



مؤسسة مستشفى سرطان
الأطفال - مصر
Children's Cancer Hospital
Foundation - Egypt

IV Mixing

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جمعية أصدقاء المبادرة
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- Important Terms & Concepts
- PPE & Handwashing
- Filters & Disinfection
- Arrangement
- Aseptic Technique
- Drugs



Introduction

IV Admixture

An IV admixture is the preparation of a pharmaceutical mixture of **two or more drugs** added to an IV fluid for administration. IV admixture must be **sterile and pyrogen, air bubbles, and particulate matter free** since it will be administered directly into the bloodstream. It is a suitable method to administer **large volume of infusion, TPN**.

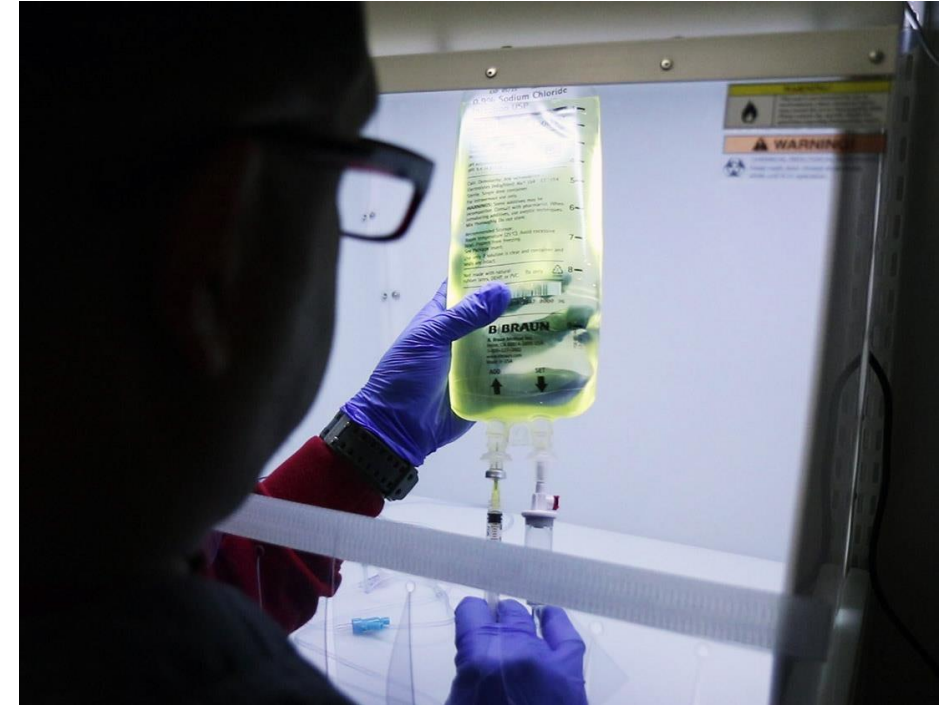


Introduction

IV Admixture

The **IV route** of administration is used:

- To save money
- To insure purity , sterility and accuracy
- To reach appropriate drug serum levels
- To guarantee compliance
- For drugs with unreliable gastrointestinal (GI) absorption
- For patients who can have nothing by mouth
- For unconscious or uncooperative patients
- For rapid correction of fluid or electrolytes

