

Preparing Sterile Formulations

Sterile Formulations

- Parenterals: Sterile Formulation
- LVP Solutions
- SVP Solutions
- Special Solutions
- Laminar Flow Hoods
- Biological Safety Cabinets
- Clean Rooms
- Aseptic Techniques in Hoods & Cabinets
- Working with vials
- Working with ampules
- Syringes & needles
- Filters
- Administration devices
- Parenteral incompatibilities
- Quality assurance & Infection Control
- Units of measurement

Parenteral Sterile Formulations

The IV route of administration is used:

- To reach appropriate drug serum levels.
- To guarantee compliance.
- For drugs with unreliable gastrointestinal (GI) absorption.
- For the patient who can have nothing PO.
- For the patient who is unconscious or uncooperative.
- For rapid correction of fluid or electrolytes.

IV Solutions

- The vehicles most commonly used for IV infusions are:
 - Dextrose in water (D5W)
 - NS solution.
 - Dextrose in saline solution.
- The two main types of IV solutions are:
 - Small-volume parenterals (SVPs) of 50 or 100 ml.
 - Large-volume parenterals (LVPs) > than 100 ml.

Characteristics of IV Preparations

- Intravenous (IV) preparations are either:
 - Solutions (in which ingredients are dissolved).
 - Suspensions (in which ingredients are suspended).
- Most parenteral preparations are made of ingredients in sterile water .
- Some parenteral preparations may be oleaginous (oily).

Intravenous Preparations

- Most parenterals are introduced **directly** into the bloodstream
- Must be **free of air bubbles** or **particulate matter**.
- The solution must be stable for its intended use.
- Must be **PYROGEN** free.
 - Chemicals that are produced by microorganisms.
 - Soluble in water and **NOT** removed by sterilizing or filtering the solutions.

Characteristics of IV Preparations

- An **isotonic solution** is a solution in which body cells can be bathed without a net flow of water across a semipermeable membrane.
 - 0.9% normal saline (NS).
- A **hypertonic solution** has greater than normal tonicity.
 - 50% dextrose or 3% sodium chloride.
- A solution of less than normal tonicity is **hypotonic**.
 - 0.45% NS.

Intravenous Formulations

- **Osmotic Pressure**

- The characteristics of a solution determined by the number of particles dissolved in it.

- **Osmolality**

- A unit of measure of osmotic pressure.
- Blood has 300 mOsmol per liter.
- Both NS and D5W solutions have a similar osmolarity.

Characteristics of IV Preparations

- The **pH value** is the degree of acidity or alkalinity of a solution.
 - Acidic solution: pH of less than 7.
 - Alkaline solution: pH value more than 7.
- **Human blood plasma has a pH of 7.4.**
 - Slightly alkaline.
 - Parenteral IV solutions should have a pH that is neutral (near 7).

Methods of Injection

- A **bolus injection** is one of the most common routes of IV administration.
- The injection is performed using a **syringe**.
 - Prepackaged in the form of filled syringes.
 - Injectable drug must be taken up into the syringe from a vial, or from a glass ampule.
- Sometimes the solid drug in the vial has to be reconstituted by addition of a liquid before use.

Methods of Injection

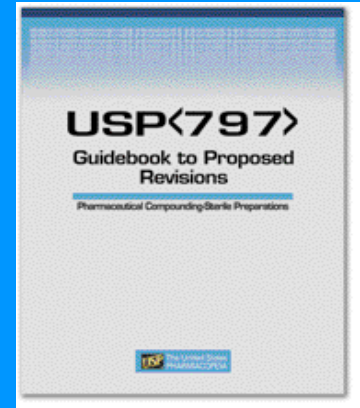
- **IV infusions** deliver:
 - Large amounts of liquid into the bloodstream over prolonged periods of time.
- IV infusion is used to deliver:
 - Blood
 - Water
 - Electrolytes
 - Drugs
 - Nutrients

Large Volume Solutions

- Packaged in containers holding **100 ml or more.**
- The most common sizes:
 - 100, 250, 500, and 1,000 ml.
- Common LVP solutions:
 - Sodium Chloride, Dextrose, Ringers Solution.
- Containers:
 - **Plastic bags:** Less weight, more compact storage, disposable.
 - **Glass bottle:** Good for drugs that interact with plastic bags. E.g. Nitroglycerin, amiodarone.

Regulatory Requirements

- Both USP and FDA have regulations.
- **Chapter of USP <797>:**
 - Pharmaceutical Compounding Sterile Preparations established requirements for the aseptic preparation of sterile dosage forms.
 - Intent is to **prevent infection and contamination.**
 - Provides guidelines for development of policies and procedures for the safe preparation of sterile preparation.



