Use appropriate aseptic technique when performing the following reconstitution st...

Health & Medicine, Alcoholism



Reconstitution: Reconstitute each 440 mg vial of Herceptin with 20 mL of Bacteriostatic Water for Injection (BWFI), USP, containing 1. 1% benzyl alcohol as a preservative to yield a multi-dose solution containing 21 mg/mL trastuzumab. In patients with known hypersensitivity to benzyl alcohol, reconstitute with 20 mL of Sterile Water for Injection (SWFI) without preservative to yield a single use solution.

Using a sterile syringe, slowly inject the 20 mL of diluent into the vial containing the lyophilized cake of Herceptin. The stream of diluent should be directed into the lyophilized cake.

Swirl the vial gently to aid reconstitution. DO NOT SHAKE.

Slight foaming of the product may be present upon reconstitution. Allow the vial to stand undisturbed for approximately 5 minutes.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Inspect visually for particulates and discoloration. The solution should be free of visible particulates, clear to slightly opalescent and colorless to pale yellow.

Store reconstituted Herceptin at 2—8° C; discard unused Herceptin after 28 days. If Herceptin is reconstituted with SWFI without preservative, use immediately and discard any unused portion.

Dilution

Determine the dose (mg) of Herceptin - see Dosage and Administration. Calculate the volume of the 21 mg/mL reconstituted Herceptin solution

https://assignbuster.com/use-appropriate-aseptic-technique-whenperforming-the-following-reconstitution-steps-essay-examples/ needed, withdraw this amount from the vial and add it to an infusion bag containing 250 mL of 0. 9% Sodium Chloride Injection, USP.

DO NOT USE DEXTROSE (5%) SOLUTION.

Gently invert the bag to mix the solution

ADMINISTRATION: Initial doses (loading), are infused over 90 minutes. Subsequent doses are infused over 30 to 60 minutes if tolerated. See Dosage and administration for additional info.

Stability and Storage: Vials of Herceptin are stable at 2–8°C (36–46°F) prior to reconstitution. Do not use beyond the expiration date stamped on the vial. A vial of Herceptin reconstituted with BWFI, as supplied, is stable for 28 days after reconstitution when stored refrigerated at 2–8°C (36–46°F). Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If visibly opaque particles, discoloration or other foreign particulates are observed, the solution should not be used.