From Plant to Bottle:

The Production of Homeopathic Nasal Sprays

By Iris Woock

Winter season is cold season. Sooner or later, it catches up with (almost) everyone: Your nose begins to itch, and you feel the beginnings of a cold. Now is the time for Euphorbium comp.-Nasal Spray,* a popular medication for cleansing, moistening, and soothing irritated mucous membranes. Thanks to its excellent tolerability, it is even suitable for pediatric use.

To ensure the safety of homeopathic medications, the manufacturing process is very strictly regulated by law. In particular, producers must adhere to the following rules and standards:

- the **German Homeopathic Pharmacopoeia** (HAB, Homöopathisches Arzneibuch), which contains detailed instructions for producing mother tinctures and potencies
- the **European Pharmacopoeia** (Ph. Eur.), which describes the production of each dosage form and the physical and microbiological testing required
- **GMP Guidelines** (Good Manufacturing Practice), which ensure the quality of pharmaceutical production processes and the production environment

The manufacture of bottled Euphorbium comp.-Nasal Spray begins with written production instructions for implementing each process step. These instructions ensure that all process steps are reproducible and always completed in the same way.

At a rate of 90 units per minute, the homeopathic nasal spray is filled into brown glass bottles. Filling, sealing, labeling, and packaging the bottles are fully automated processes.

* Marketed as "Sinusin" in the US and Israel.

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All steps are very carefully monitored and documented in the production report according to the principle of dual control: for safety reasons, all critical steps are always checked and documented by a second person.

On the basis of the production instructions, the first step is production of a mother tincture through extraction (plant materials) or solution or trituration (minerals).

The mother tincture is then tested in the laboratory (for identity, relative density, dry residue, heavy metals, pesticides, microbial impurities, etc.) and must conform to test specifications before it is released for further processing.

Mother tinctures are then potentized with an ethanol/water mixture in accordance with HAB regulations. The carrier for the last two potentizations is purified water because ethanol would irritate the nasal mucosa. Individual potencies are then blended, and the resulting potency mixture is combined with a base of isotonic salt solution to form the nasal spray mixture. Some formulas contain an additional preservative. Now the bulk product is finished.

Filling is accomplished under a laminar flow hood, where a stream of ultra-clean air displaces any air that might contaminate the product with germs. But first the finished mixture is filtered and samples are drawn for testing in the quality control lab. Test parameters include Hazen color number, relative density, pH, osmolality, and microbiological purity. Once it has passed all of these tests, the nasal spray mixture is cleared for bottling. Six parallel nozzles pump the exact fill quantity (20 ml per bottle) into brown glass bottles.

Tamper-proof seal

Finally, to maximize ease of use for patients, spray heads with sealed patented caps are applied to the filled bottles. An unbroken seal ensures that the bottle has not been opened before the patient uses it for the first time.

The new patented seal immediately shows if the bottle has been opened before the patient uses it for the first time.

The optimum rate for filling and sealing is 90 bottles per minute. In the next step, each bottle receives an appropriate label with product data including the expiration date and batch number. Then the bottle, along with a product insert, goes into a folding box (so-called secondary packaging) and the batch number and "best before" date are printed on the top flap.

The completed packages are weighed as a final check to ensure that none of the bottles are under-filled. They are then film-wrapped in batches of five for easier handling and packed into shipping cartons.

Samples are drawn and tested throughout the entire filling process, and before the medication is released for sale, it is cleared one last time by the so-called Qualified Person in accordance with § 15 of the AMG (German Pharmaceuticals Act). Clearances are registered continually, so all steps of the production process as well as all tests are traceable. The product is then ready for shipping to wholesalers or pharmacies in Germany or anywhere else in the world.

This is how approximately three million packages of Euphorbium comp.-Nasal Spray are produced each year.