

Notes:

- Gammagard SD may be reconstituted to a 5% or 10 % solution; verify the prescribed concentration ordered, prior to adding diluent.
- **Please Note: DO NOT USE MANUFACTURER PROVIDED TRANSFER DEVICE FOR 10 % CONCENTRATION; see below.**
- DO NOT reconstitute until venous access has been established.
- Reconstitute immediately before use.
- Reconstitute 1 vial at a time; prepare subsequent vials once brand tolerance has been established.
- Bring Gammagard SD to room temperature prior to reconstituting.

TABLE 1 Diluent Volume:

Concentration	5 gram vial	10 gram bottle
5 %	96 ml (entire content of SWFI vial)	192 ml (entire content of SWFI vial)
10 %	48 ml (partial content of SWFI vial)	96 ml (partial content of SWFI vial)

SWFI = sterile water for injection

Reconstitution Instructions for 10% Solution:

- 1) Clean the surface area used for mixing and preparation with isopropyl alcohol and then place a clean towel on it.
- 2) Set up the mixing supplies.
 - a) Gammagard SD vial(s)
 - b) Sterile water for injection (SWFI) vial(s)
 - c) 18 gauge needles
 - d) 60 ml syringes
 - e) Alcohol wipes

Discard the transfer device supplied in the Gammagard SD box.
- 3) Wash hands for at least 20 - 30 seconds with soap. Wash hands again anytime there is contact with a surface outside of the cleaned and prepared work area.
- 4) Bring Gammagard SD and SWFI to room temperature. If necessary, may hold vials in the hands or against the body to warm. Do NOT microwave or heat Gammagard SD or SWFI in any other manner.
- 5) Remove the protective caps from the vial(s) of Gammagard SD and SWFI to expose the rubber stoppers.
- 6) Clean the top of each vial with an alcohol wipe. Swipe in one direction away from you.
- 7) Attach 18 gauge needle to 60 ml syringe.
- 8) Place SWFI vial on a flat surface. Remove the protective cap from the needle. Pull back on the barrel of the syringe to fill the syringe with air to the 48ml mark (perform this and subsequent steps once for a 5 gm vial and twice [96 ml total] for a 10 gm vial)
- 9) Using anti-coring technique, insert the needle into the center of the rubber stopper of the SWFI vial at a 90 degree angle.
- 10) Invert the SWFI vial and inject the air a small amount at a time, into the SWFI vial; this will displace the SWFI with air to avoid the creation of a vacuum in the vial.
- 11) Remove the syringe/needle from the stopper of the SWFI vial.
- 12) Using anti-coring technique, insert the needle of the 60 ml SWFI-filled syringe into center of the rubber stopper of the Gammagard SD vial at a 45 degree angle. This will prevent the product from foaming as the SWFI flows along the walls of the glass bottle, rather than on the Gammagard SD concentrate.

- 13) There is a vacuum in the Gammagard SD vial(s); the SWFI will rapidly be pulled into the vial. Once all the SWFI has transferred, remove the needle from the stopper of the Gammagard SD vial(s). Discard the empty syringe/needle into the sharps container.
- 14) Thoroughly wet the dried material by tilting or gently rotating the vial.
- 15) DO NOT SHAKE VIALS TO AVOID FOAMING. It may take 20 - 40 minutes for the Gammagard SD to become fully dissolved. Gently swirl the vial on a flat surface until solution is clear.
- 16) Allow Gammagard SD vial to sit until it appears evenly distributed, clear, and fully dissolved.
- 17) Infuse directly from the Gammagard SD vial using a tubing with a filter size of at least 15 microns.
- 18) When using a Curlin 4000 or 6000 infusion pump, attach a vented spike adaptor to the Curlin tubing with a 1.2 micron filter. The vented spike will allow flow of drug and prevent a vacuum and upstream occlusion alarm.
- 19) Administer each Gammagard SD vial sequentially. Immediately before a vial is infused, swab the top of the vial with an alcohol swab (swipe in one direction away from you) and then insert the spike/tubing.

Reconstitution Instructions for 5% Solution:

- 1) Clean the surface area used for mixing and preparation with isopropyl alcohol and then place a clean towel on it.
- 2) Set up the mixing supplies.
 - a. Gammagard SD vial(s)
 - b. Sterile water for injection (SWFI) vial(s)
 - c. Transfer device supplied in the Gammagard Liquid box
 - d. Alcohol wipes

You may use the transfer device supplied in the Gammagard SD box.
- 3) Wash hands for at least 20 - 30 seconds with soap. Wash hands again anytime there is contact with a surface outside of the cleaned and prepared work area.
- 4) Bring Gammagard SD and SWFI to room temperature. If necessary, may hold vials in the hands or against the body to warm. Do NOT microwave or heat Gammagard SD or SWFI in any other manner.
- 5) Remove the protective caps from the vial(s) of Gammagard SD and SWFI to expose the rubber stoppers.
- 6) Clean the top of each vial with an alcohol wipe. Swipe in one direction away from you; allow to air dry, no fanning or blowing.
- 7) Remove the transfer device(s) from the packaging
- 8) Place SWFI vial on a flat surface. Remove the protective cap from one end of the transfer device and spike the rubber stopper of the Gammagard SD vial.
- 9) Remove the second protective cover from the opposite side of the transfer device; then spike the rubber stopper of the SWFI vial (the SWFI vial will be inverted during this step)
- 10) There is a vacuum in the Gammagard SD vial(s); the SWFI will rapidly be pulled into the vial.
- 11) Once all the SWFI has transferred, remove the transfer device with the empty SWFI vial attached and discard.
- 12) Thoroughly wet the dried material by tilting or gently rotating the vial.
- 13) Perform these steps for each vial of Gammagard SD requiring reconstitution to a 5% solution.
- 14) DO NOT SHAKE VIALS TO AVOID FOAMING. It may take 20 - 40 minutes for the Gammagard SD to become fully dissolved. Gently swirl the vial on a flat surface until solution is clear.
- 15) Allow Gammagard SD vial to sit until it appears evenly distributed, clear, and fully dissolved.
- 16) Infuse directly from the Gammagard SD vial using a tubing with a filter size of at least 15 microns.
- 17) When using a Curlin 4000 or 6000 infusion pump, attach a vented spike adaptor to the Curlin tubing with a 1.2 micron filter. The vented spike will allow flow of drug and prevent a vacuum and upstream occlusion alarm.
- 18) Administer each Gammagard SD vial sequentially. Immediately before a vial is infused, swab the top of the vial with an alcohol swab (swipe in one direction away from you) and then insert the spike/tubing.