



Reference Substances for Herbal Products

phy | **proof**®
Proof of Quality for Markers

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The quality of herbal drugs and the extracts and finished products made from them is essentially defined by their content of active substances or specific marker substances. High-quality reference substances are required in order to determine the quantitative content exactly. In its capacity as a laboratory specialising in herbal products, PhytoLab offers a wide range of extensively documented reference substances for all

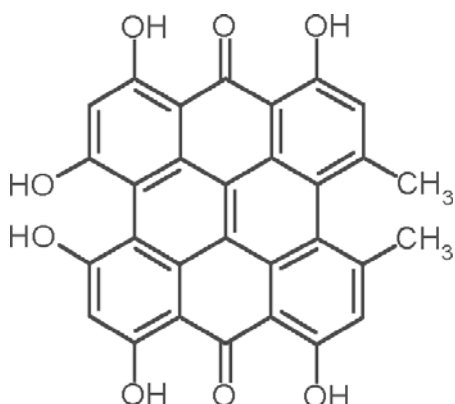
of the usual herbal drugs found in medicinal products and foodstuffs, including a large number of drugs from the Traditional Chinese Medicine (TCM) sector, under the name **phyproof®**.

- Content standards
- Primary standard documentation
- Customized isolation
- Substance characterisation

Content standards

The **phyproof®** Reference Substances offered by PhytoLab constitute content standards that are ideal for use in daily quality control routines. The absolute content of each **phyproof®** Reference Substance has been tested so comprehensively that there is no need for any further comparison against a primary standard – and this can help to save money! Apart from determining its chromatographic purity by means of HPLC or GC, each substance also undergoes coulometric water determination on a micro-scale, a validated headspace GC procedure is used to test for the presence of any residual solvents and any inorganic impurities are detected by means of ICP-MS (Inductively Coupled Plasma Mass Spectrometry).

It goes without saying that the identity of every **phyproof®** Reference Substance is verified – by means of $^1\text{H-NMR}$ or $^{13}\text{C-NMR}$ spectroscopy, mass spectrometry or IR spectroscopy. Apart from the results of the individual assays, the certificate of analysis enclosed with the reference substance free of charge also contains information relating to the absolute content calculated from the results. This not only ensures that each **phyproof®** Reference Substance is ready to use, but also that the quoted absolute content is always up to date, as the chromatographic purity is checked at regular intervals.



Primary standard documentation

PhytoLab draws up extensive primary standard documentation that complies with all current regulatory requirements for every **phyproof[®]** Reference Substance, particularly for registration and marketing authorisation purposes. The documentation contains all of the raw analytical data from identity testing and content analysis (¹H-NMR, ¹³C-NMR, MS, IR, elemental analysis, TLC, water content, residual solvent content, inorganic impurity content, chromatographic purity testing by means of two independent chromatographic methods), as well as the requisite extensive interpretation of the results, the validation data from the two chromatographic procedures and more in-depth scientific literature. Our primary standard documentations have been officially acknowledged by the regulatory authorities for many years now.

Contract isolation

In the unusual event that a particular reference substance is not included in our portfolio, we join forces with our partners all over the world to investigate the availability of the substance concerned. We are also happy to isolate and characterise the substance that you need in the required quantity and to the specified extent in our preparative laboratory.

Substance characterisation

Do you need characterisations and qualifications for your specific reference substances? PhytoLab offers you a service that is completely tailored to your individual requirements; beginning with chromatographic purity testing and determination of the water content, right through to complete primary standard documentation.

PhytoLab also provides support with respect to the identification and characterisation of marker substances in your drugs or extracts, whereby there is often no need to isolate the substance for this. Coupled HPLC-MS and HPLC-NMR procedures can frequently be used for identification purposes with a minimum of sample preparation work.

Up-to-date information in the Internet

Because the range of **phyproof[®]** Reference Substances is expanding all the time, you will find the most up-to-date information relating to the currently available reference substance spectrum at www.phytolab-referencesubstances.com – which also offers you an easy-to-use search function. Furthermore, you can use the **phyproof[®]** web shop as a source of information concerning the physico-chemical data of the offered substances, and as a convenient means of purchasing on-line.

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