- Containers for parenteral preparations should be made, where possible, from transparent, inert materials such as glass or plastic. They must be airtight to maintain the sterility of the preparation prior to use.

Introduction

In medicine and pharmacy, *enteral administration* is the term used to describe drug administration via the gastrointestinal tract. The majority of medicines are administered orally via this route in the form of tablets, capsules or liquids. The enteral route also encompasses rectal administration utilizing dosage forms such as suppositories, enemas or rectal ointment. In contrast to this, the term *parenteral administration* literally means any method of drug administration which does not utilize the gastrointestinal tract, such as by inhalation or application to the skin. In practice however, parenteral administration is commonly taken to mean drug administration by injection.

In this chapter, we will explore why the parenteral route of administration may be chosen by the clinician or the manufacturer of a medicine. The routes available for parenteral administration and the tissues, organs and anatomical spaces that can be accessed by injection are outlined. The various forms or types of parenteral product commonly manufactured are described and the pharmacopoeial standards for injectable products are discussed. The ingredients of formulated injectable products with regard to vehicles or solvents, excipients and preservatives are described along with physiological considerations, such as the pH and tonicity of the product prior to administration. Finally the containers, closures and primary packaging commonly used for parenteral products are discussed.

Reasons for choosing parenteral administration

The vast majority of patients would prefer to receive their medication as an oral tablet or liquid to swallow, or as a cream, ointment or transdermal patch to apply to the skin rather than receive treatment via injection, which can be painful or stressful (indeed some patients suffer from needle phobia). From a manufacturer's point of view it is often simpler and much cheaper to prepare medicines such as tablets or liquids, particularly given the less stringent requirements for manufacturing premises for these non-sterile products, compared to the costs associated with manufacturing sterile medicines, such as injections, in highly specialized, controlled environments. There are, however, a number of clinical advantages associated with parenteral administration.

Many medicines are administered parenterally simply because the drug molecule itself would be rapidly broken down in the gastrointestinal tract and would thus become inactivated before it could be absorbed into the circulatory system. Good examples of this are aminoglycoside antibiotics, such as gentamicin. The injectable route may be chosen to provide a highly localized effect. This is particularly true when the injection route accesses a particular anatomical area or organ system. Examples of this include the injection of drugs, such as steroids, into joint spaces (intra-articular injection), intra-ocular injections to treat eye diseases or intrathecal injections where medicines are administered into the spinal column to deliver drugs into the cerebrospinal fluid, that otherwise might not accumulate sufficiently in this tissue to achieve the desired effect.

Intravenous injection delivers the drug directly into the circulatory system, where it is then rapidly distributed around the body. This is important clinically as the drug will rapidly produce an effect, whereas peak blood levels may not be achieved for one to two hours after a drug is administered orally. This rapid onset of action for an intravenously administered drug may be critical in emergency situations. Conversely, by choosing to administer a drug by intramuscular injection, the release of the medicine from the injection site into the circulation can be delayed and prolonged. Indeed, as will be seen later, by manipulation of the formulation of intramuscular injections it is possible to provide prolonged drug release allowing doses to be required at only once-monthly intervals. Finally, the intravenous route of injection is routinely used to administer medication to the unconscious patient who is unable to swallow. This route is also employed in conscious or unconscious patients if the gastrointestinal tract is not working. In this scenario, not only are medicines, but fluids for hydration and electrolyte replacement, plus all the nutrients, vitamins and trace elements normally obtained from a healthy diet supplied by parenteral nutrition provided intravenously.