Ministry of Health King Saud Medical City Pharmaceutical Services Administration



2019 - 2020

INTRAVENOUS PREPARATION MANUAL TRAINING FOR NURSES

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Aseptic Technique Preparation of Compounded Sterile Product

The goal of using specific cleanroom equipment and procedures for proper aseptic technique is to allow the manipulation of sterile products without contamination with microorganisms, pyrogens, and particles. Room air typically contains many thousands of suspended particles per cubic foot, most of which are too small to be seen with the naked eye, including contaminants such as dust, smoke, and bacteria.

Parenteral compounding procedure in the ward :

- Proper hand hygiene.
- Wear sterile gloves and apply 70% isopropyl alcohol.
- Clean the workbench or table surface (stainless steel table) with 70% isopropyl alcohol
- Collect the substances that must be compounded, no more than three components.
- Check the expiration dates of all substances.
- Check any leaks in the bag.
- Sterilize top of vials (puncture surfaces) with alcohol wipes three times in the same direction.
- Draw a volume of air into the syringe that is equal to the volume being replaced.
- Puncture the vial with proper 45 to 60-degree angles using a downward pressure while the vial is placed on a flat surface, move the needle to a 90-degree angle
- Invert the vial and pull back on the plunger to fill the syringe, trapping it so that any air bubbles come to the top.
- Transfer the solution into the final container.

• 1- Personnel aseptic procedure:

Touch is the most common method of contamination of CSP (Compounded Sterile Products).

* Steps to reduce the possibility of touch contamination:

- 1- Scrub hands, nails, wrists, and forearms thoroughly for at least 30 seconds using warm water and appropriate bactericidal soap before performing aseptic manipulation
- 2- Wash hands frequently, especially upon leaving and returning to the compounding area. Must be the last step done before wearing sterile gloves.
- 3- Disinfect gloves frequently with 70 % isopropyl alcohol.

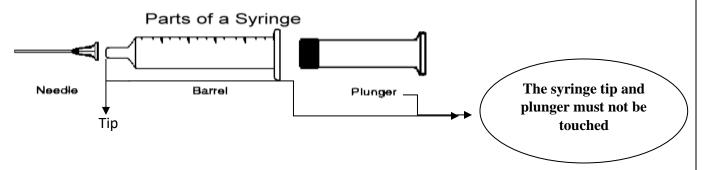


2-Aseptic Technique Using Needles and Syringes:

Three Main Parts of a Needle Don't Touch

Syringe:

Parts of a Syringe:



Syringe Sterility:

- A. Two parts of the syringe must not be touched, the tip and the plunger.
- B. Discard syringes if their packages are damaged/opened.

Attaching Needles to Syringes:

Insert the needle hub onto the tip of the syringe carefully to a convenient position using both hands. The user's finger should be held far back from the point of the needle-syringe attachment.



Removing Air Bubbles from a Syringe:

It is a common problem that air may also be drawn in the syringe.

To remove the air bubbles, please do the following:

- 1. Hold the syringe in a vertical position
- 2. Pull the plunger back a short distance
- 3. Firmly, tap the barrel of the syringe with the fingers or knuckles.

3-Proper aseptic Manipulation of Vials and Ampoules:

A) Vials:

All vials should be cleaned with 70% isopropyl alcohol spray and swab the top three times in the same direction with 70% isopropyl alcohol and allow it to dry before you start the preparation.

Washing/ swabbing specifications:

- 1. The isopropyl alcohol acts as a disinfecting agent
- 2. The physical of swabbing acts in one direction to remove any particles from the vial.

Reconstitution of Powder within a Vial:

Reconstitution will be performed if the medication is in a powder form by using the following:

- 1. Add the volume of diluents, such as Sterile Water for Injection (SWFI), or the drug diluents recommended in medication leaflet
- 2. After adding the diluents, remove an equivalent volume of air (vacuum formation) to prevent any positive pressure that might be developed inside the vial. This is accomplished by allowing the air to flow into the syringe before removing the needle from the vial.
- 3. Even though many drugs can be dissolved by rapidly shaking, the complete dissolution of the drug powder verification should be done. This can be obtained by having a clear or particle-free solution before proceeding further manipulations.



B) Ampoules:

• Procedure for opening an ampoule:

- 1- Clean the ampules with 70% isopropyl alcohol spray.
- 2- Slightly rotate the ampoule to exert the pressure to a weaker point.
- 3- Swab ampoule neck by 70% isopropyl alcohol.
- 4- The ampoule head should be held between the thumb and index finger of one hand while the ampoule body should be held using the thumb and index finger of the other hand.
- 5- The pressure should be exerted on both thumbs by pushing away from oneself in a quick motion to snap open the ampoule.

