PHARM.D • YEAR 3

Pharmaceutical Formulations

CHAPTER 5

Parenteral Preparations

PPT CHAPTER COVER



DOCTOR OF PHARMACY

PARENTERALS – DEFINITION AND ROUTES

Parenteral preparations

Sterile products administered by injection, infusion or implantation, bypassing the gastrointestinal tract.

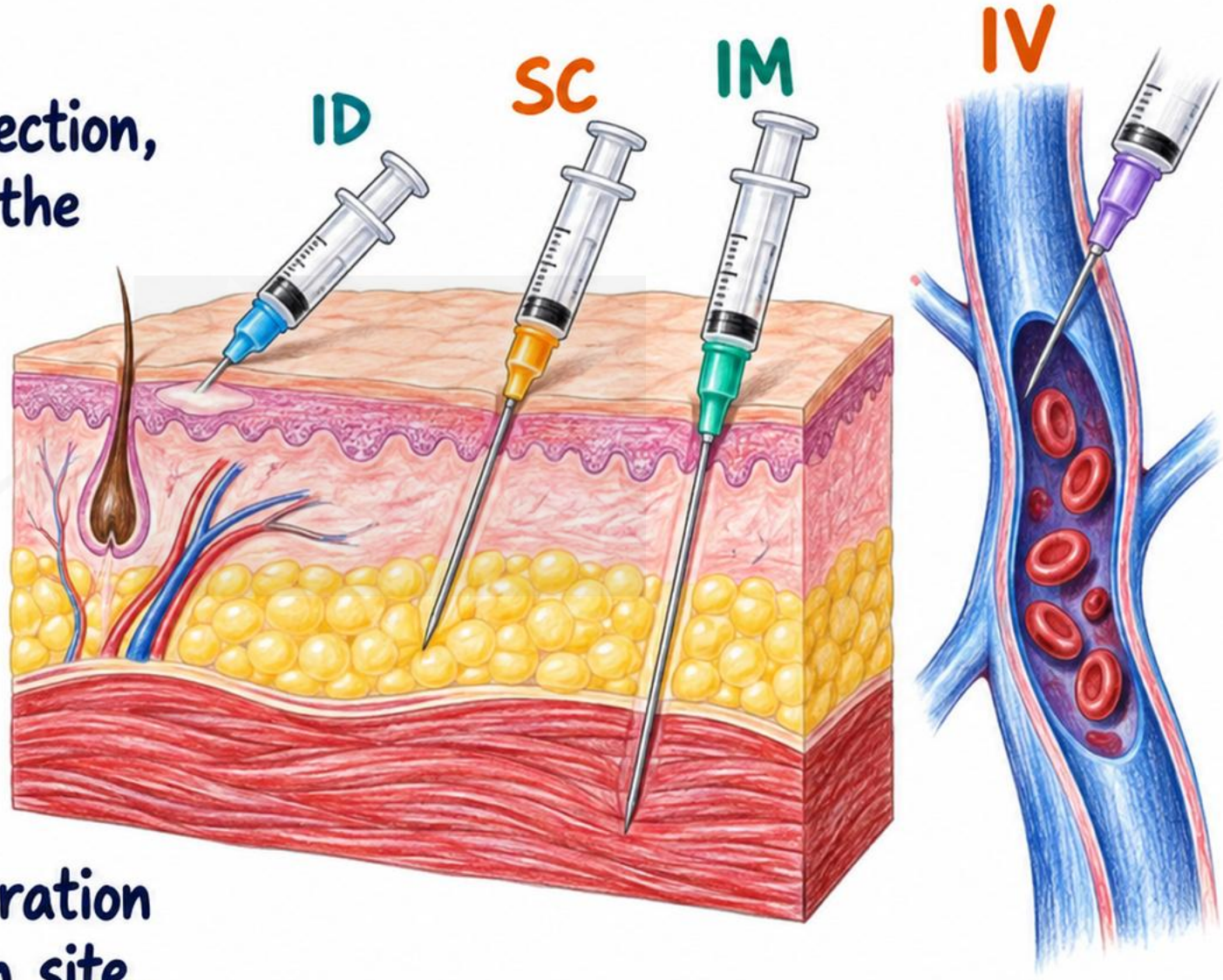
IV: into a vein

Direct entry into the bloodstream.