Common LVP Solutions

- Four common solutions used as LVP solutions or as the primary part of an admixture solution are:
 - Sodium chloride solution
 - Dextrose solution
 - Ringer's solution
 - Lactated Ringer's solution
- Various combinations of different strengths of sodium chloride and dextrose solutions are also available.
 - E.g., 5% dextrose and 0.45% sodium chloride, or 5% dextrose and 0.225% sodium chloride.

Small Volume Solutions

- **SVP solutions** are 100 ml or less.
 - Primarily used for delivering medications.
 - Ampules, Prefilled syringes, Single or Multidose vials.
- **Additive:** a drug that is added to a parenteral solution.
- **Admixture:** the resulting solution when a drug is added to a parenteral solution.

Small Volume Solutions

- **Lyophilized** – freeze dried powders
- **Diluent** – solvent used to reconstitute a powdered drug
- **Ready-to-mix systems** - Add-Vantage®, Add-a-Vial®, Mini-Bag Plus®



Total Parenteral Nutrition (TPN)

- Provide **nutritional support** to patients who are unable to take in adequate nutrients through their digestive tract.
- Contains **macro and micro nutrients**.
 - **Macronutrients:** dextrose, fat, and protein.
 - **Micronutrients:** electrolytes, vitamins, and trace elements.
 - **Lipid emulsion** may be added.
- Available in 2 or 3 Liter sizes.
- Administered via the **subclavian vein** over 8-24 hours.

Dialysis Solutions

- **Dialysis** - the passage of small particles through membranes.
- **Renal dialysis** – artificial kidney
- **Peritoneal dialysis** – a solution placed in and emptied from the peritoneal cavity to remove toxic substance from the body.

Irrigation Solutions

- Not administered IV but are subject to the same stringent controls as IV fluids .
- Container size, usually larger than 1 liter.
- **Surgical irrigation** solution used.
 - To bath and moisten body tissue, dressing, or wash instruments.
- **Urological irrigation solution** used
 - To maintain tissue integrity, remove blood, maintain a clear field of vision.
 - E.g. Glycine 1.5%, Sorbitol 3%

Laminar Flow Hoods

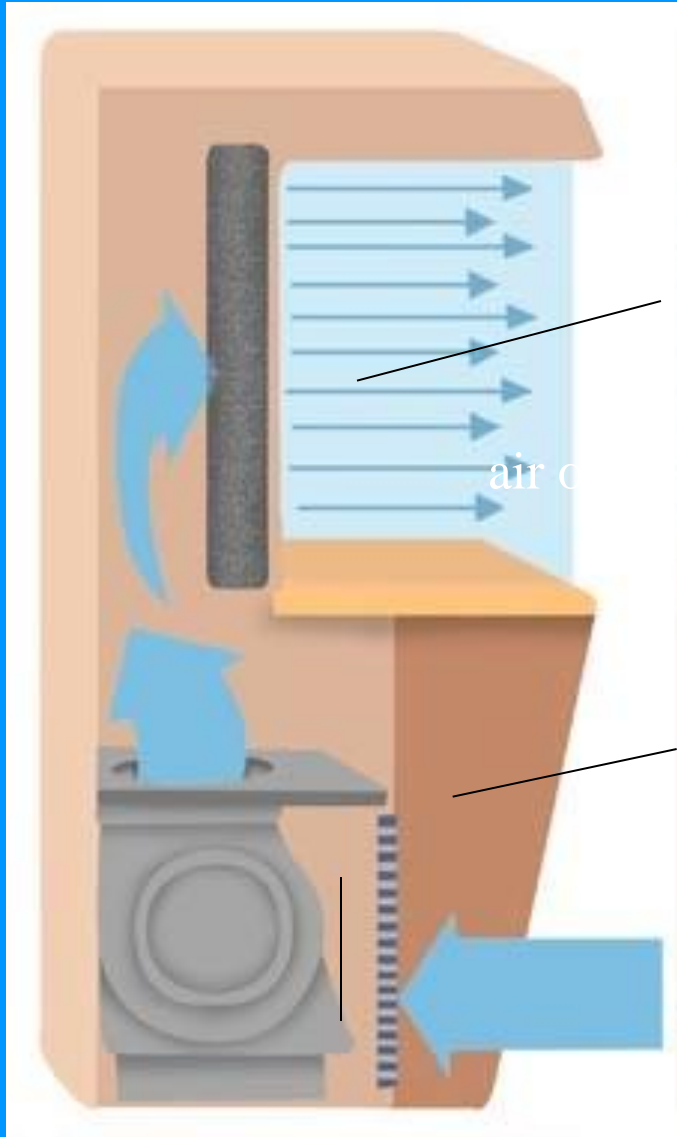
- Carefully enclosed work area designed to prevent contamination.
- Air is drawn through a high efficiency particulate air (**HEPA**) filter that removes particles larger than 0.5 microns.
- The purified air flows over the work surface at a uniform velocity (i.e. **laminar flow**) of 80-100 ft./min.
- The cabinet is usually made with no gaps or joints where spores might collect.

