QUALITY CONTROLS OF PARENTERAL PREPARATIONS

Quality Control Test for Parenteral Preparations

1) Sterility Test

2) Pyrogen Test

3) Test for Particulate Contamination

4) Ambalaj bütünlük testi (çatlaklık ve sızdırmazlık kontrolü)

Sterility Tests

All lots of injections in their final containers must be tested for sterility.

The sterility test may be carried out using the technique of membrane filtration or by direct inoculation of the culture media with the product to be examined.

Membrane Filtration

The technique of membrane filtration is used whenever the nature of the product permits, that is, for filterable aqueous preparations, for alcoholic or oily preparations and for preparations miscible with or soluble in aqueous or oily solvents provided these solvents do not have an antimicrobial effect in the conditions of the test.

According to BP, use membrane filters having a nominal pore size not greater than 0.45 µm whose effectiveness to retain micro-organisms has been established. Cellulose nitrate filters, for example, are used for aqueous, oily and weakly alcoholic solutions and cellulose acetate filters, for example, for strongly alcoholic solutions.

The filtration apparatus and membrane are sterilised by appropriate means. The apparatus is designed so that the solution to be examined can be introduced and filtered under aseptic conditions; it permits the aseptic removal of the membrane for transfer to the medium or it is suitable for carrying out the incubation after adding the medium to the apparatus itself.

Direct Inoculation of the Culture Medium

Transfer the quantity of the preparation to be examined directly into the culture medium so that the volume of the product is not more than 10 percent of the volume of the medium, unless otherwise prescribed.

If the product to be examined has antimicrobial activity, carry out the test after neutralising this with a suitable neutralising substance or by dilution in a sufficient quantity of culture medium. When it is necessary to use a large volume of the product it may be preferable to use a concentrated culture medium prepared in such a way that it takes account of the subsequent dilution. Where appropriate, the concentrated medium may be added directly to the product in its container.

Pyrogen Test

The USP evaluates the presence of pyrogens in parenteral preparations by a qualitative fever response test in rabbits, the Pyrogen Test, and by the Bacterial Endotoxins Test.

Particulate Evaluation

Particulate matter in parenteral solutions long has been recognized as unacceptable since the user could be expected to conclude that the presence of visible dirt would suggest that the product is of inferior quality.

Today, it is recognized that the presence of particles in solution, particularly if injected intravenously, can be harmful.

It has been shown that particles of lint, rubber, insoluble chemicals, and other foreign matter can produce emboli in the vital organs of animals and man. Further, it has been shown that the development of infusion phlebitis may be related to the presence of particulate matter in intravenous fluids.