

agents such as methotrexate or cytarabine. Volumes up to 10 mL can be administered by intrathecal injection.

Intracisternal injections are given between the atlas and axis vertebrae into the cisterna magna. This route is also used for antibiotic administration into the CSF, or to withdraw CSF for diagnostic purposes.

Epidural injections or infusions are given into the peridural space between the dura mater (the outermost protective membrane covering the spinal cord) and the vertebrae. This route is commonly used for spinal anaesthesia, for example during childbirth.

Intra-articular injections

Intra-articular (IA or i.a.) injections are given into the synovial fluid of joint cavities such as the knee. Aqueous solutions or suspensions can be administered by this route. This route of injection produces a local effect, and typically anti-inflammatory drugs are administered to treat arthritic conditions or sports injuries.

Ophthalmic injections

Ophthalmic injections are administered either around or into the eye; in the latter case these are referred to as intraocular injections (Chapter 41). Subconjunctival injections usually of 1 mL or less are administered under the conjunctiva or into the skin surrounding the eye (inside the eyelid for instance). Intraocular injections can be further classified as intracameral injections into the anterior chamber of the eye (in front of the lens), or intravitreal injections into the vitreous chamber (behind the lens). Intracameral injections can be from 0.1 mL to 1 mL in volume depending on whether the drug is left in the eye or administered during surgery on the open eye. This route has been used to administer antibiotics or local anaesthetics during eye surgery (e.g. cataract surgery). Intravitreal injections are used to administer a number of different drugs used to treat various ocular diseases. Because of the danger caused by raising intraocular pressure which can damage the retina, a maximum volume of only 0.1 mL can be administered by the intravitreal route. Ophthalmic drug delivery by injection is discussed further in Chapter 41.

Pharmacopoeial requirements

General requirements

Almost all pharmacopoeias lay down the requirements for parenteral products in a series of general monographs, with which all parenterally administered medicines are expected to comply. Most pharmacopoeias are very similar in their requirements, although details do differ and these need to be checked closely. Several different categories of parenteral preparation are described and further requirements specific to a given medicinal form are specified. This is discussed below.

Sterility

All parenteral preparations are sterile preparations intended for injection, infusion or implantation into the body. The requirement for sterility is vital as the method of administration of these products bypasses the body's natural defence systems and barriers (such as the skin or gastrointestinal system), and introduces the medicine directly into the bloodstream or other body tissues. The methods of sterilization of parenteral medications are discussed in Chapters 16 and 17.

Excipients

Excipients may be added to parenteral preparations to serve a number of purposes. They can be added to make the preparation isotonic in relation to human blood, to adjust the pH, to increase the solubility of the drug substance, to increase the stability of the drug substance and increase the shelf-life of the product or to act as a preservative. The use of such excipients will be discussed more fully below. However it is worth noting here that the use of excipients should not adversely affect the action of the drug substance, or cause any side effects or toxicity at the concentrations used in a given formulation.

Containers

Containers for parenteral preparations should be made, wherever possible, from materials that are sufficiently transparent to allow the contents to be visually inspected for particles, prior to use. Containers can be made from glass or plastic. Whatever