

electrolyte solute is required to exert that same osmotic pressure as a nonelectrolyte solution. More information about tonicity and formulation is covered in chapters 6 and 8. The United States Pharmacopeia contains general chapter <785> that defines osmotic pressure, osmolality and osmolarity, and measurement of osmolality.

CHARACTERISTICS OF STERILE DOSAGE FORMS FROM THE UNITED STATES PHARMACOPEIA

The first general chapter of the USP is entitled “<1> INJECTIONS.” Within this section are the following subcategories with the content under each subcategory summarized. Of course, wording of these characterizations might change over time so the reader must consult the current edition of the USP for current wording.

Introduction

Parenteral products are defined as preparations intended for injection through the skin or other external boundary tissue where the active ingredient is introduced directly into a blood vessel, organ, tissue, or lesion. Parenteral products are to be prepared scrupulously by methods designed to ensure that they meet Pharmacopeial requirements for and, where appropriate, contain inhibitors of the growth of microorganisms.

- Sterility
- Pyrogens
- Particulate Matter
- Other Contaminants

NOMENCLATURE AND DEFINITIONS

There are five general types of parenteral preparations listed in the USP:

- [Drug] Injection: Liquid preparations that are drug substances or solutions thereof.
- [Drug] for Injection: Dry solids that, upon the addition of suitable vehicles, yield solutions conforming in all respects to the requirements of injections.
- [Drug] Injectable Emulsion: Liquid preparations of drug substances dissolved or dispersed in a suitable emulsion medium.
- [Drug] Injectable Suspension: Liquid preparations of solids suspended in a suitable liquid medium.
- [Drug] for Injectable Suspension: Dry solids that, upon the addition of suitable vehicles, yield preparations conforming in all respects to the requirements of Injectable Suspensions.

Definitions included in the USP are as follows:

- Pharmacy Bulk Package: A pharmacy bulk package is a single product containing a sterile drug injection, sterile drug for injection, or sterile drug injectable emulsion (i.e., suspensions cannot be contained in pharmacy bulk packages. A pharmacy bulk package contains many single doses of the active ingredient to be used for the preparation of admixtures for infusion, or, using a sterile transfer device, for filling empty sterile syringes. The closure of the bulk package shall be penetrated only once with a sterile device that will allow measured dispensing of the contents.
- Large- and Small-Volume Injections: The demarcation of volume differentiating a small- from large-volume injection is 100 mL. Any product 100 mL or less is a small-volume injection. The main purpose for differentiating large- from small-volume injections is the method of sterilization. With perhaps a single exception for blood products, all large-volume injections must be terminally sterilized while most small-volume injections are not terminally sterilized.
- Biologics: This definition simply states that pharmacopeial definitions for sterile preparations for parenteral use do not apply to biologics because of their special nature and licensing requirements. Biologic requirements are covered in USP <1041> general chapter.