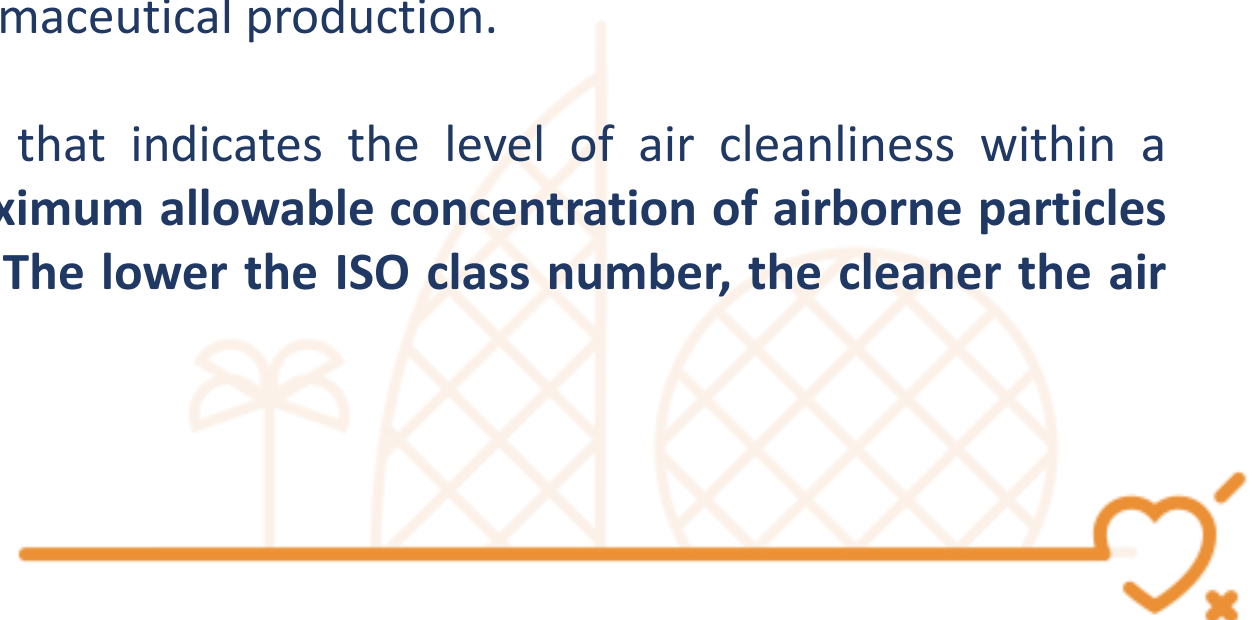


Important Terms & Concepts

ISO Class

ISO class refers to the classification system for cleanrooms and controlled environments. Cleanrooms are specialized environments designed to minimize the presence of particulates, such as dust, microbes, and other contaminants, in order to maintain a high level of cleanliness for specific applications like manufacturing, research, or pharmaceutical production.

The ISO class designation is a numerical value that indicates the level of air cleanliness within a cleanroom. The classification is based on the **maximum allowable concentration of airborne particles of a specified size within a given volume of air**. The lower the ISO class number, the cleaner the air and the higher the level of cleanliness.