Laminar Flow Hoods

The surfaces of the hood's work area are CLEAN, but NOT sterile.

It is necessary to use techniques which maintain the sterility of all sterile items called aseptic techniques.

Laminar Flow Hood



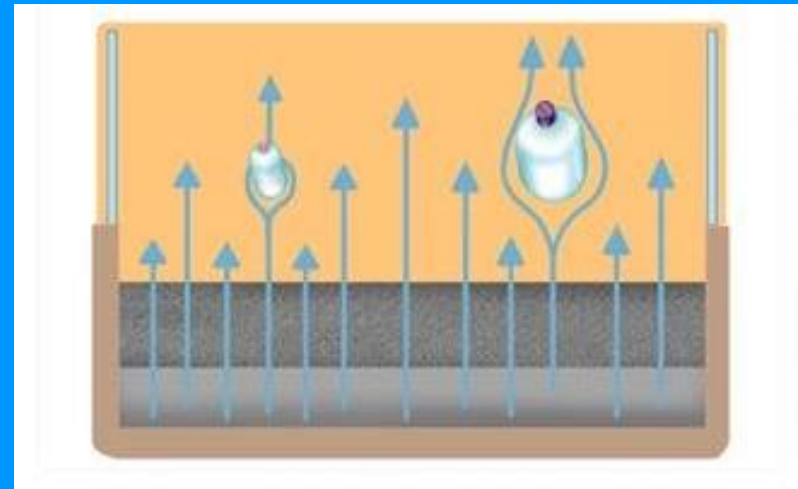
HEPA filter

air out

intake filter

air in

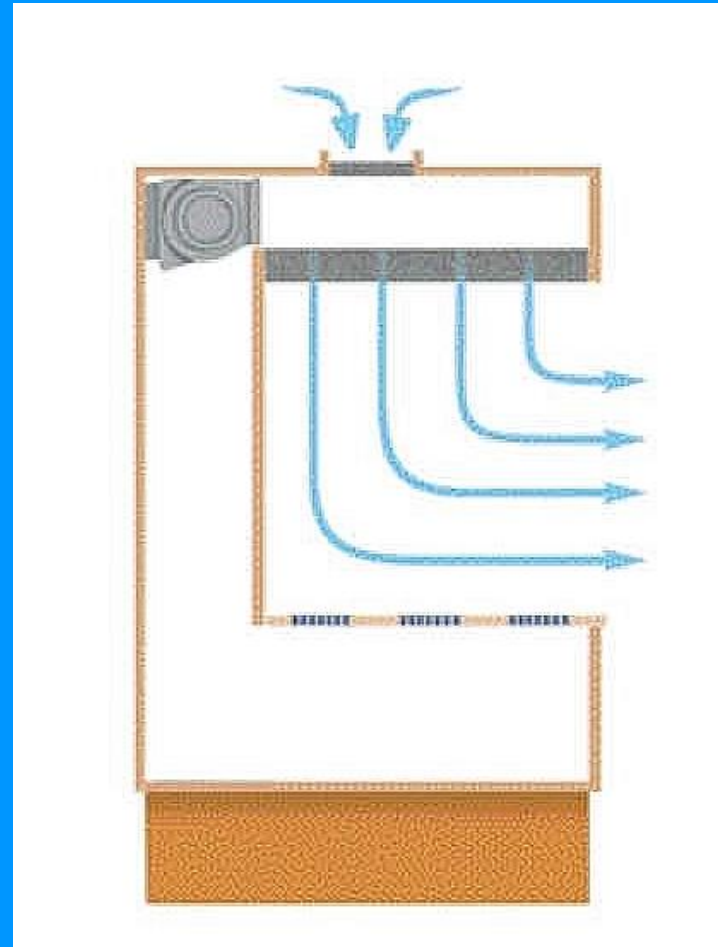
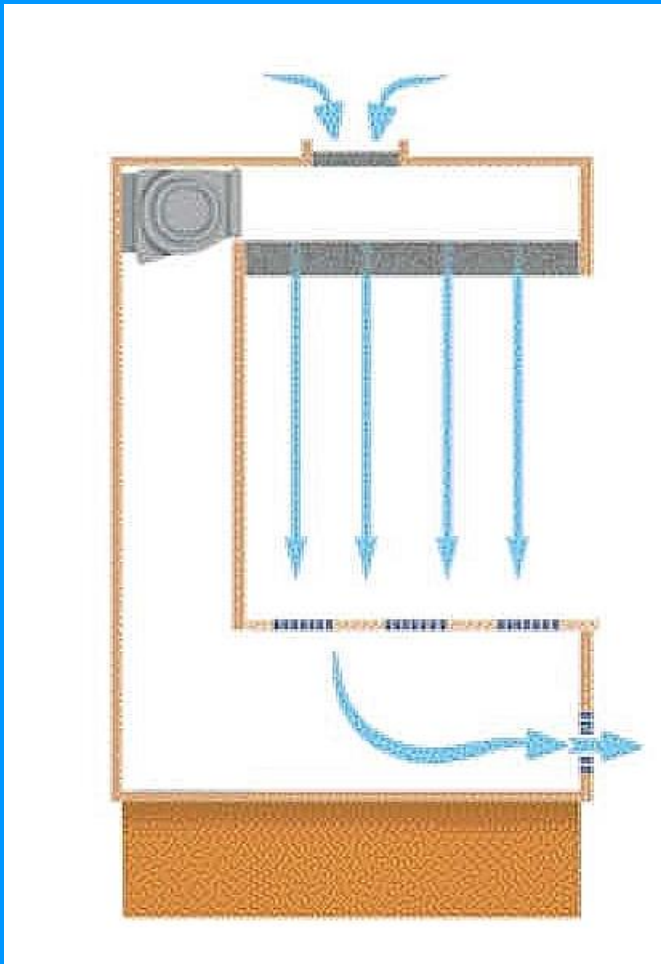
laminar flow from
above



