The total number of doses delivered is not less than the number stated on the label (this test may be combined with the test for uniformity of delivered dose).

PREPARATIONS FOR IRRIGATION

Praeparationes ad irrigationem

DEFINITION

Preparations for irrigation are sterile, aqueous large volume preparations intended to be used for irrigation of body cavities, wounds and surfaces, for example during surgical procedures.

Preparations for irrigation are either solutions prepared by dissolving one or more active substances, electrolytes or osmotically active substances in water complying with the requirements for Water for injections (0169) or they consist of such water alone. In the latter case, the preparation may be labelled as water for irrigation. Irrigation solutions are usually adjusted to be isotonic with blood.

Examined in suitable conditions of visibility, preparations for irrigation are clear and practically free from particles.

Preparations for irrigation are supplied in single-dose containers. The containers and closures comply with the requirements for containers for preparations for parenteral use (3.2.1 and 3.2.2) but the administration port of the container is incompatible with intravenous administration equipment and does not allow the preparation for irrigation to be administered with such equipment.

PRODUCTION

Preparations for irrigation are prepared using materials and methods designed to ensure sterility and to avoid the introduction of contaminants and the growth of micro-organisms; recommendations on this aspect are provided in the text on Methods of preparation of sterile products (5.1.1).

TESTS

Deliverable mass or volume (2.9.28). Preparations for irrigation supplied in single-dose containers comply with the test.

Sterility (2.6.1). Preparations for irrigation comply with the test for sterility.

Bacterial endotoxins (2.6.14): less than 0.5 IU/ml.

Pyrogens (2.6.8). Preparations for which a validated test for bacterial endotoxins cannot be carried out comply with the test for pyrogens. Inject per kilogram of the rabbits mass, 10 ml of the preparation, unless otherwise justified and authorised.

LABELLING

The label states:

– that the preparation is not to be used for injection,
– that the preparation is to be used for one occasion only and that any unused portion of preparation is to be discarded.

PRESSURISED PHARMACEUTICAL PREPARATIONS

Praeparationes pharmaceuticae in vasis cum pressu

Additional requirements for preparations presented in pressurised containers may be found, where appropriate, in other general monographs, for example Preparations for inhalation (0671), Liquid preparations for cutaneous application (0927), Powders for cutaneous application (1166), Nasal preparations (0676) and Ear preparations (0652).

DEFINITION

Pressurised pharmaceutical preparations are presented in special containers under pressure of a gas and contain one or more active substances. The preparations are released from the container, upon actuation of an appropriate valve, in the form of an aerosol (dispersion of solid or liquid particles in a gas, the size of the particles being adapted to the intended use) or of a liquid or semisolid jet such as a foam. The pressure for the release is generated by suitable propellants.

The preparations consist of a solution, an emulsion or a suspension and are intended for local application to the skin or to mucous membranes of various body orifices, or for inhalation. Suitable excipients may also be used, for example solvents, solubilisers, emulsifying agents, suspending agents and lubricants for the valve to prevent clogging.

Propellants. The propellants are either gases liquefied under pressure or compressed gases or low-boiling liquids. Liquefied gases are, for example, fluorinated hydrocarbons and low-molecular-mass hydrocarbons (such as propane and butane). Compressed gases are, for example, carbon dioxide, nitrogen and nitrous oxide.

Mixtures of these propellants may be used to obtain optimal solution properties and desirable pressure, delivery and spray characteristics.

Containers. The containers are tight and resistant to the internal pressure and may be made of metal, glass, plastic or combinations of these materials. They are compatible with their contents. Glass containers are protected with a plastic coating.

Spraying device. The valve keeps the container tightly closed when not in use and regulates the delivery of the contents during use. The spray characteristics are influenced by the type of spraying device, in particular by the dimensions, number and location of orifices. Some valves provide a continuous release, others (“metering dose valves”) deliver a defined quantity of product upon each valve actuation.

The various valve materials in contact with the contents are compatible with them.

Requirements for pressurised pharmaceutical preparations. Pressurised preparations are provided with a delivery device appropriate for the intended application.

Special requirements may be necessary for the selection of propellants, for particle size and the single-dose delivered by the metering valves.

LABELLING

The label states:

– the method of use,
– any precautions to be taken,