Important Terms & Concepts

ISO Class

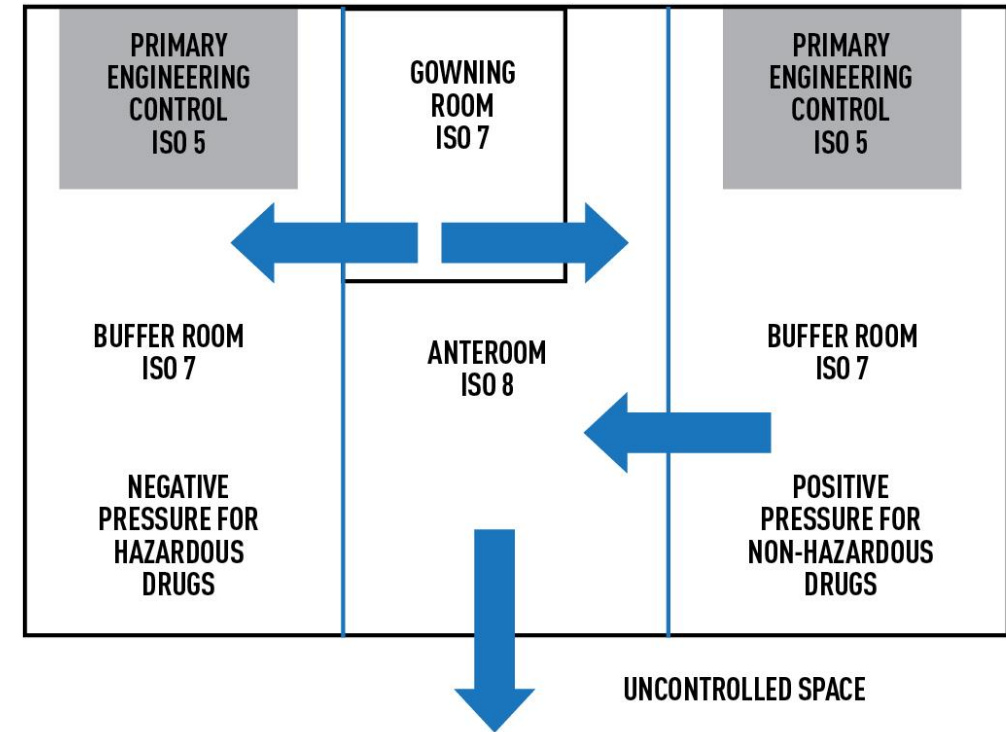
The most commonly referenced ISO classes for cleanrooms are **ISO 1 to ISO 9**, with **ISO 1 being the cleanest and ISO 9 being the least clean**. ISO 1 cleanrooms have the strictest requirements, allowing the fewest particles per cubic meter of air, while ISO 9 cleanrooms have more relaxed requirements, allowing a higher concentration of particles.



Important Terms & Concepts

Ante-Area

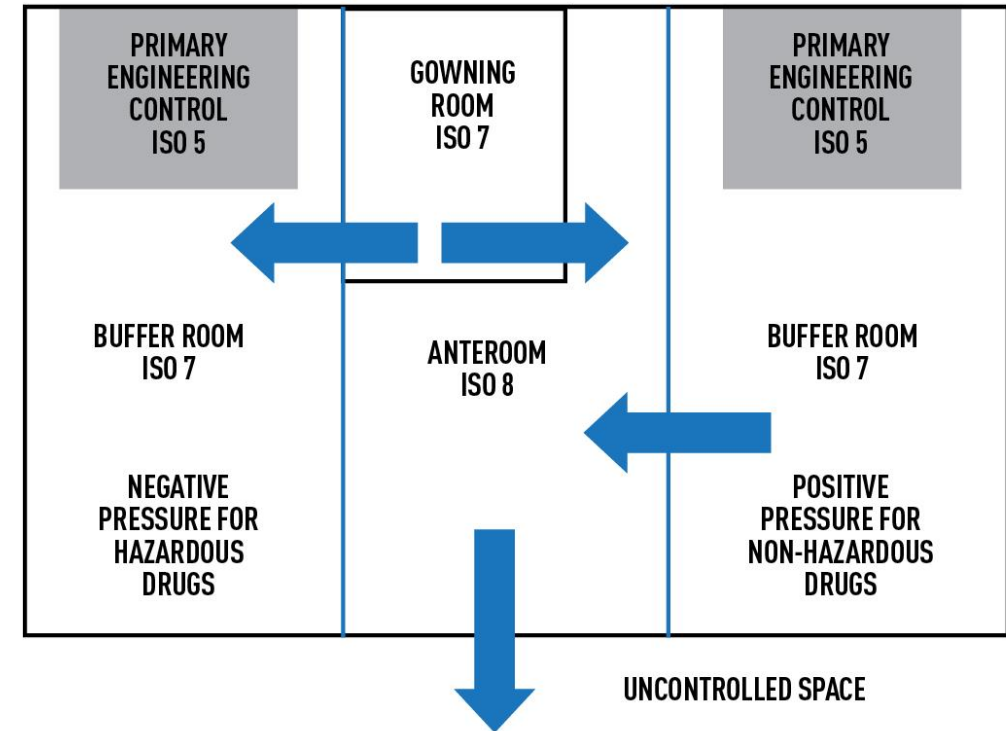
An ISO Class 8 or better area where personnel **hand hygiene and garbing procedures**, staging of components, order entry, CSP labeling, and other high-particulate-generating activities are performed. It is also a **transition area** that provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas and reduces the need for the heating, ventilating, and air-conditioning (HVAC) control system to respond to large disturbances.