IM: into muscle

SC: into subcutaneous tissue

ID: into the dermis

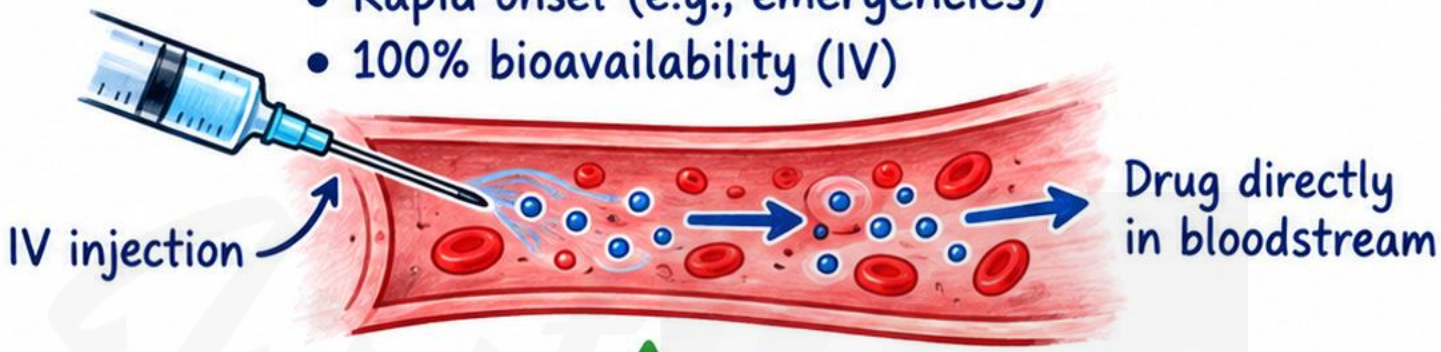


Absorption after IM or SC administration depends on the product and injection site.

WHY USE PARENTERALS?

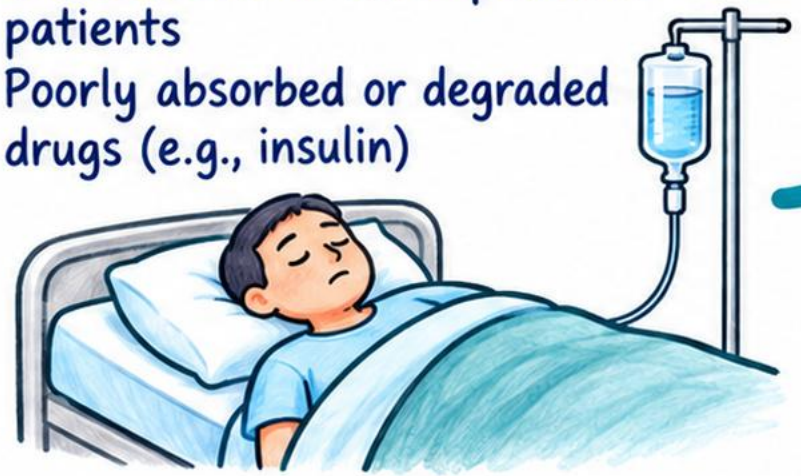
1. RAPID & RELIABLE DELIVERY

- Rapid onset (e.g., emergencies)
- 100% bioavailability (IV)



2. SUITABLE WHEN ORAL NOT POSSIBLE/RELIABLE

- Unconscious or uncooperative patients
- Poorly absorbed or degraded drugs (e.g., insulin)





3. IMPORTANT LIMITATIONS

- Invasive; risk of pain, infection or tissue damage
- Irretrievable once administered