• Proper use of the filter needle

- 1- Using a filter needle is recommended as the glass will fall into the solution during the ampoule breaking.
- 2- Withdraw the drug from the ampoule by a filter needle.
- 3- Change the filter needle to a regular needle, then push the drug out of the syringe.
- 4- Use the recommended filter needle, such as a filter size of 5 microns in its hub.

4- Pharmaceutical calculations:

• Conversion of units:

1 kg	1000 gram		
1 gram	1000 mg		
1 mg	1000 μg		
1 kg	2.2 pound		
1 liter	1000 ml		
1 dL	100 ml		
1 hr	60 min		
1 min	60 sec		

To convert a larger unit into a small unit: Multiply

To convert a small unit into a larger unit: **Divide**

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• Reconstitution of medications in a powder form:

- 1- Check the IV manual on the KSMC portal or medication leaflet to know how many ml to dilute the powder for each medication.
- 2- Some medication needs shaking the vial to dissolve the powder, and some medication not allowed to shake; you can be found this information in IV manual or medication leaflet.

For example, *Azithromycin 500mg* in a powder form, after check the IV manual, we need to dilute it in 4.8ml sterile water for injection.

• Volume Required:

Examples:

Physician order to administer 500mg of injectable medicine A. the available strength is 100mg/ml. How many ml is to be administered?

Answer:

(500mg×1ml)÷ 100ml= 5ml

Infusion rate:

Examples:

The physician order For insulin 100 unit in 250ml normal saline to be infused IV over 4 hours. How many ml/min to be infused?

Answer:

250ml \div 4 hrs= 62.5 ml/hr, but we want it in min

62.5ml ÷ 60 min (1h)= 1.04 ml/min



5- Inspections the final preparation:

- 1- Squeeze the final product if it is blastic bottles or bags to check the leaks.
- 2- Visually examined the final product for the presence of particulate matter against the light. Do not dispences if particulates are observed.

6- The expiry date of the final preparation:

- According to the standard USP797, we should use (beyond use date (BUD)); all the
 preparations that are prepared outside the ISO class 5 the maximum expiry date inroom temperature or in the refrigerator will be 4 hours only, after 4 hours, the product
 should be discarded.
- If the medication leaflet mansion the expiry date less than 4 hours, we should follow the shortest expiry date.

7- Store the final preparation:

Check the IV Manual or medication leaflet to see the appropriate storage.

Very important to check the IV Manual on the KSMC portal for the medication compatibility.

References:

1-Joint Commission on Accreditation of Healthcare Organization (JCAHO) 20082-USP General Chapter 797 Pharmaceutical Compounding Sterile Preparations 2019

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COMPETENCE CHECKLIST FOR NURSES HANDLING INTRAVENOUS MEDICATION

Name of Employee assessed / ID:			Date:	
The qualified evaluator will check each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed*			NO	COMMENT
1.	Presents in clean appropriate attire and manner			
2.	Wear no cosmetics or jewelry (watches, rings, earrings, etc.; piercing jewelry included)			
	upon preparations.			
3.	. Completes the Hand Hygiene, Garbing, and Gloving Assessment Forms			
4.	l. Performs proper hand hygiene, garbing, and gloving procedures according to SOPs			
5.	5. At the beginning of each preparation, cleans the work surface prior to compounding			
6.	11 1 0			
7.	Disinfects components/vials with an appropriate agent prior to placing it into the work surface.			
8.	B. Ensures syringes, needles, and tubing remain in their individual packaging and are only opened in the work area			
9.	Do not expose critical sites to contact contamination.			
10.	10. Disinfects stoppers, injection ports, and ampoule necks by wiping with sterile 70% IPA and allows sufficient time to dry.			
11.	11. Affixes needles to syringes without contact contamination			
	12. Punctures vial stoppers and spikes infusion ports without contact contamination			
13. Disposes of sharps and waste according to institutional policy or recognized guidelines				
	14. Check the expiry date of all substances			
15.	15. Check any leakage in the piggy-bag			
16.	16. Correctly performs all calculation prior to admixture preparation			
17.	17. Demonstrates an understanding of the volume of IV solutions needed for medications.			
18.	18. Minimize positive pressure in vials during reconstitution or withdrawal of medication.			
19.	19. Demonstrates correct use of appropriate transfer devices (filter needles, vented needles, and syringes)			
20.	20. Demonstrates knowledge of the multiple-dose vials after initial entry (e.g., storage, beyond-use date).			
21.	21. Demonstrates knowledge of the difference between single-dose vials and multiple-dose vials.			
22.	22. Demonstrates knowledge of the use of ampoules. (does not retain after use).			
23.	23. Verifies the correct amounts of solutions and additives before injecting it into the			
containers. Ensure that contents of containers are thoroughly mixed.				
24. Inspects the final admixture for incompatibilities, cores, particulate matter, and other defects.				
* The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking checkmarks, N/A, or N/O) and shown and informed of specific corrections.				
Name and Signature of Employee Assessed Name and Signature of Qualified Evaluator		valuator		