Important Terms & Concepts

Buffer Area

An area where the **primary engineering controls (PEC)** is **physically located**; Activities that occur in this area include the preparation and staging of components and supplies used when compounding CSPs.



Important Terms & Concepts

Aseptic Processing

A mode of processing pharmaceutical and medical products that involves the **separate sterilization of the product and of the package** (containers– closures or packaging material for medical devices) and the **transfer of the product into the container and its closure** under at least ISO Class 5 conditions.



Important Terms & Concepts

Primary Engineering Control (PEC)

A device or room that provides an **ISO Class 5 environment** for the exposure of critical sites when compounding CSPs. Such devices include, but may not be limited to, laminar airflow workbenches (**LAFWs**) and biological safety cabinets (**BSCs**).



Important Terms & Concepts

Biological Safety Cabinet (BSC)

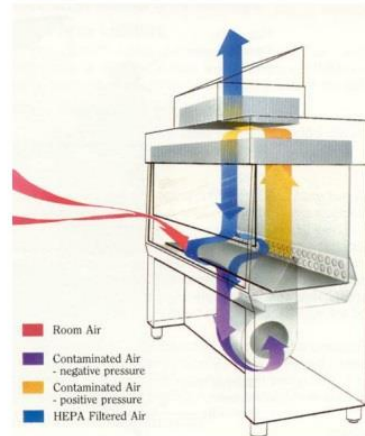
A ventilated cabinet for CSPs, personnel, product, and environmental protection having an open front with inward air high-efficiency particulate air (HEPA) filtered laminar flow for personnel protection; downward airflow for product protection, and HEPA-filtered exhausted air for environmental protection.



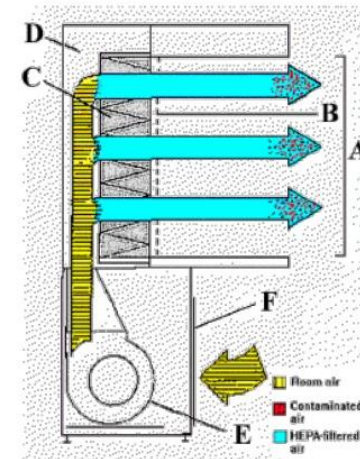
Important Terms & Concepts



BSC vs. LFC



VS



Biological Safety Cabinet

- HEPA filtered laminar air flow and exhaust
- personnel, environment & often product protection

Laminar flow hoods

- **NOT** biological safety cabinets
- Vertical or horizontal laminar flow
- HEPA filtered air (intake)
- product protection only



PPE & Handwashing

How to Handrub?

RUB HANDS FOR HAND HYGIENE! WASH HANDS WHEN VISIBLY SOILED

⌚ Duration of the entire procedure: 20-30 seconds



World Health
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Patient Safety
A World Alliance for Safer Health Care

SAVE LIVES
Clean Your Hands

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May 2020



PPE & Handwashing

Garbing

ISO 4/5

(Class 10–100)

Recommended Gowning Procedure

Ångstrom | **supply**
CLEANROOM

BEFORE ENTERING THE GOWNING ROOM



Bouffant Cap: Put on hair cover/ bouffant cap. Make sure all hair is tucked in and both ears are covered.



If facial hair is present...



Beard Cover: Fasten ear loops behind ears. Ensure that mouth and any facial hair is completely concealed under beard cover.



Gloves: Pull glove over hand. Avoid touching the outside of the glove and ensure that the cuff is donned over sleeve.



