



Checking the Quality of Herbal Products

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Quality inspection and testing constitutes a central element of quality assurance with respect to herbal starting materials and active substances, as well as pharmaceutical products and food. PhytoLab offers you an extensive range of facilities for examining your raw materials and products with **phycheck** – using conventional methods and ultra-modern instrumental analysis.

- Checking for identity, purity and content
- Microbiological testing
- Method development and validation
- Stability testing
- Accredited laboratory with GMP certification

Checking for identity, purity and content

All pharmacopoeias demand tests to determine identity, purity and content for medicinal products, active substances and excipients. Requirements like these are also becoming increasingly important for foodstuffs. Emerging from the in-house laboratory of Martin Bauer, PhytoLab can call on many years of experience with traditional pharmacopoeial procedures and methods. Since PhytoLab was founded in 1993, these services have also been available to companies outside **the nature network®** alliance.

Identity

Pharmacognostic tests, primarily including microscopic assays by comparison with authentic reference material, as well as organoleptic testing, are indispensable for identity testing. PhytoLab has a comprehensive collection of botanical reference drugs at its disposal, including TCM drugs. In addition to this,

herbal products are also identified by means of thin-layer chromatography (TLC) with state-of-the-art video documentation and, to an increasing extent, gas chromatography (GC) and high-performance liquid chromatography (HPLC).

Purity

Conventional methods are usually used to test purity. However, instrumental analytical techniques are also being employed, such as HPLC and GC with highly selective detectors.

Content

Apart from the classical volumetric, gravimetric and photometric methods, instrumental chromatographic techniques (HPLC, GC, DC) have been gaining considerable significance as a means of determining content in recent years. PhytoLab has a broad spectrum of ultra-modern analytical instruments at its disposal, including more than 30 HPLC units

with all of the commonly used detection systems, such as UV, fluorescence, refractive index, light-scattering and conductivity detection. We also use coupled techniques, such as LC-MS/MS. There are 25 GC units with such selective detectors as FID, ECD, FPD, MS, MS/MS available in the GC sector. Our equipment and facilities enable us to perform assays according to all of the standard procedures laid down in the usual national and international pharmacopoeias as the German Pharmacopoeia (DAB), the European Pharmacopoeia (Ph. Eur.), the United States Pharmacopoeia (USP) or acknowledged collections of methods as the German Pharmaceutical Codex (DAC) and those described in § 64 of the German Food and Feed Code (LFGB) or by the Association of Analytical Chemists (AOAC), for example. In addition to this, we are continuously developing and validating methods and procedures of our own to provide customised analytical solutions for our customers.

Microbiological testing

Verifying microbiological purity is one of the most essential integral elements of quality inspection and testing, offering a means of drawing conclusions regarding the hygienic status of the production process. PhytoLab not only analyses in accordance with the stipulations laid down in the pharmacopoeias – particularly including the Ph. Eur. – but also in accordance with methods practiced in the food sector. Testing for the presence of specific, critical bacteria, such as Salmonella, is performed by means of a time-saving, highly specific analysis of the genetic materials, the polymerase chain reaction (PCR).

Method development and validation

Specific procedures for the identification and quantitation of active substances are especially needed for the registration and marketing authorisation of herbal medicinal products. These and

other methods must be validated in accordance with state-of-the-art requirements, particularly including ICH Guidelines, in order to ensure that reliable results are obtained. The phytochemical marker substances used for this are often only present in very small quantities. Experience and sophisticated equipment are therefore required in order to develop and validate selective methods with adequate sensitivity. The knowledge that we have acquired over many years in this field and our first-class instruments and equipment are supplemented by the use of innovative software for optimisation of chromatographic separation systems. This also constitutes the basis for the development of practical, registration-suited solutions for complex combination products.

Stability testing

The stability of medicinal products and active substances must be proven and documented in accordance with the applicable ICH Guidelines.

We are able to carry out complete stability studies on behalf of our customers thanks to our extensive storage capacity at 25 C / 60 % rF (long-term stability), 30 C / 65 % rF (intermediate testing) and 40 C / 75 % rF (accelerated testing), as well as refrigerator and freezer storage facilities. Formal and economic considerations are such that careful planning and a competent interpretation of the results are of utmost importance for the relatively new field of ongoing stability to an even greater extent than for the highly standardised stability studies for the registration procedure.

Accredited laboratory with GMP certification

PhytoLab gives top priority to quality assurance. PhytoLab has therefore been accredited in accordance with DIN EN

17025 for all laboratory fields and is authorised to test official control food and drug samples. PhytoLab has GMP certification and is authorised to carry out tests on drugs in accordance with the stipulations of § 14 (4) of the German Drug Law (AMG). Official experts for drug and food samples are at your disposal if you need advice. By taking part in national and international proficiency testing schemes on a regular basis, we have our performance continuously and successfully monitored by independent parties. Increasingly stringent requirements imposed by legislative bodies and users demand maximum safety and security for quality inspection and testing of drugs and food. With **phycheck**, we offer you an all-inclusive service for quality control of your herbal products with experienced specialists, as well as first-class instruments and equipment.

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