

... Traumeel: How Does the Ointment Get into the Tube?

By Sven Schäffer, PhD



It's a familiar scenario for every active person: You overdo it and end up with sore muscles, or a hard hit produces a painful bruise. Perhaps you apply Traumeel ointment to the affected area to aid and accelerate healing. But have you ever wondered how that ointment gets into the tube?



The active ingredients are first diluted and succussed (right); the Becomix mixer then incorporates them into the ointment base (left).



Most of the active ingredients in Traumeel ointment are derived from medicinal herbs such as Arnica montana.

Empty tubes approach the filling machine (top), where they are ...

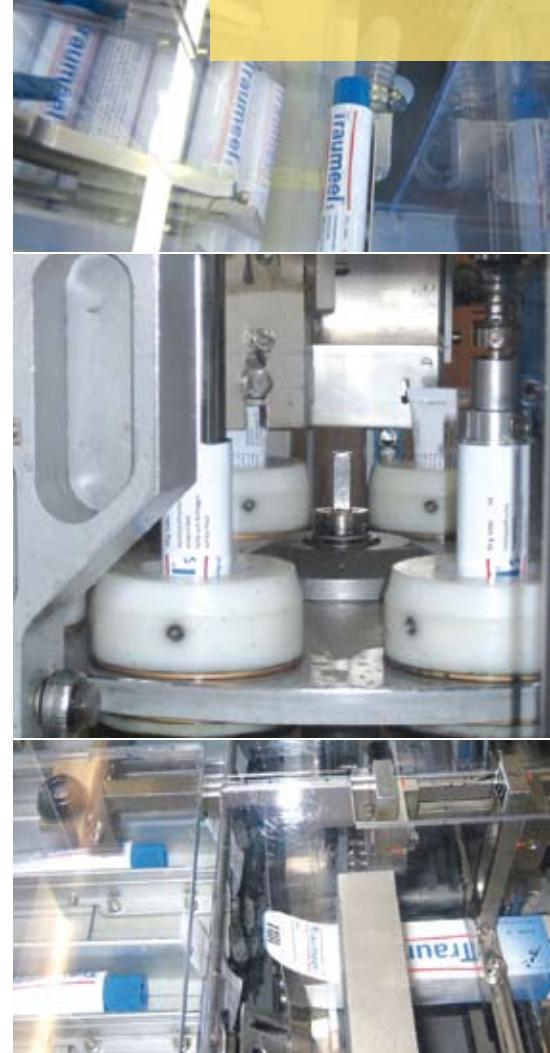
... filled (middle) ...

and inserted into cartons along with package inserts (bottom).

First of all, the ointment contains fourteen active ingredients. Twelve are extracts of well-known medicinal plants such as arnica, calendula, and chamomile. They come in liquid form, as so-called mother tinctures. The remaining two ingredients are mineral salts, supplied in powder form.

When an order for Traumeel ointment is received, those twelve mother tinctures and two mineral salts are transferred from the warehouse to the production facilities, where each liquid ingredient is diluted and *succussed* (shaken) separately to the required dilution or "potency." The two solid ingredients are first *triturated* (pulverized) with lactose and then diluted and succussed with ethanol. Collectively, these processes are known as "potentization." Once the potentization process is completed, the ingredients are mixed together in specific proportions to produce a complete solution containing the right dilutions of all fourteen ingredients. It goes without saying that all of these steps are implemented and documented in accordance with GMP ("Good Manufacturing Practice") principles.

Meanwhile, the ointment base is being prepared in a huge stirring vat. (A typical production run is 500 kg, 17 kg of which are active ingredients.) A small window in the vat allows workers to check on the progress of the mixing process. To produce a consistently emulsified ointment base, the fatty ingredients (petroleum jelly and paraffin) and the water phase must be heated separately to about 80°C before being introduced into the vat for mixing. Once the mixture is fully emulsified, it is cooled to 58°C before ethanol and the active ingredients are added to complete the formula. The final product is then cooled to room temperature and transferred to a large storage vessel, where it is monitored by Quality Control before packaging. All this takes about three days. Once Quality Control has released the ointment for packaging, the next step is filling the tubes. The container of ointment attaches directly to the filling machine, which does all the rest automatically: the open lower end of each tube is inserted into the machine, which has a filling rate of 50-60 tubes per minute. After filling, each tube is crimped, sealed, and imprinted with the lot number and the expiration date for post-production tracking.



Next, the package inserts are folded, and one insert is placed alongside each tube for insertion into the box. Optical scanning confirms the presence of the insert in each unit, and the packages are weighed to ensure all parts have been included. Finally, the packages are inserted into cartons in bundles of five. Here, too, each tube that has been produced is documented to allow tracking. Now the Traumeel ointment is ready to be delivered to wholesalers and pharmacies in more than 60 countries throughout the world, where patients can purchase it to treat their injuries.

This is how more than 2 million tubes of Traumeel ointment are produced in Baden-Baden each year. ■