Shoe Covers: Pull shoe covers over shoes, ensuring that all laces and tassels are contained within the shoe covers.

ENTERING THE GOWNING ROOM

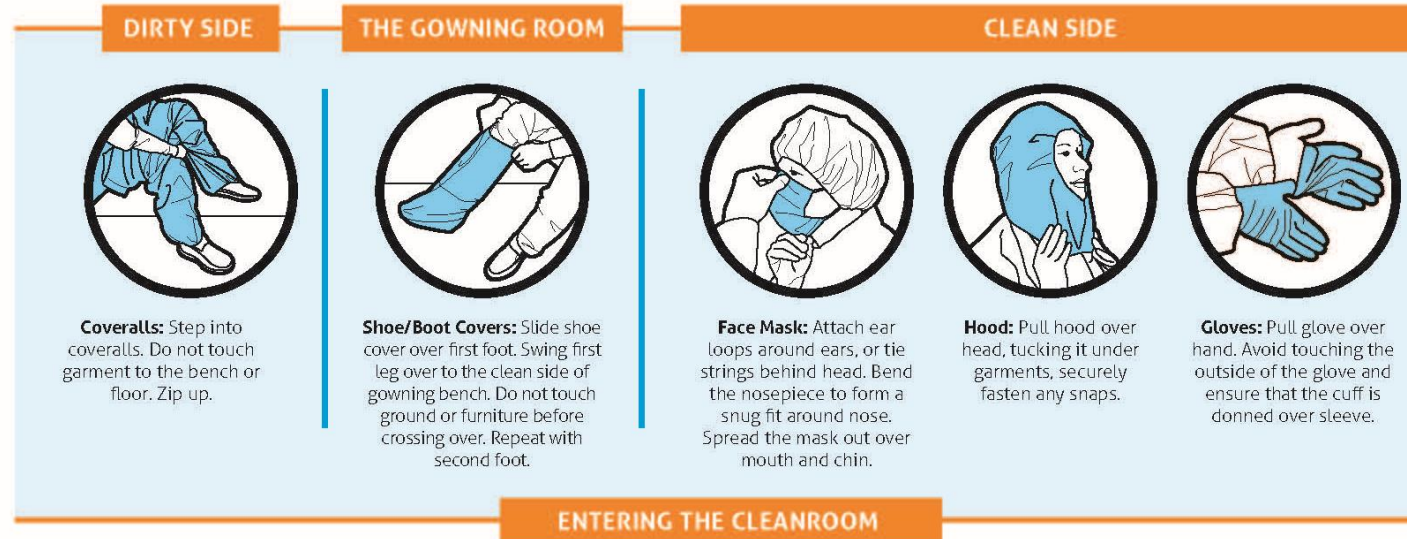


Entering the Room: Step on cleanroom sticky mat and take 3-4 small steps before entering gowning room or cleanroom.