Horizontal Flow Hood

- Hoods exist in both **horizontal and vertical** configurations.
- **Horizontal**
 - Blows air toward the operator.
- **Used for preparing**
 - IVs, TPNs, compounding, eye solutions, and any drug that is not hazardous.

Vertical Flow Hood



Vertical Flow & Biological Safety Hoods

- **Protects personnel and the environment**
- Air is passed into a **HEPA** filter and directed down toward the work surface and is pulled through vents at the front, back and sides of the hood.
- Used for **chemotherapy and mixing live viruses.**
- **Two types**
 - Class 2, Type A
 - Class 2, Type B (exterior venting)

Cleaning Hoods or Cabinets

- **Let it operate for at least 30 minutes** before use.
- Clean using a suitable disinfectant.
- First clean the metal pole used to hang the containers.
- Then the sides of the hood are cleaned using up and down motions moving from the back of the hood toward the front.
- Then the bottom of the hood is cleaned using side-to-side motions moving from the back of the hood toward the front.
- If using a spray bottle to dispense the disinfectant, be sure not to spray the HEPA filter.

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Clean Rooms

- Clean rooms are rooms that have a **controlled** level of contamination and are used to prepare sterile preparations.
- Only **designated personnel** should enter the space.
- **ISO Class 7 environment** means any air flow unit used in the clean room is capable of producing an environment containing no more than 10,000 air born particles of a size 0.5 microns or larger per cubic foot of air.

Aseptic Techniques

- Aseptic Techniques are the sum total of methods and manipulations required **to minimize the contamination of sterile products.**
- Contaminants are microorganisms and/or particulate material.
- Working in a laminar flow hood **DOES NOT**, by itself, guarantee a sterile formulation.

IV Preparation

- Preparing IV's should always be done **under the supervision of a licensed pharmacist.**
- Medication that is prepared by the technician must always be reviewed and approved by the pharmacist.

Preparing IVs

- Pharmacists and technicians prepare drugs and IV solutions in a form ready to be administered to a patient.
- **IV bolus and IV infusions should be prepared in laminar airflow hoods using aseptic techniques**
 -
 - Products used during the preparation must always be **sterile** and handled in such a manner as to prevent contamination.

IV Preparation Guidelines

- Begin all IV preparations by **washing your hands** thoroughly.
- **All jewelry** should be removed from the hands and wrists before scrubbing and while making a sterile product.
- Wear **gloves** during all procedures.
- Laminar airflow hoods are normally **kept running**.
- Eating, drinking, talking, or coughing is prohibited in the laminar airflow hood.
- Working in the laminar flow hood should **be free from interruptions**.

IV Preparation Guidelines

- Before making the product, thoroughly clean all interior working surfaces.
- Gather all the necessary materials for the operation and make sure they are:
 - Not expired.
 - Free from particulate matter such as dust.
 - Check for leaks by squeezing plastic solution containers.
- Only essential objects and materials necessary for product preparation should be placed in the airflow hood.

IV Preparation Guidelines

- Work in the center of the work area within the laminar airflow hood.
 - At least **six inches** inside the edge of the hood
 - Make sure nothing obstructs the flow of air from the HEPA filter over the preparation area.
 - Nothing should pass behind a sterile object and the HEPA filter in a horizontal airflow hood or above a sterile object in a vertical airflow hood.

