PREPARING INJECTABLE MEDICATIONS

PURPOSE: The purpose of this Standard Operating Procedure (SOP) is to establish a standard procedure for the safe handling and storage of sterile, injectable products to ensure safe delivery of medication by injection or intravenous route.

SCOPE: Applies to all clinical research personnel who are registered practitioners authorized to administer injections and/or infusions within his/her scope of practice.

RESPONSIBILITY: Only registered clinical research personnel who have education, experience and training shall prepare medications for injection or infusion.

DEFINITIONS:

Aseptic technique: A set of specific practices and procedures performed under carefully controlled conditions with the goal of minimizing contamination by pathogens, agents that cause disease.

Investigator's Brochure (IB): A compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects. Its purpose is to provide the investigators and others involved in the trial with the information to facilitate their understanding of the rationale for, and their compliance with, many key features of the protocol, such as the dose, dose frequency/interval, methods of administration and safety monitoring procedures.

Investigational Product (IP): A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

Parenteral medication: Any medication that is administered by a route other than the digestive tract such as directly into a vein (intravenous), muscle (intramuscular), or subcutaneous tissue.

PROCEDURE:

1. General Preparation of Injectable Medications:

1.1 Prepare all injectable medications in a clean, uncluttered area on a clean surface separate from potentially contaminated items and surfaces.

1.2 Perform hand washing prior to accessing supplies, handling vials and IV solutions and preparing or administering medications.

PROCEDURE (cont.):

1.3 Check the following:
   a. Name of drug, strength, formulation and route of administration
   b. Expiration date
   c. Any damage to container, vials or packaging
   d. The medication has been stored according to package insert and Investigator's Brochure (IB)
   e. The formulation, dose, diluent and infusion rate of administration
   f. The subject's allergic status; question the subject if appropriate
   g. Method of preparation in accordance with package insert and IB

1.4 When necessary, calculate the volume of medication solution needed for prescribed dose.

1.5 Aseptic technique must be used to avoid contamination of sterile medications and injection equipment.

1.6 Use unopened needles and syringes only to ensure sterility.

1.7 Medications administered from a syringe will not be used for multiple research subjects, even if the needle or cannula on the syringe is changed. Needles, cannulae and syringes are sterile, single- use items.

1.8 Fluid infusion and administration sets (e.g. intravenous bags, tubing and connectors) will be used for one subject only and properly disposed after use. A syringe, needle or cannula will be considered contaminated once is has been used to enter or connect to a subject's IV port, intravenous infusion bag or administration set.

1.9 Single- dose vials for parenteral medications will be used whenever possible. Single-use medication vials labeled for use should not be punctured more than once as the sterility of the product cannot be guaranteed.

1.10 Multi-dose medications should be assigned to a single subject whenever possible. If multi-dose vials must be used, both the needle or cannula and syringe used to access the vial will be sterile.

1.11 Multi-dose vials with preservative, ophthalmic and reconstituted oral products will be dated when opened and discarded when recommended by the manufacturer or after **28 days**, **whichever comes first.**

1.12 Multi- dose vials without preservative must be discarded within **24 hours**.

1.13 Use opened vials of insulin within **28 days**. Exception to **28 day** disposal of opened multi-dose vials: Multi-dose Vaccine vials may be used until the expiration date on the vial if stored properly, not contaminated, and the manufacturer does not specify a shorter expiration date.

PROCEDURE (cont.):

1.14 Multi-dose vials will not be kept in the immediate research subject treatment area and will be stored in accordance with the manufacturer's recommendations; they will be discarded if sterility is compromised or becomes questionable.

1.15 Remaining contents from medication vials will not be combined with "like" solutions for later use.

1.16 All opened vials, IV solutions and prepared or opened syringes used in an emergency situation must be discarded.

1.17 Glucose monitoring devices will be thoroughly cleaned and disinfected between each use with an EPA-registered disinfectant (e.g.: Cavicide wipes).

1.18 Single-use retractable lancets will be used to obtain finger stick blood sample and disposed of after each subject use.

2. Withdrawing a Solution or Suspension from a Vial into a Syringe:

2.1 Remove the tamper-evident seal from the vial and wipe the rubber septum with an alcohol wipe. Allow to dry for 30 seconds.

2.2 With the appropriate sized needle, draw into the syringe a volume of air equivalent to the required volume of solution to be withdrawn.