PPE & Handwashing

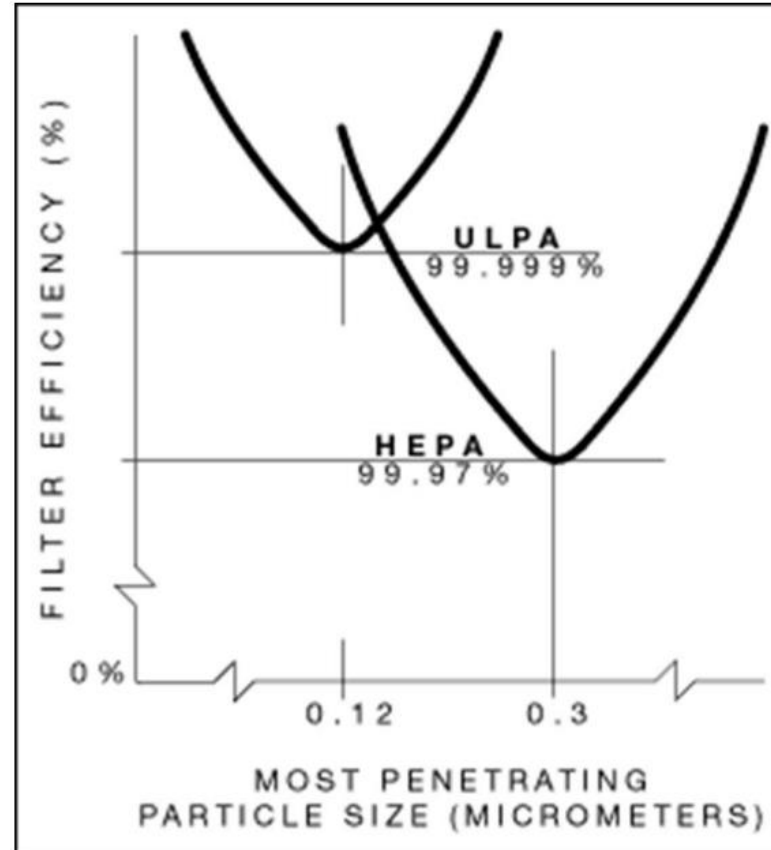
Garbing



Entering the Room: Step on cleanroom sticky mat and take 3-4 small steps before entering gowning room or cleanroom.