Aseptic Technique

- Put on non-shedding coats, gowns, or coveralls (hospital scrubs), head and facial hair covers, face masks, and shoe covers. Note that it is important to follow the sequence of items indicated in this step.

IV Preparation Guidelines

- Follow proper procedure for handling sterile devices and medication containers.
- Remember that **the plunger** and the **tip of the syringe** are sterile and **must not be touched**.
- For greatest accuracy, use the smallest syringe that can hold the desired amount of solution.
- Complete a **quality check** of the product for container integrity and leaks, solution cloudiness, particulates, color of solution, and proper preparation of product.

Working with Vials

- Vials are closed systems.
 - The amount of air introduced should be equal to the volume of fluid removed .
- There are two types:
 - The drug already in the solution.
 - A powder that must be dissolved in a dilute to make a solution.
 - Powders are reconstituted by introducing a diluent (e.g., sterile water for injection).



Coring

- Coring occurs when a needle damages the rubber closure of a Parenteral container causing fragments of the closure to fall into the container and contaminate its contents.
- To prevent coring:
 - Place the vial on a flat surface and position the needle point on the surface of the rubber.
 - Put downward pressure on the needle while gradually bringing the needle to an upright position.

Vial Containing Solutions

- Use the smallest gauge needle for the task.
- Attach the needle to the syringe.
- Draw air into the syringe equal to the amount of drug to be drawn from the vial.
- Swab the top of the vial with alcohol before entering the laminar flow hood; allow the alcohol to dry.
- Puncture top of the vial with the needle bevel up.
- Bring the syringe and needle straight up, penetrate the stopper, and depress the plunger of the syringe, emptying the air into the vial.

Vial Containing Solutions

- Invert the vial with the attached syringe.
- Draw up from the vial the amount of liquid required.
- Withdraw the needle from the vial. In the case of a multi-dose vial, the rubber cap will close, sealing the contents of the vial.
- Remove and properly dispose of the needle, and cap the syringe. A new needle will be attached at the time of injection into a patient.

Vials Contain Lyophilized Powder

- Determine the correct volume of diluent.
- Transfer the diluent into the vial.
- Withdraw the volume of air into the syringe once the diluent is added.
- Swirl the vial until the drug is dissolved.
- Using a new needle and syringe, transfer the reconstituted solution to the final container.

Ampules

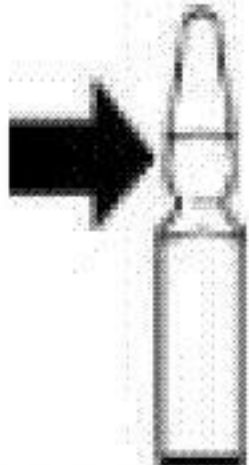
- An **ampule** is a single-dose-only drug container.
- You must first break the top off the ampule before withdrawing the medication.



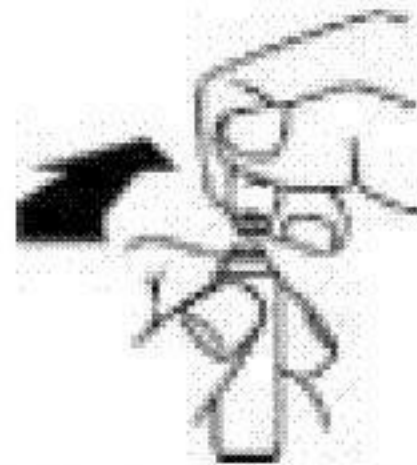
Ampules

- **Gently tap the top** of the ampule to bring the medication to the lower portion of the ampule.
- **Clean the neck** with an alcohol swab, then grasp the ampule between your thumb and index finger at the neck with the swab still in place.
- **Forcefully snap** the neck away from you.

Instructions for Use



One-point-cut ampule with cut below colored line.



To break, place thumb on the color line and snap back.

Ampules

- **To withdraw** from an ampule, tilt the ampule, place the needle bevel of a filter or the tip of a filter straw in the corner near the opening, and withdraw the medication.
- Use a needle equipped with a filter for **filtering out** any tiny glass particles, fibers, or paint chips that may have fallen into the ampule.

Ampules

- Before injecting the contents of a syringe into an IV, the **needle must be changed** to avoid introducing glass or particles into the admixture.
- A standard needle could be used to withdraw the drug from the ampule; it is then replaced with a filter device before the drug is pushed out of the syringe..
- **Filter needles are for one directional use only.**

Equipment Used in IV Preparation

- **Plastic disposable** products:
 - Save time and money.
 - An inexpensive sterile product.
- Often the entire system sent out to the patient is composed of plastic.
 - Thin, flexible plastic catheters are replacing metal shafts that deliver the medication into the vein.
 - Usually the only non-disposable product used to is the IV pump or controller.

