

Production steps 1 to 8

1. Production Of High-Purity Water - WFI (Water For Injection)

A special sterile water – so-called "water for injection" (WFI) – is needed to manufacture infusion solutions. It is made from fully deionized drinking water, which is distilled a second time. The WFI is then stored at a specific temperature until it is pumped through stainless steel pipes into the production process. The quality requirements of WFI are defined in national pharmacopoeia.



2. Receiving Inspection Of The Raw Materials

The individual raw materials for the infusion solutions (e.g. common salt or glucose) must satisfy high quality requirements. They are therefore checked carefully after delivery and can only be used for production after approval by the receiving laboratory..

3. Weighing Of The Raw Materials

Before actual preparation of the infusion solutions can begin, the raw materials needed are first weighed into doses for the order and recipe in question and then filled into containers until used.

4. Preparation Of The Infusion Solution

The mixing tanks are first filled to 80 percent with WFI. The previously weighed raw materials are then added and dissolved in the water by stirring. When the raw materials have been dissolved completely, the tank is filled to 100 percent with WFI. The finished infusion solution then runs through two filters, which can filter particles up to a size of 0.2 micrometers out of the solution.

5. Filling Of The Infusion Solution

The finished infusion solution preparations are filled either into glass bottles or into Ecoflac plus containers (a "bag bottle" made of polyethylene). We would like to describe the filling process on the basis of an Ecoflac plus container because the innovative "blow-fill-seal-technology" is used here. The remarkable feature of this technology is that a homogenous product is manufactured from a material (polyethylene) in one work step. The molten polyethylene is blown into shape, filled with the finished infusion solution and sealed in one work cycle. This makes it possible to produce an infusion solution container that combines the advantages of a bag with those of a bottle, thereby representing a completely new category of container that supports users optimally in the hospital in their everyday work routines. The technical process begins with the polyethylene granulate being fed into a so-called "Bottlepack® machine." In this machine, the granulate is passed into an extruder and melted. This mass is then pressed over a tube die and formed into a tube. It is then welded from below and a hanger formed so that the container can later be hung up. An immersion unit then drives into the tube, seals the top of the container again and blows it up. The infusion solution is then filled into the bag by the immersion unit. Finally the bag is welded closed. The volume of the infusion solution containers ranges from 100 to 1,000 ml.



6. Further Processing And Testing Of The Full Infusion Solution Container

When the container has been filled and welded closed, it is passed on to a leak testing machine. When the container has been checked for leaks, a cap is placed on it and connected to the bag by an injection molding machine. During the production process the bags are randomly subjected to various tests, partly visual (e.g. is the shape of the container okay and is the bag clean) and partly physical

(e.g. are the weight of the empty container, its wall thickness and volume in order). The head assembly is also checked.

7. Sterilization Of The Infusion Solution

The bag is then passed on for sterilization in sterilizers, which heat it with hot water. The individual containers must then be cooled and dried before being labeled. Control samples are also taken of every batch after sterilization for approval testing of the batch. These tests include testing of sterility, testing for the presence of pyrogens, chemical analysis of the solution and particle testing.

8. Labeling And Packing Of The Infusion Solution Containers

After a final inspection, the infusion solution containers are labeled for the particular country for which they are destined and packed into cartons. In addition to the infusion solution containers, user information is also packed into every carton. In addition to the infusion solution containers, user information is also packed into every carton. When the cartons have been packed, their weight is checked and they are labeled. The individual cartons are palletized and labeled automatically and then stored in the Goods Distribution Center. When all the results of the quality controls are available, the pallet is approved for sale.



Packing



Labeling