

What is claimed is:

1. A method of reconstituting Annamycin, such method comprising:
adding pre-warmed saline to one or more containers of preliposomal Annamycin lyophilizate, to form suspended liposomal Annamycin with a concentration of 0.5-1.5 mg/mL;
maintaining said one or more containers at 24 -45 °C;
diluting said suspended liposomal Annamycin, with pre-warmed saline to provide diluted liposomal Annamycin at a concentration in saline of 0.3-0.7 mg/mL;
and
maintaining said one or more containers of suspended liposomal Annamycin and said diluted liposomal Annamycin at 24 -45 °C during and after the dilution.
2. The method of claim 1 wherein said suspended liposomal Annamycin has a concentration of approximately 1 mg/mL.
3. The method of claim 1 or 2 wherein the total weight of the diluted liposomal Annamycin is equal to the effective dose required.
4. The method of any one of claims 1-3 wherein the suspended liposomal Annamycin is diluted by adding it into a pre-warmed, saline-containing IV bag.
5. The method of any one of claims 1-4 wherein the pre-warmed saline is at a temperature of 30-45 °C.
6. The method of any one of claims 1-5 wherein the temperature of the suspended liposomal Annamycin is maintained at a temperature of 37 °C $\pm$ 4 °C before, during, and after dilution.
7. The method of any one of claims 1-6 wherein the diluted liposomal Annamycin has a concentration of approximately 0.5 mg/mL.
8. The method of any one of claims 1-7 wherein the suspension of liposomal Annamycin is maintained at or near 37 °C and the diluted liposomal Annamycin is maintained at or near 37 °C.
9. A method of preparing an effective dose of a reconstituted liposomal formulation of Annamycin, such method comprising:
warming syringes and non-PVC IV bags, each containing saline (about) 0.9% aqueous injection USP sodium chloride at 37 °C $\pm$ 4 °C for at least about three hours, in an oven or bag warmer, wherein the volume of saline in mL in a syringe is equal to the weight in mg of preliposomal lyophilizate Annamycin to be reconstituted, and
the volume of saline within said IV bag equivalent to the total amount of saline in all syringes, and
the volume of said IV bag is of sufficient capacity to contain the total volume of saline and liposomal Annamycin. for dilution of the total dose of liposomal Annamycin;
removing a sufficient number of vials containing preliposomal Annamycin lyophilizate to provide the desired total dose of Annamycin from the freezer and allowing the vials to stand at room temperature for 30 minutes to 2 hours;

vigorously shaking each vial of preliposomal lyophilizate Annamycin to break up any dry cake;
injecting air into each vial from air filled syringes until pressure in each vial is equalized;
adding a volume of $37^{\circ}\text{C} \pm 4^{\circ}\text{C}$ saline from a syringe kept at $37^{\circ}\text{C} \pm 4^{\circ}\text{C}$ in an oven to a vial containing a weight equivalent vial of preliposomal lyophilizate Annamycin such that the final Annamycin concentration is approximately 1 mg/mL, maintaining negative pressure throughout the addition of saline;

immediately shaking the vial back and forth vigorously by hand for 15 seconds, then placing the vial in a resealable polyethylene storage bag;

repeating the steps of adding saline, shaking the vial, and placing the vial in the storage bag until all vials required for the total dose of Annamycin are similarly prepared;

shaking, for a second time, all vials, 2-4 at a time for 1-2 minutes;

storing all vials of reconstituted liposomal Annamycin at $37^{\circ}\text{C} \pm 4^{\circ}\text{C}$ until ready for dilution, for 30 minutes up to 1 hour;

removing vials of reconstituted liposomal Annamycin from storage at $37^{\circ}\text{C} \pm 4^{\circ}\text{C}$ no more than two at a time, and after gently inverting each vial once, withdrawing a foam-free suspension from the vial while maintaining negative pressure throughout the withdrawal of the suspension;

introducing the withdrawn foam-free suspension of reconstituted liposomal Annamycin slowly into a pre-warmed non-PVC IV bag of saline, prepared as described above and repeating the steps for the second vial;

repeating the steps of removing the vials, withdrawing the suspension, and introducing the suspension into the pre-warmed IV bag until all vials of reconstituted liposomal Annamycin required for the total dose of Annamycin have been introduced into the non-PVC IV bag, providing an IV bag containing the final reconstituted liposomal Annamycin with a concentration of about 0.5 mg/mL; and

agitating the saline and reconstituted liposomal Annamycin in the IV bag by gently inverting the container several times, without generating foam.

10. A method of treating cancer comprising administering to a patient in need thereof an effective dose of diluted liposomal Annamycin, said diluted liposomal Annamycin prepared as in any one of claims 1-9.
11. The method of claim 10 wherein said liposomal Annamycin is prepared as in claim 5.
12. The method of claim 10 wherein said liposomal Annamycin is prepared as in claim 6.
13. The method of claim 10 wherein said liposomal Annamycin is prepared as in claim 8.
14. The method of any one of claims 10-13 wherein said patient is human and said cancer is selected from leukemias and lymphomas.
15. The method of claim 14, wherein said cancer is selected from the group consisting of acute myeloid leukemia (AML), chronic myeloid leukemia (CML), acute lymphocytic leukemia (ALL), chronic lymphocytic leukemia (CLL), Hodgkin lymphoma, and non-Hodgkin lymphoma.