Manufacturing of Traumeel Injection Solution

Part II: Sterilization, Quality Control, Labeling, and Packaging

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With regard to both equipment and personnel, the production of Traumeel ampoules is subject to more stringent regulation than the production of non-sterile dosage forms such as ointment, tablets, or drops. Preparing the ingredients, producing and filtering the injection solution and filling it into glass ampoules all take place in Class C cleanrooms, which can be entered only by specially trained personnel wearing protective clothing.

After filling, the ampoules are marked for identification, placed in stainless steel containers, and transferred to the Sterilization department, where they are autoclaved in accordance with the requirements of the *European Pharmacopeia (Ph. Eur.)*. In this process, hot steam under pressure of 1 bar over atmospheric pressure is used to effectively kill all microorganisms. The sterilizers used in this process are very large, tall compartments of stainless steel that can be vented on two sides. The ampoules to be sterilized enter from a Class C cleanroom on one side and are discharged on the other.

Duration, temperature, and pressure of the sterilization process are constantly and precisely monitored and recorded by measuring devices built into the sterilizer. In addition, the ampoules are marked with an indicator stripe showing that the required temperature has been attained. Only then is the sterilizer emptied. Samples are taken to monitor microbiological and chemical quality.

Quality control testing

In the next step, an optical testing procedure is used to monitor every ampoule (100 percent control) for

Device for testing ampoules for visible particles

Photos by Sonja Bell

Manual loading of ampoules into a sterilizer

A star wheel feeding ampoules into the testing device for visible particles

Right:
Device for testing ampoules for leaks

mobile and visible particles such as bits of glass that might develop when the ampoules are sealed. The testing device detects visible particles down to 50 µm in size. All defective ampoules are sorted out and destroyed. All the ampoules that pass this test are carried by a conveyor belt to the next testing site, where they are tested for leaks. Measuring conductivity under high voltage determines whether each ampoule is intact or cracked. Here, too, every ampoule is tested (100 percent). This machine can test up to approximately 200,000 ampoules per day.

All of the intact ampoules then continue on to the labeling department, where self-adhesive labels are applied. Product-specific printing plates are first used to hot-stamp the required data on the blank labels. Immediately downstream, a camera system checks to ensure that the printing is complete and correct. The label is then detached from its carrier film, applied to an ampoule, and secured by a roller. A sensor uses a mark on each label to guide it into position. As each ampoule is discharged from the labeler, it is monitored by another sensor that confirms the presence of a label. This equipment can label about 330,000 ampoules per day.

After labeling, the finished Traumeel ampoules are spot-checked for correctly applied and printed labels.

Packaging

The labeled ampoules still have to pass through one last department, namely, the Packaging department. A machine inserts the ampoules into special trays shaped out of heated plastic film. Another machine inserts each filled tray into a folded cardboard box along with a package insert. After a scanner confirms the identity of the secondary packaging (box and package insert), the batch number and expiration date are stamped on the box. At the end of the assembly line, the package is weighed to confirm that all components have been included in the box. The finished boxes are then bundled and packed into shipping cartons.

The production head then checks the manufacturing report to confirm that the ampoules were produced in accordance with the production instructions. The head of Quality Control also checks the report to confirm that all testing was conducted in accordance with the test instructions to ensure the required quality. As the very last step, the batch of medication is released by the Qualified Person in accordance with §15 of the German Pharmaceuticals Act (AMG).

Now the Traumeel ampoules are ready to be shipped out to wholesalers and pharmacies in more than 50 countries around the globe. With a production of 100 million units per year, Heel is the world's leading manufacturer of homeopathic injection medications.

Inserting ampoules into plastic trays on the assembly line