2.3 Remove the needle cover and insert the needle into the vial though the rubber septum.

2.4 Insert the vial. Keep the needle in the solution and slowly depress the plunger to push the air into the vial.

2.5 Release the plunger so that the solution flows back into the syringe.

2.6 If a large volume of solution is to be withdrawn, use a push-pull technique (e.g.: repeatedly inject small volumes of air and draw up an equal volume of solution until the required total is obtained). This "equilibrium method" helps to minimize the build-up of pressure in the vial.

2.7 The tip of the vent needle must always be kept above the solution to prevent leakage.

2.8 With the vial still attached, invert the syringe with the needle and vial, tap the syringe lightly to aggregate the air bubbles at the needle end, and push the air back into the vial.

2.9 Fill the syringe with the required volume of solution in accordance with prescribed dose. Withdraw the needle from the vial.

2.10 Expel excess air from the syringe. Remove the needle from the syringe and fit new needle or sterile blind hub.

2.11 Keep the vial and any unused medicine until administration to the subject is

PROCEDURE (cont.):

complete.

2.12 If the vial contains a suspension rather than a solution, it should be gently swirled to mix the contents immediately before they are drawn into the syringe.

3. Reconstituting Powder in a Vial and Drawing the Resulting Solution or Suspension into a Syringe:

3.1 Remove the tamper-evident seal from the vial and wipe the rubber septum with an alcohol wipe. Allow to dry for at least 30 seconds.

3.2 Check the prescribed diluents for the reconstitution and the volume required.

3.3 Inject the diluents into the vial. Keeping the tip of the needle above the level of solution in the vial, release the plunger. The syringe will fill with air, which has been displaced by the solution (if the contents of the vial were packed under a vacuum, solution will be drawn into the vial and no air will be displaced). If a large volume of diluents is to be added, use a push-pull technique.

3.4 With the syringe and needle in place, gently swirl the vial(s) to dissolve all the powder, unless otherwise indicated by the product information. This may take a few minutes. Release the plunger so that the solution flows back into the syringe.

3.5 Withdraw the required volume of solution from the vial into the syringe.

3.6 Label the syringe if appropriate.

3.7 Keep the vial and any unused medicine until the administration to the subject is complete. This enables further verification to take place if required.

4. Adding a Medication to an infusion:

4.1 Check to ensure that the infusion solution is the prescribed fluid for which the medication is to be added.

4.2 Check the medication to be added against the prescription chart.

4.3 Prepare the medicine, as described in sections above.

4.4 Check the outer wrapper of the infusion container for any signs of damage.

4.5 Check the wrapper of the infusion container for any signs of damage.

4.6 Check the infusion container itself in good light to ensure that it is intact without evidence of leaks or punctures.

4.7 Visibly check the solution, which should be free of haziness, particles and discoloration.

4.8 When necessary, remove the tamper-evident seal on the additive port according to the manufacturer's instructions or wipe the rubber septum on the infusion container with an alcohol wipe and allow to dry for at least 30 seconds.

PROCEDURE (cont.):

4.9 Inject the medication into the infusion container through the center of the injection port, carefully keeping the tip of the needle away from the side of the infusion container. Withdraw the needle and invert the container at least 5 times to ensure thorough mixing before starting the infusion.

4.10 Do not add anything to the infusion container when hung on the infusion stand.

4.11 Check the appearance of the final infusion for absence of cloudiness, discoloration or particles.

4.12 Label the infusion in accordance with guideline.

5. Labeling Injectable Medicines/ Infusion Containers:

5.1 The person preparing the injectable medication must label the syringe and/or infusion container immediately after preparation.

5.2 A practitioner must not be in possession of more than one unlabeled syringe.

5.3 Labels must contain:

- Name of subject
- Name of drug or drugs mixed
- Dose of drug
- Volume
- Diluents, if used
- Date and time of preparation
- Signature/ initial of registered practitioner who performed preparation

REFERENCES:	Center for Disease Control (CDC) Safe Injection Practices to Prevent Transmission of Infections to Patients; CDC Safe Practices for Medication Preparation; CDC Safe Practices for Medication Administration, CDC Injection Safety
RELATED POLICIES:	
APPENDICES:	None

REVISION HISTORY: Keep a running history of all revision dates.

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