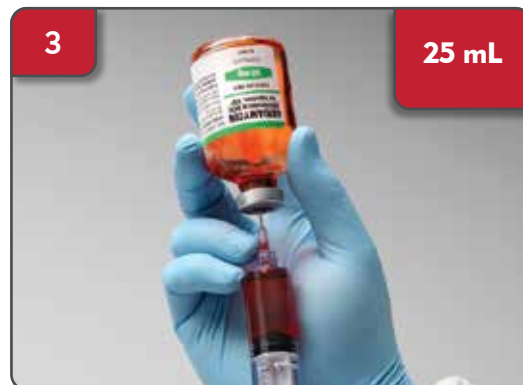
- 1 x doxorubicin 50 mg (in 25 mL) presolubilised vial at room temperature
- HepaSphere Microspheres vial
- 3 x 20G needles or larger (18G preferred)
- 1 x 30 mL syringe or larger
- 1 x syringe cap



Lift the cap from the **HepaSpheres Microspheres** vial, taking care NOT to remove the cap or the metal retaining ring from the vial.



Roll the **HepaSpheres Microspheres** vial several times to disperse microspheres.



With a 30 mL syringe and a new needle, withdraw 25 mL of presol doxorubicin. **Note:** Presol doxorubicin should be at room temperature.



Using a new needle, inject **10 mL** of the presol doxorubicin from Step 3 into the **HepaSpheres Microspheres** vial. **Note:** there may be a vacuum in the **HepaSpheres Microspheres** vial.



Gently rotate and invert the **HepaSpheres Microspheres** vial back and forth 5 to 10 times so that the liquid contacts the gray stopper. Let the vial stand for 10 minutes. Invert and shake every few minutes to continue mixing the spheres with the doxorubicin.



After the 10 minutes from Step 5, using a new needle, withdraw the entire contents of the **HepaSpheres Microspheres** vial into the 30 mL syringe containing the remaining doxorubicin solution (15 mL). (Do not attempt to extract every sphere.) Gently agitate the syringe back and forth to completely mix and disperse the contents.



Remove the needle and cap the syringe. Wait a minimum of 60 minutes to allow the **HepaSpheres Microspheres** to expand fully and load the doxorubicin. During the 60 minutes, the syringe should be inverted every 10-15 minutes to optimize the drug distribution into the spheres. **Note:** Let the presol doxorubicin and/or the reconstituted spheres solution with doxorubicin come to room temperature before use.

HepaSpheres™

Microspheres

150 mg
IN 2 VIALS

PREPARE IN
BIOHAZARD HOOD

Supplies:

- 3 x doxorubicin 50 mg powder vials
- 2 x HepaSpheres Microspheres vials
- 11 x 20G needles or larger (18G preferred)
- 2 x 20 mL syringes or larger
- 5 x 30 mL syringes or larger
- 6 x 10 mL vials preservative-free 0.9% sodium chloride for injection - **DO NOT USE STERILE WATER**
- 2 x syringe caps

Steps 1 & 2



Lift the cap from two **HepaSpheres Microspheres** vials to the vertical position taking care NOT to remove the cap or the metal retaining ring from the vials.



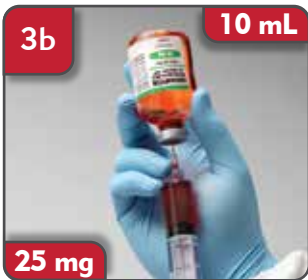
Roll the **HepaSpheres Microspheres** vials several times to disperse microspheres.

Step 3



Using a 30 mL syringe and a 20G needle, reconstitute one 50 mg doxorubicin vial with 20 mL preservative-free 0.9% sodium chloride.

DO NOT USE STERILE WATER



Using two new 20 mL syringes and new 20G needles, withdraw **10 mL** of doxorubicin (from Step 3a) into each of the two 20 mL syringes.



Vial 1

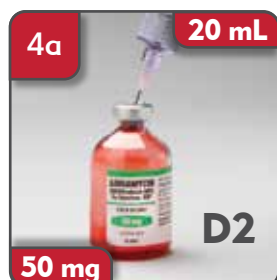
Vial 2



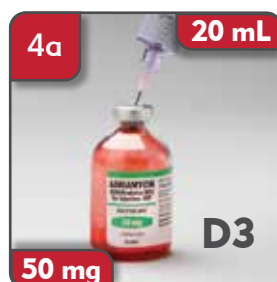
10 min.

Using a new 20G needle on each 20 mL syringe inject the entire contents of one syringe (10mL) into each of the **HepaSpheres Microspheres** vials. This results in 25 mg of doxorubicin in each of the two **HepaSpheres Microspheres** vials. **Note:** There may be a vacuum in the **HepaSpheres Microspheres** vial. Rotate and invert the **HepaSpheres Microspheres** vials back and forth so that the liquid contacts the gray stopper. Invert and shake every few minutes to continue to mix spheres with doxorubicin.

Step 4



D2 +
VIAL 1



D3 +
VIAL 2



Using new 30 mL syringes and new 20G needles, reconstitute 2 additional vials of 50 mg of doxorubicin with 20 mL preservative-free 0.9% sodium chloride in each vial.