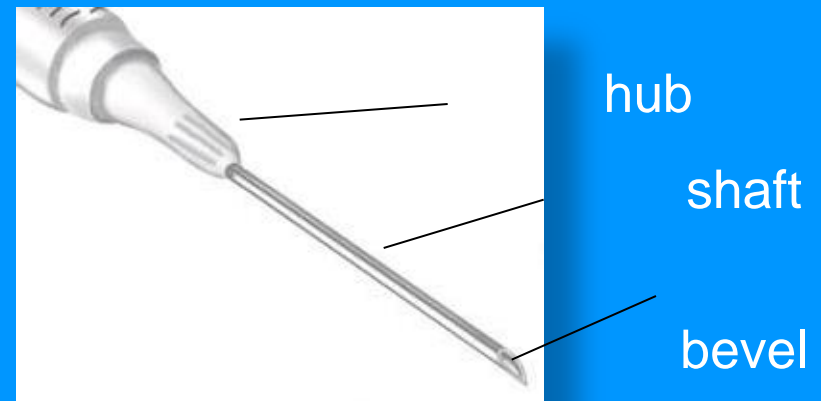
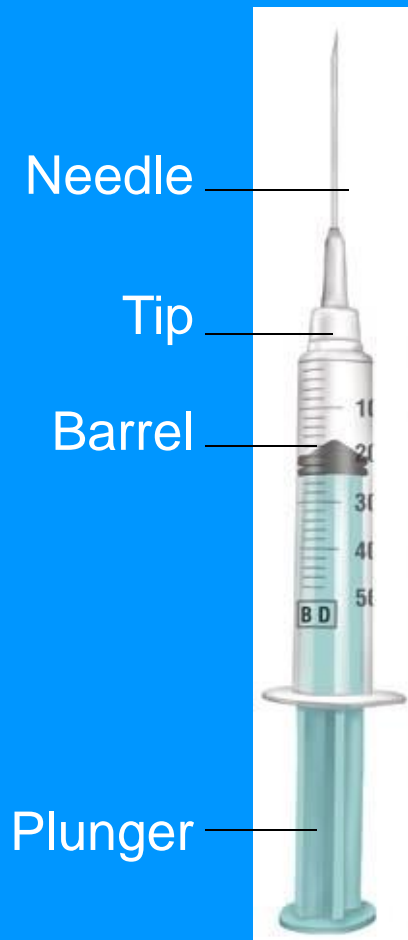
Syringes and Needles

- Syringes are used for IV push and in the preparation of infusions; they are made of glass or plastic.
- **Glass syringes** are more expensive & need care and sterilization
 - Use limited to medications that are absorbed by plastic
- **Plastic syringes**
 - Less expensive.
 - Disposable.
 - Arrive from the manufacturer sterile.

Syringes and Needles

- Basic parts of a syringe
 - Barrel is a tube that is open at one end and tapers into a hollow tip at the other end.
 - Plunger is a piston-type rod with a slightly cone-shaped stopper that presses the barrel.
 - Tip provides the point of attachment for a needle.
- Common types: Slip-Tip®, Luer-Lock®, and Eccentric tips®.

Syringes and Needles



Different size needles



Syringes and Needles

- Needles are made of stainless steel or aluminum.
 - Needle lengths range from 1/4 of an inch to 6 inches.
 - Needles come in gauges ranging from 34 to 13 (higher the #, smaller the lumen).
- After use, needles must be discarded in a designated sharps container.

Syringes and Needles

- Various types & have several characteristics
 - Graduation marks
 - Sizes
 - Gauges



Filters

- Filters are devices used to remove contaminants such as glass, paint, fibers, and rubber cores.
- Will not remove virus particles or toxins.
- Occasionally become clogged, thus slowing expected flow rates.

Filters

- **Depth filters**
- Inside the hub of a filtered needle **5 micron**
- **Membrane filters.**
- Filter solution when it is being expelled from the syringe. **0.22 micron.**
- **Final filter**
- Used immediately before it enters the patient's vein.

Filters



Membrane filter



Using a
membrane filter



Filter needle

IV Sets



- An **IV administration set**
 - Sterile, pyrogen-free, disposable.
 - Device used to deliver IV fluids to patients.
- The set may be sterilized before use by means of radiation or ethylene oxide.
- Comes in sterile packaging & a sealed plastic wrap.
- Sets do not carry expiration dates.
- Sets carry the legend
 - **“Federal law restricts this device to sell by or on the order of a physician.”**

IV Sets

- IV sets are sterile and nonpyrogenic.
- Each unit is supplied in packaging that ensures the maintenance of sterility.
- Most of the length of the tubing is molded from a pliable **polyvinyl chloride (PVC)**.
- PVC sets should not be used for:
 - **Nitroglycerin**, which is absorbed by the tubing.
 - **IV fat emulsions**, which may leach out of the tubing.