Filters & Disinfection

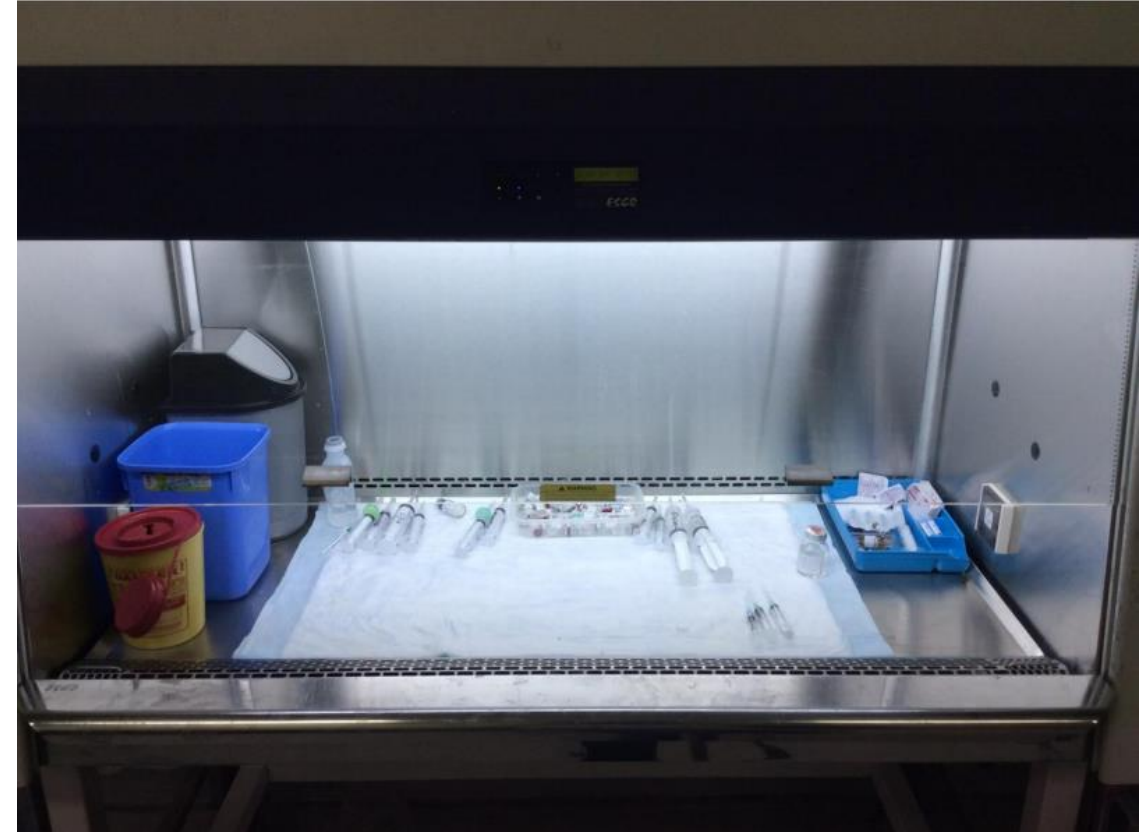


Filters & Disinfection



Arrangement

Each device should separate into working area in the middle, wasting area in the left (contain two basket one for papers and the other for vials, sharp container for needle) and supply area in the right. Keep your hand 6 inch inside laminar (For BSC)

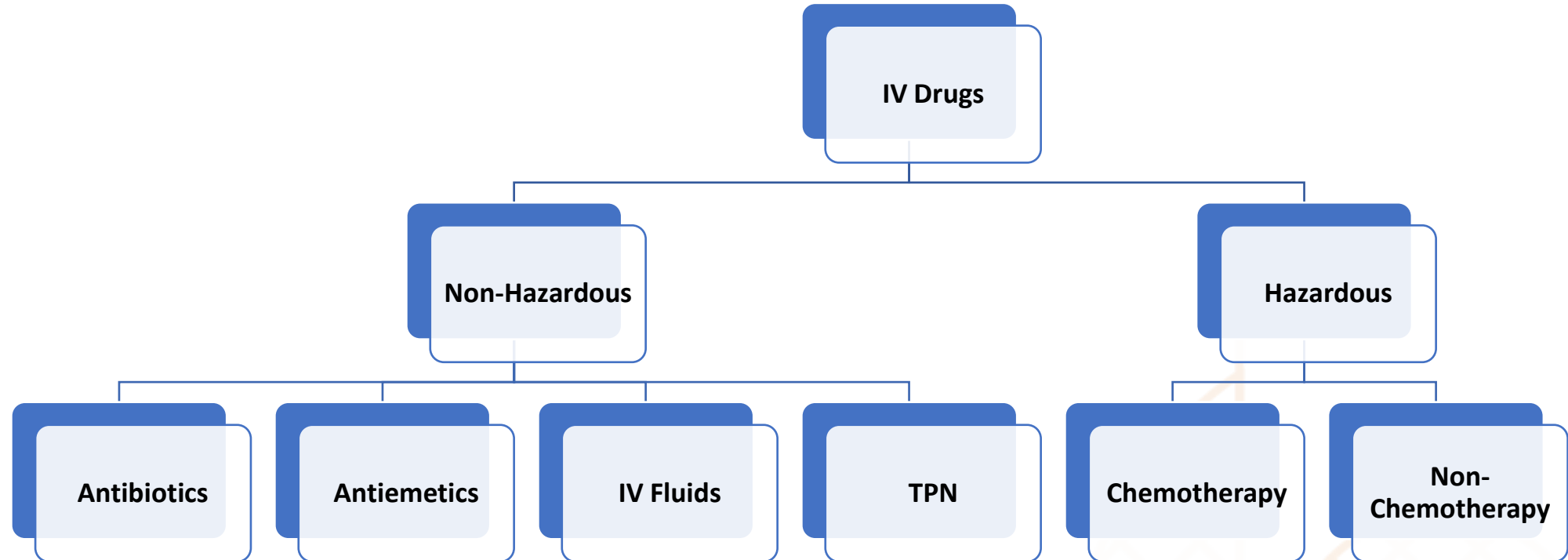


Aseptic Technique

Non-Corking Method



Drugs





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Thank You

Your Feedback will be much Appreciated!



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References

- USP 797
- ASHP
- IV Mixing Manual, CCHE 57357

