

**OVERVIEW OF UNIQUE CHARACTERISTICS OF PARENTERAL DOSAGE FORMS** 495**FORMULATION PRINCIPLES** 496**VEHICLES** 496**SOLUTES** 496**ADMINISTRATION** 499**PARENTERAL COMBINATIONS** 499**GENERAL CONSIDERATIONS** 499**GENERAL MANUFACTURING PROCESS** 500**COMPONENTS** 501**WATER FOR INJECTION (WFI)** 501**CONTAINERS AND CLOSURES** 504**CONTAINER TYPES** 504**RUBBER CLOSURES** 506**NEEDLES** 508**PYROGENS (ENDOTOXINS)** 509**PRODUCTION FACILITIES** 510**FUNCTIONAL AREAS** 510**MAINTENANCE OF CLEAN ROOMS** 514**PERSONNEL** 514**ENVIRONMENTAL CONTROL EVALUATION** 515**PRODUCTION PROCEDURES** 517**CLEANING CONTAINERS AND EQUIPMENT** 517**PRODUCT PREPARATION** 519**FILTRATION** 520**FILLING** 521**SEALING** 523**STERILIZATION** 524**FREEZE-DRYING (LYOPHILIZATION)** 525**QUALITY ASSURANCE AND CONTROL** 528**STERILITY TEST** 528**PYROGEN TEST** 529**PARTICULATE MATTER EVALUATION** 529**CONTAINER/CLOSURE INTEGRITY TEST** 530**SAFETY TEST** 530**PACKAGING AND LABELING** 530

Parenteral (Gk, *para* *entron*, beside the intestine) dosage forms differ from all other drug dosage forms, because they are injected directly into body tissue through the primary protective systems of the human body, the skin, and mucous membranes. They must be exceptionally pure and free from physical, chemical, and biological contaminants. These requirements place a heavy responsibility on the pharmaceutical industry to practice current good manufacturing practices (cGMPs) in the manufacture of parenteral dosage forms and on pharmacists and other health care professionals to practice good aseptic practices (GLAPs) in dispensing parenteral dosage forms for administration to patients.

Certain pharmaceutical agents, particularly peptides, proteins, and many chemotherapeutic agents, can only be given parenterally, because they are inactivated in the gastrointestinal tract when given by mouth. Parenterally-administered drugs are relatively unstable and generally highly potent drugs that require strict control of administration to the patient. Due to the advent of biotechnology, parenteral products have grown in number and usage around the world.

This chapter focuses on the unique characteristics of parenteral dosage forms and the basic principles for formulating, packaging, manufacturing, and controlling the quality of these unique products. The references and bibliography at the end of this chapter contain the most up-to-date texts, book chapters, and review papers on parenteral product formulation, manufacture, and quality control.

**OVERVIEW OF UNIQUE CHARACTERISTICS OF PARENTERAL DOSAGE FORMS**

Parenteral products are unique from any other type of pharmaceutical dosage form for the following reasons:

- All products must be sterile.
- All products must be free from pyrogenic (endotoxin) contamination.
- Injectable solutions must be free from visible particulate matter. This includes reconstituted sterile powders.
- Products should be isotonic, although strictness of isotonicity depends on the route of administration. Products administered into the cerebrospinal fluid must be isotonic. Ophthalmic products, although not parenteral, must also be isotonic. Products to be administered by bolus injection by routes other than intravenous (IV) should be isotonic, or at least very close to isotonicity. IV infusions must be isotonic.
- All products must be stable, not only chemically and physically like all other dosage forms, but also 'stable' microbiologically (i.e., sterility, freedom from pyrogenic and visible particulate contamination must be maintained throughout the shelf life of the product).
- Products must be compatible, if applicable, with IV diluents, delivery systems, and other drug products co-administered.

# Chapter 26 Parenteral Preparations Pharmaceutical Press

**Sebastian Brünink**



**Chapter 26 Parenteral Preparations Pharmaceutical Press :**

The Top Books of the Year Chapter 26 Parenteral Preparations Pharmaceutical Press The year 2023 has witnessed a remarkable surge in literary brilliance, with numerous compelling novels enthraling the hearts of readers worldwide. Lets delve into the realm of popular books, exploring the engaging narratives that have enthralled audiences this year. The Must-Read : Colleen Hoover's "It Ends with Us" This heartfelt tale of love, loss, and resilience has captivated readers with its raw and emotional exploration of domestic abuse. Hoover masterfully weaves a story of hope and healing, reminding us that even in the darkest of times, the human spirit can triumph. Chapter 26 Parenteral Preparations Pharmaceutical Press : Taylor Jenkins Reids "The Seven Husbands of Evelyn Hugo" This captivating historical fiction novel unravels the life of Evelyn Hugo, a Hollywood icon who defies expectations and societal norms to pursue her dreams. Reids captivating storytelling and compelling characters transport readers to a bygone era, immersing them in a world of glamour, ambition, and self-discovery. Discover the Magic : Delia Owens "Where the Crawdads Sing" This mesmerizing coming-of-age story follows Kya Clark, a young woman who grows up alone in the marshes of North Carolina. Owens spins a tale of resilience, survival, and the transformative power of nature, captivating readers with its evocative prose and mesmerizing setting. These top-selling novels represent just a fraction of the literary treasures that have emerged in 2023. Whether you seek tales of romance, adventure, or personal growth, the world of literature offers an abundance of captivating stories waiting to be discovered. The novel begins with Richard Papen, a bright but troubled young man, arriving at Hampden College. Richard is immediately drawn to the group of students who call themselves the Classics Club. The club is led by Henry Winter, a brilliant and charismatic young man. Henry is obsessed with Greek mythology and philosophy, and he quickly draws Richard into his world. The other members of the Classics Club are equally as fascinating. Bunny Corcoran is a wealthy and spoiled young man who is always looking for a good time. Charles Tavis is a quiet and reserved young man who is deeply in love with Henry. Camilla Macaulay is a beautiful and intelligent young woman who is drawn to the power and danger of the Classics Club. The students are all deeply in love with Morrow, and they are willing to do anything to please him. Morrow is a complex and mysterious figure, and he seems to be manipulating the students for his own purposes. As the students become more involved with Morrow, they begin to commit increasingly dangerous acts. The Secret History is a masterful and gripping novel that will keep you guessing until the very end. The novel is a cautionary tale about the dangers of obsession and the power of evil.

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