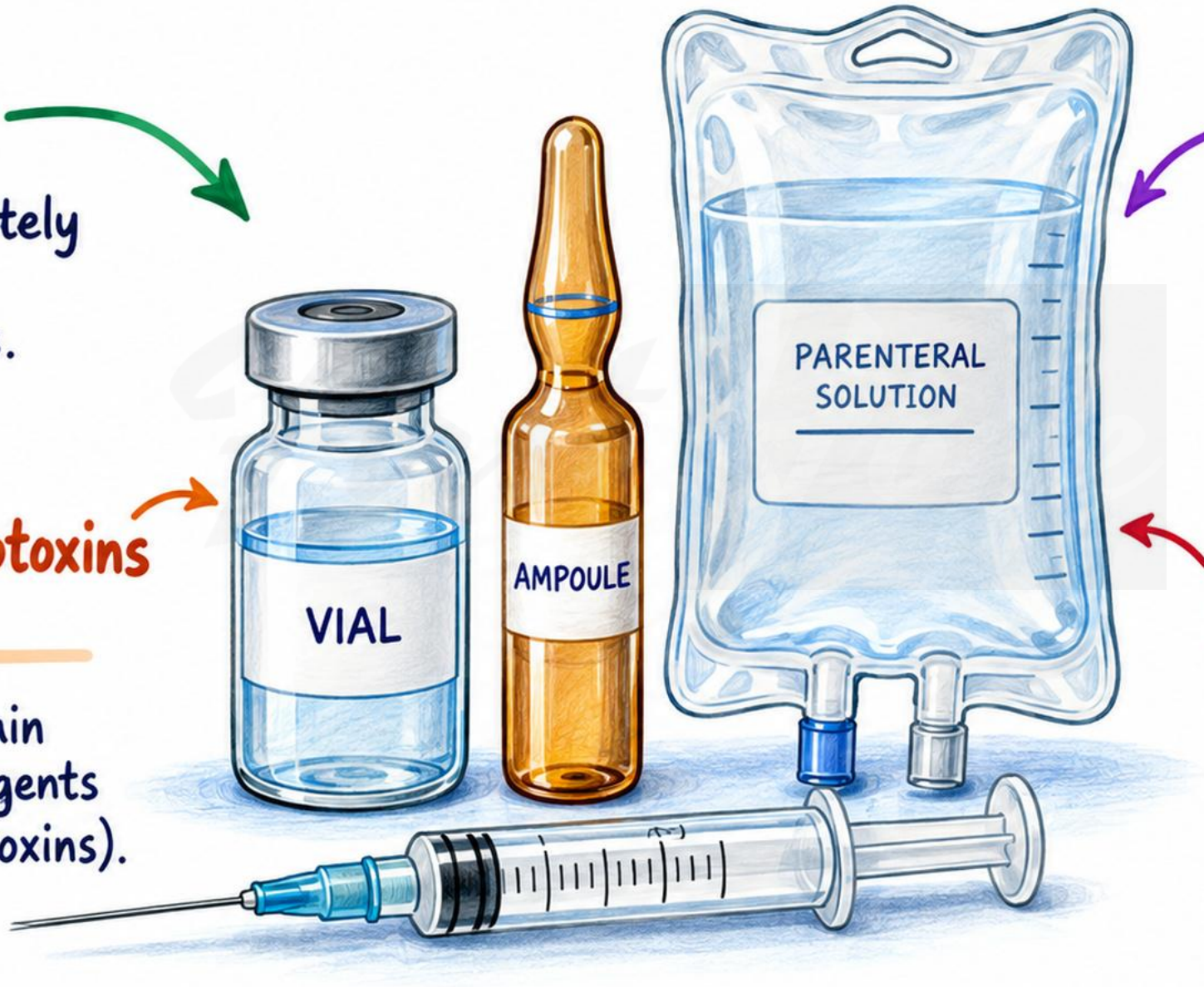
CRITICAL QUALITY ATTRIBUTES OF PARENTERALS

Sterility

Must be completely free from microorganisms.

Bacterial Endotoxins (Pyrogens)

Should not contain fever-inducing agents (bacterial endotoxins).



pH & Osmolality

pH and osmolality as appropriate to ensure stability and tolerability.

Visible /Subvisible Particles & Potency

Should be free from particulate matter and meet potency as per applicable monograph/ specification.

SVP AND LVP

SVP

- Small-volume parenteral
- 100 mL or less
- Several injection routes
- Single-dose or multiple-dose containers



Preservatives may be used in some multidose SVPs only when permitted and suitable for the route.



LVP

- Large-volume parenteral
- More than 100 mL
- Usually intravenous infusion
- Single-dose container
- Ordinarily no antimicrobial preservative

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