HepaSphere™
MICROSPHERES

Loading **HepaSphere** Microspheres with Lyophilized Doxorubicin

50mg

75mg

150mg

A Step-by-Step Reference for Clinicians

MERIT MEDICAL™

HepaSphere™
MICROSPHERES

50mg
IN 1 VIAL

Supplies

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

Prepare in Biohazard Hood

1



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 vial.

2



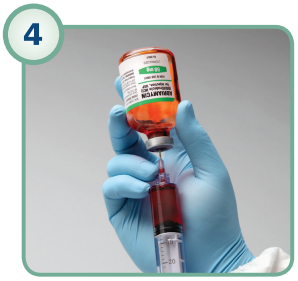
Roll the HepaSphere Microspheres vial several times to disperse microspheres.

3



Using a 30mL syringe and a 20G needle, reconstitute the 50mg doxorubicin vial with 20mL preservative-free 0.9% sodium chloride. **DO NOT USE STERILE WATER.**

4



Using a new 30mL syringe with a new 20G needle, withdraw 20mL (the entire contents) from the doxorubicin vial (50mg) prepared in Step 3.

5



Using a new 20G needle, inject 10mL of doxorubicin from Step 4 into the HepaSphere Microspheres vial. Note: there may be a vacuum in the HepaSphere Microspheres vial.

6



Rotate and invert the HepaSphere 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 to mix the spheres with the doxorubicin.



Wait 10 min.

7



After the 10 minutes from Step 6, using a new 20G needle, withdraw the entire contents of the HepaSphere Microspheres vial into the 30mL syringe containing the remaining doxorubicin (25mg/10mL) prepared in Step 4. This results in a total of 50mg of doxorubicin in 20mL of fluid. (Do not attempt to extract every sphere). Gently agitate the syringe to completely mix and disperse the contents.

8



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.



Wait 60 min.

HepaSphere™ MICROSPHERES

75mg IN 1 VIAL

Supplies

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

Prepare in Biohazard Hood

1



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.

2



Roll the HepaSphere Microspheres vial several times to disperse microspheres.

3



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

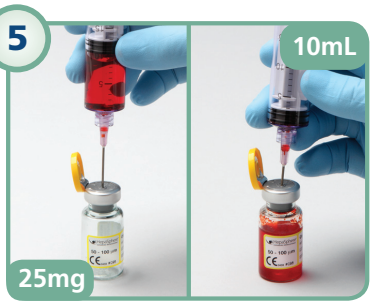
DO NOT USE STERILE WATER

4



Using a new 20mL syringe with a new 20G needle, withdraw 10mL of doxorubicin (D1) into the syringe.

5



Using a new 20G needle on the 20mL syringe, inject the entire contents (10mL) into the HepaSphere Microspheres vial. This results in 25mg 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.



Wait 10 min.

6



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

DO NOT USE STERILE WATER

7



Using a new 30mL syringe with a new 20G needle, withdraw the entire contents of second doxorubicin vial (20mL) (D2).

8



After the 10 minutes from Step 5, using a new 20G needle, withdraw the entire contents of the HepaSphere Microspheres vial (10mL) into the syringe from Step 7. This results in a total of 75mg of doxorubicin in 30mL 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.



Wait 60 min.

HepaSphere™ MICROSPHERES

Prepare in Biohazard Hood

Steps 1 & 2



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



Roll the HepaSphere Microspheres vials several times to disperse microspheres.

Step 3



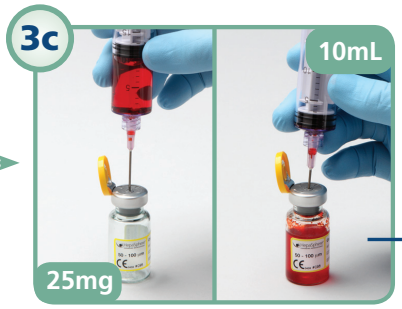
Using a 30mL syringe and a 20G needle, reconstitute one 50mg doxorubicin vial with 20mL preservative-free 0.9% sodium chloride.