IV Sets

- The **length of sets** varies from 6-inch extensions up to 110- to 120-inch sets used in surgery.
- The priming of tubing depends on the length of the set
- Standard sets have a lumen diameter of 0.28 cm.
- Varying sizes of the lumen diameter achieves different flow rates.
- Regulation of flow rates is critical in neonates and infants.

IV Sets

- A **spike** to pierce the rubber stopper or port on the IV container.
- A **drip chamber** for trapping air and adjusting flow rate.
- A **control clamp** for adjusting flow rate or shutting down the flow.
- Flexible tubing to convey the fluid.



IV Sets

- A needle adapter for attaching a needle or a catheter.
- A **catheter** may be implanted into the patient and fixed with tape to avoid repeated sticks.
- Most IV sets contain a **Y-site**, or injection port and used for adding medication to the IV.
- Some IV sets also contain **resealable in-line filters** to protect the patient against particulates, including bacteria and emboli.

IV Sets

- Clamps allow for adjusting the rate of flow and for shutting off the flow.
- Clamps may be located at any position along the flexible tubing.
- Usually a clamp moves freely, allowing its location to be changed to one that is convenient for the health professional administering the medication.

Pumps and Controllers

- Fluids and drugs are often delivered by some form of device to control the infusion rate.
- The first system to deliver a drug IV was the **syringe system**.
- The syringe system is very nurse labor-intensive and pharmacy labor-intensive.

Pumps and Controllers

- The **Buretrol** or **Soluset** were in use before infusion pumps and replaced the syringe system.
 - Fluid is run into the cylinder of the system.
 - Drug can be added in the top of the cylinder injection port for dilution and mixing before it is infused.
- Safer than the syringe system because the drug is being diluted in the cylinder and it can be infused over a long period of time.

Pumps and Controllers

- Infusion pumps are preferred by both nurses and physicians.
 - Produce a positive pressure of 10 to 25 psi.
 - More accurate than controllers.
 - Have fewer flow interruptions.
- Infusion pumps control the flow of IV medications.
- Maximum flow is 999 mL/hr.
 - Provides a higher rate of infusion.
 - Higher pressure increases possibility of infiltration.



Pumps and Controllers

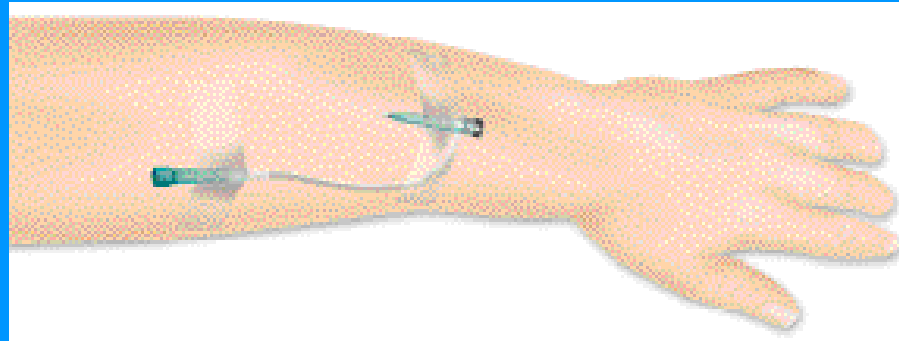
- **A patient-controlled analgesia (PCA)** device is a type of medication delivery that uses a parenteral route and allows the patient to administer analgesics by pressing a button.
 - Controls the medication so the patient cannot overdose or give the medication too soon after the previous dose.
- Often, after surgery or severe injuries, a physician will order PCA for the patient for 24 to 72 hours.

Catheters

- IV administration for fluids and drug therapy can be accomplished through needle-like devices called catheters.
- **Catheters** are devices inserted into veins for direct access to the blood vascular system and are used in two primary ways:
 - **Peripheral venous catheters** are inserted into a vein close to the surface of the skin.
 - **Central venous catheters** are inserted deeper in the body.

IV Solutions

- A **piggyback** is a small-volume parenteral admixture attached to an existing IV line .
- The piggyback solution is infused into the tubing of the running IV.
 - Usually over a short time, from 30 minutes to 1 hour.
- **Heparin Lock** – a short piece of tubing attached to a needle or IV catheters used to prevent blood from clotting in the tube.



Preparing a Label for an IV Admixture

Labels for IV admixtures should bear the following information:

- Patient's name and identification number
- Room number
- Fluid and amount
- Drug name and strength (if appropriate)
- Infusion period
- Flow rate (e.g., 100 ml/h or infuse over 30 min)
- Expiration date and time
- Additional information as required by the institution or by state or federal guidelines.

