

The Pharmaceutics and Compounding Laboratory

Content	Labs	Videos	Test
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Sterile Compounding

Introduction

Routes

Injection Dependent Routes

Injection Independent Routes

Equipment

Devices and Supplies

Aseptic Techniques

Additional Considerations

Routes of Administration Requiring Sterile Formulations

Some routes of administration demand that products do not bring microbial contamination with them into the body. This is required because some routes of administration by-pass the body's natural defense mechanisms, or some tissues or organs are so sensitive and vital that such contamination could be serious.

All of these "sterility demanding" routes are parenteral routes.

NOTE: But not all parenteral routes are "sterility demanding" routes.



The term *parenteral* means next to or beside the enteral. *Enteral* refers to the alimentary tract, so parenteral means sites that are outside of or beside the alimentary tract. Since oral, buccal, sublingual, and rectal comprise the enteral routes of administration, any other route is considered a parenteral administration site. Topical administration is a parenteral route that does not require sterile formulations.

The parenteral routes of administration are used for various reasons.

- If a drug is poorly absorbed when orally administered or is degraded by stomach acid or the gastrointestinal enzymes, then a parenteral route would be indicated.
- The parenteral routes are also preferred when a rapid and predictable drug response is desired as in a emergency situation.
- Parenteral routes of administration are also useful when a patient is uncooperative, unconscious, or unable to take drug via an enteral route.
- Parenteral routes are used when localized drug therapy is desired.
- They provide a predictable and nearly complete bioavailability.

But there are major disadvantages.

- Most of these parenteral formulations are more expensive than enteral route formulations.
- Most these parenteral formulations must be sterile.
- Many formulations require that a skilled or trained person administer them.
- Once the drug is administered, it may be difficult to remove the dose if there is an adverse or toxic reaction.