DO NOT USE STERILE WATER

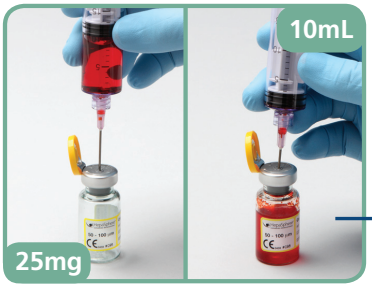




Using two new 20mL syringes and new 20G needles, withdraw 10mL of doxorubicin (from D1) into each of the two 20mL syringes.



VIAL 1



VIAL 2



Wait 10 min.

Using a new 20G needle on each 20mL syringe inject the entire contents of one syringe (10mL) into each of the HepaSphere Microspheres vials. This results in 25mg of doxorubicin in each of the 2 HepaSphere Microspheres vials. Note: There may be a vacuum in the HepaSphere Microspheres vial.

Rotate and invert the HepaSphere Microspheres vials back and forth so that the liquid contacts the gray stopper.

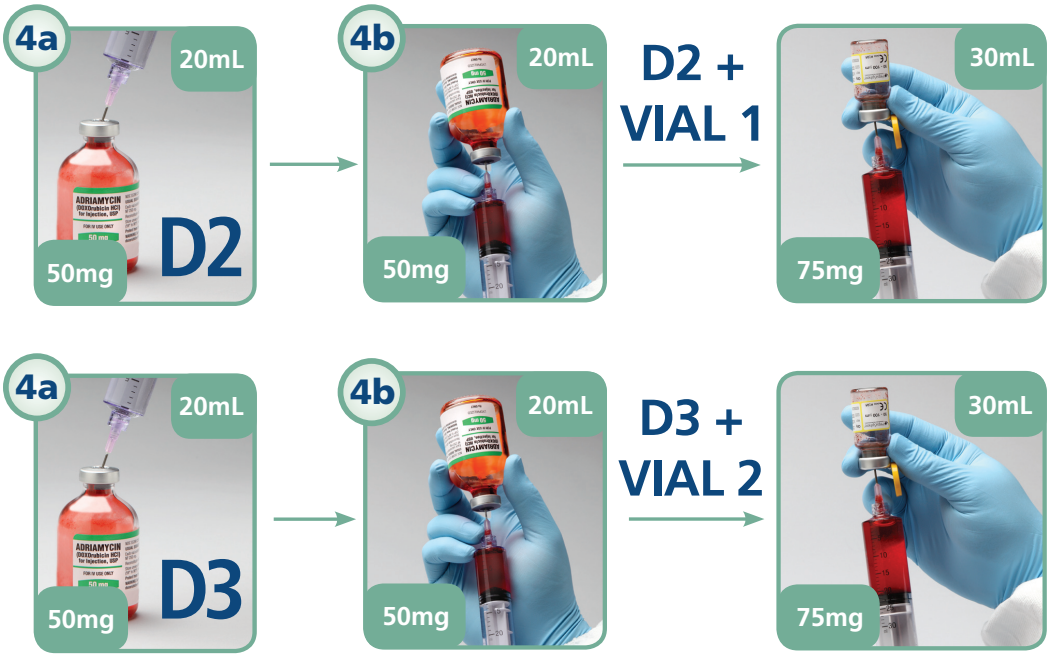
Invert and shake every few minutes to continue to mix spheres with doxorubicin.

Supplies

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

150mg in two vials

Step 4



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

DO NOT USE STERILE WATER

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

After the 10 minutes from Step 3c, using new 20G needles on each of these two 30mL syringes, withdraw the entire contents of one of the HepaSphere Microspheres vials prepared in step 3 (vial1 and vial2) into each syringe from Step 4 (D2 and D3).

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

Step 5



Wait 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.



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