Parenteral Incompatibilities

- **NOT** all drugs are compatible with each other
- **Incompatibilities**
 - When two or more drugs react that are incompatible with each other, one drug can cause the degradation of the other drug.
- **Characteristics** of incompatibilities:
 - Color change
 - Hazy appearance
 - Precipitates

Parenteral Incompatibilities

- NOT all incompatibilities are dangerous.
- **Color change**
 - Imipenem-cilastatin or dobutamine may show some color change but NOT a sign of incompatibility.
- **Hazy Appearance**
 - When ceftazidime is reconstituted, carbon dioxide gas is released.
- **Precipitation**
 - The precipitate that forms when paclitaxel is refrigerated dissolves at room temperature.

Incompatibilities – Contribution Factors

- **Light**
 - Amphotericin B, cisplatin, metronidazole must be protected from light.
- **Temperature**
 - Cefazolin stable at room Temp for 24 hrs but under refrigeration for 96 hrs.
- **Dilution**
 - Up to 15 mEq of Calcium can be added to a liter of solution containing 30mEq of PO₄.
- **Buffer capacity, pH, and Time**

Incompatibilities – Contribution Factors

- **Filters**

- Inline filter cause 90% reduction in nitroglycerin.

- **Solutions**

- Amphotericin B is not compatible in NS.

- **Chemical Complexation**

- Needle or filter containing aluminum should not be used with Cisplatin-AQ.

- **Plastics**

- Albumin should be used in glass bottle because it binds to PVC plastics.

Quality Assurance & Infection Control

- USP/NF <797> requires that every compounding facility must have a QA program.
- **Major components**
 - Semi-annual testing and certification.
 - Routine monitoring of environmental airborne contaminants.
 - Routine monitoring of operating temperature.
 - Maintain continuous positive pressured.
 - Continuous HEPA filtered air.

Hazardous Waste Regulations

- The Resources Conservation and Recovery Act (RCRA) regulates handling hazardous waste from its generation to disposal.
- Hazardous waste must be collected and stored according to specific EPA and DOT requirements.

Hazardous Waste Regulations

- Hazardous materials classification
 - P-list waste includes epinephrine, NTG, and physostigmine.
 - U-list wastes includes toxic, flammable, corrosive, or reactive and cyclophosphamide.

Sharps Disposal

- **Sharps**

- An object that might puncture or cut the skin of anyone who handles them.
- Needles, jagged glass, or metal objects.

- **Sharp containers**

- should be easily identified, leak proof, puncture proof, and be able to be sealed permanently.

Hazardous Waste Regulations

- **Protective Clothing**
 - A disposable, lint-free, nonabsorbent, closed-front gown with cuffed sleeves should be worn.
 - Hair and shoe covers should be worn to reduce the potential for contamination.
 - Eye protection
 - Mask
 - Use latex gloves when disposing of damaged packages.

Units of Measurement

- Molarity
 - A mole is the number of grams numerically equal to the **molecular weight** of the drug.
- Osmoles
 - Equal to the molecular weight of the drug divided by the number of **ions** formed when a drug dissolves in solution.
 - Osmole = $\frac{\text{molecular weight}}{\text{\# of ions}}$

Units of Measurement

- Equivalents
 - Another expression for an amount of drug is the equivalent weight (Eq).
 - Equivalent weight
= $\frac{\text{molecular weight}}{\text{valence}}$

Units of Measurement

- Percentage weight per volume
 - Refers to the drug's weight per 100 ml if the drug is a solid
 - The drug's volume per 100 ml if the drug is a liquid.
 - Solid: $\% = \frac{\text{weight (g)}}{100 \text{ ml}}$
 - Liquid: $\% = \frac{\text{volume (ml)}}{100 \text{ ml}}$

Terms to Remember

1. Horizontal flow hood
2. Hub
3. Hypertonic
4. Hypotonic
5. Ions
6. Irrigation solution
7. Isotonic
8. Laminar flow
9. Lumen
10. Lyophilized
11. Membrane filter
12. Molecular weight
13. Osmosis
14. Osmotic pressure
15. Peritoneal dialysis solution
16. Piggybacks
17. Pyrogen
18. Ready-to-mix
19. Shaft
20. Sharps
21. Slip-tip®, luer-lok®, eccentric, oral

Terms to Remember

22. Total parenteral nutrition (TPN) solution

23. Additive

24. Admixture

25. Ampules

26. Aseptic techniques

27. Bevel

28. Compounded sterile

29. Coring

30. Depth filter

31. Dialysis

32. Diluent

33. Equivalent weight

34. Final filter

35. Flow rate

36. Gauge

37. HEPA filter

38. Heparin lock

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