

Manufacturing Liquid Medications: How Do Those Drops Get Into the Bottle?

By Rüdiger Schneider, PhD

No one thinks twice about using liquid medications, especially drops for detoxification and drainage. I'm sure you've prescribed the Detox-Kit for your patients or perhaps even used it yourself. But have you ever wondered how those drops get into the bottle?



It all starts with the active ingredients. The mother tinctures are inspected before they are introduced into the manufacturing process. The German Homeopathic Pharmacopoeia (HAB), the basis for all production of homeopathic medications, dictates exactly which lab parameters must be tested. Heel's internal rules require additional testing to ensure that production meets GMP standards, so tests for microbiological purity are always performed in addition to tests for physical properties.

Each liquid product has its own sheet of production instructions with a bill of material detailing exact quantities of the various components.

After the mother tinctures pass inspection, the next step is making single-ingredient dilutions. A number of these dilutions are then combined into a "potency mixture" and potentized together by adding a precisely specified amount of an ethanol/water blend. The potentized mixtures are then combined to produce the finished product.

A variety of active ingredients, usually in the form of mother tinctures or single potencies, are used in manufacturing homeopathic drops. Exact quantities are given in the manufacturing instructions, which are specific to each medication.



Every step of production is carefully monitored and precisely documented.



Alternatively, single-ingredient dilutions may be potentized directly with the ethanol/water blend to create the finished product. Whether potency mixtures or individual potencies are used is precisely defined by the HAB and depends on which raw materials or mother tinctures are involved. To prevent mix-ups when weighing out single-ingredient dilutions, each dilution is labeled not only with its classical homeopathic description but also with a bar code that includes the batch number and material number.

Before the newly completed finished product is packaged, it undergoes another series of tests for physical and microbiological properties, including pH, Hazen number, density, and TLC (thin-layer chromatography). The product is cleared for packaging only when all of the test results are satisfactory.

Automated recording of all individual steps in the process allows the origins of each batch to be traced at

One of the active ingredients of Lymphomyosot drops: Juglans regia, better known as walnut. Equal parts of the fresh leaves and the fresh rind of the green fruit are used to produce the mother tincture.



any time. Clearance to proceed to the next step is also issued automatically. In addition, in-process monitoring ensures correct completion of individual production stages and intermediate stages even in complex production runs involving large numbers of ingredients.

All workstations involved in either manufacturing or packaging the finished product are doubly inspected before being cleared for use. (Since four eyes are better than two, two employees complete the same checklist.)

Before the finished product is packaged, the filling equipment is first cleaned and rinsed. Depending on the fill quantity (30 or 100 ml), the bottling machines can fill either four or six bottles simultaneously. Each assembly line can process approximately 4,000 units per hour, depending on the fill volume. The filling operation is followed by an initial automated inspection of fill levels.

Next the tamper evident bottle caps are screwed on and tightened to a predetermined torque; labels (which already include the batch number and expiration date) are then applied. To avoid mix-ups and ensure automatic rejection of any incorrect or damaged packaging, all labels, package inserts, and boxes are marked with bar codes that are read by a scanner.

Filling, labeling, and packing the bottles are fully automated processes. Of course they are also monitored constantly.

At this point, the process is nearing completion. The bottles (along with package inserts) are boxed, and the expiration date and batch number are printed on the boxes, which are checked again for completeness before each unit is sealed.

A belt weigher at the end of the production line rechecks the fill level and rejects any underfilled bottles. After banding, the new batches are then ready for shipping.

The process of manufacturing liquid homeopathic medications is highly complex and requires a correspondingly high degree of documentation. Every step of the way is monitored, and the documentation is constantly checked by the team leader and the production manager. The end result? Those familiar bottles of drops, which are easy to use and ensure accurate dosing. The best-known example is the Detox-Kit, which includes three liquid medications – Lymphomyosot, Nuxvomica-Homaccord, and Berberis-Homaccord – for detoxification and drainage. The Detox-Kit is becoming increasingly popular worldwide, but that's hardly surprising, is it? |