HOMEOPATHIC DRUG: Quality control linked to the Pharmacopoeia

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Abstract

The homeopathic medicine, like any other medicine, must comply with the quality rules and guidelines defined by law such as the Pharmacopoeia, the ICH standards, the Good Manufacturing Practices and the European Directives in force.
After an introduction on the definition and the regulatory status of the homeopathic medicine according to the European Directive 2001/83 / CE, the pharmacopoeia-specific standards are developed.
Several examples of monographs of raw materials used in homeopathy are detailed.
Thus, a monograph of each of the origins is exposed i.e. plant, animal and chemical.
Other examples of monographs of finished products were discussed. They concern several galenic forms (solid forms, granules, tablet, syrup, eye drops).
Due to the specificity of the homeopathic medicine, the infinitesimal dilution of the active ingredient and the impossibility of quantifying it in the finished product, the control of "strains" or mother tinctures and homeopathic raw materials (vegetable drugs, chemicals, etc.), galenic forms and validation of the manufacturing processes are carried out.
The rules and requirements are a guarantee of reliability and credibility vis-à-vis the authorities, the body of health (doctors, pharmacists, midwives ...) and the patient.

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