**DO NOT USE
STERILE WATER**

Using two new 30 mL syringes and new 20G needles, withdraw the entire contents from each doxorubicin vial into one of the syringes. This results in 2 syringes containing 50 mg doxorubicin in 20 mL of fluid in each.

After the 10 minutes from Step 3c, using new 20G needles on each of these two 30 mL syringes, withdraw the entire contents of one of the **HepaSphere Microspheres** vials prepared in step 3 (vial 1 and vial 2) into each syringe from Step 4 (D2 and D3).

This results in two 30 mL syringes, each containing the contents of one **HepaSphere Microspheres** vial with 75 mg of doxorubicin in 30 mL of fluid.

Step 5



60 min.

Remove the needles and cap the syringes. **Note:** the time and wait 60 minutes to optimize the uptake of the doxorubicin into the spheres. Agitate every few minutes during loading. **Note:** Let the presol doxorubicin and/or the reconstituted spheres solution with doxorubicin come to room temperature before use.

HepaSphere™

Microspheres

75 mg
IN 1 VIAL

PREPARE IN BIOHAZARD HOOD

Supplies:

- 2 x doxorubicin 50 mg powder vial
- 3 x 30 mL syringes or larger
- 1 syringe cap
- 1 HepaSphere Microspheres vial
- 4 x 10 mL vials preservative-free 0.9% sodium chloride for injection - **DO NOT USE STERILE WATER**
- 6 x 20G needles or larger (18G preferred)



Lift the cap from the **HepaSphere Microspheres** vial to the vertical position taking care **NOT** to remove the cap or the metal retaining ring from the vials.



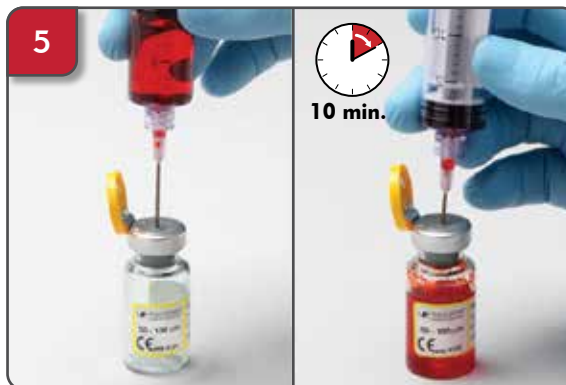
Roll the **HepaSphere Microspheres** vial several times to disperse microspheres.



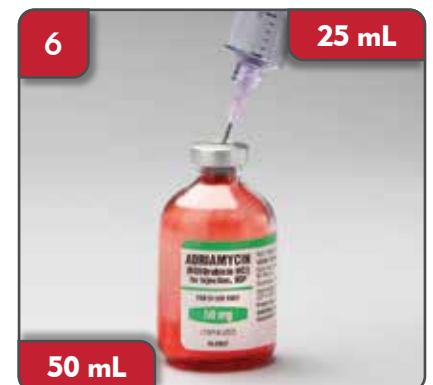
Using a 30 mL syringe and a 20G needle, reconstitute one 50mg doxorubicin vial with **20 mL** preservative-free 0.9% sodium chloride.



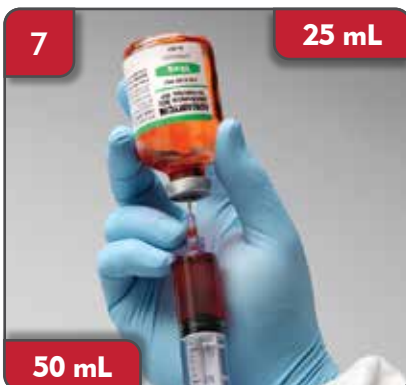
Using a new 20 mL syringe with a new 20G needle, withdraw **10 mL** of reconstituted doxorubicin (from Step 3) into the syringe.



Using a new 20G needle on the 20 mL syringe, inject the entire contents (10 mL) into the **HepaSphere Microspheres** vial. This results in 25 mg of doxorubicin added to the vial. **Note:** there may be a vacuum in the **HepaSphere Microspheres** vial. Rotate and invert the **HepaSphere Microspheres** vial back and forth 5-10 times so that the liquid contacts the gray stopper. Invert and shake every few minutes to continue to mix spheres with doxorubicin. Let the vial stand 10 minutes.



Using a new 30 mL syringe and a new 20G needle, reconstitute a second 50 mg doxorubicin vial with 20 mL preservative-free 0.9% sodium chloride.



Using a new 30 mL syringe with a new 20G needle, withdraw the entire contents the second reconstituted 20 mL vial of doxorubicin (from Step 6).



After the 10 minutes from Step 5, using a new 20G needle, withdraw the entire contents of the **HepaSphere Microspheres** vial (10 mL) into the syringe from Step 7. This results in a total of 75 mg of doxorubicin in 30 mL of fluid. (Do not attempt to remove every sphere.) Gently agitate the syringe to completely mix and dispense the contents. Remove the needle and cap the syringe. Note the time and wait 60 minutes to optimize the uptake of the doxorubicin into the spheres. Agitate every few minutes during loading.

Note: Let the presol doxorubicin and/or the reconstituted spheres solution with doxorubicin come to room temperature before use.



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