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Herbals

The European Pharmacopeia contains different chapters dealing with the requirements of Herbals.

Herbal Drugs (1433)
Herbal drugs are mainly whole, fragmented, or broken plants, parts of plants, algae, fungi or lichen, in an unprocessed state, usually in a dried form but sometimes fresh.

Herbal Drug Preparation (1434)
Herbal drug preparations are homogeneous products obtained by subjecting herbal drugs to treatment such as extraction, distillation, expression, fractionation, purification, concentration or fermentation.

Herbal Teas (1435)
Herbal teas consist exclusively of one or more herbal drugs intended for oral aqueous preparations by means of decoction, infusion or maceration.

Herbal Drug Extracts (0765)
Herbal drug extracts are liquid, semi-solid or solid preparations obtained from herbal drugs using suitable solvents.

Additionally, many products are described individually in the product monographs, e.g. Senna leaf, Matricaria flowers.

Why Choose Eurofins BioPharma Product Testing?

With 28 facilities in 16 countries we are the largest network of harmonized bio/pharmaceutical GMP product testing labs worldwide.

Our service offerings are fully comprehensive and include testing of drug substance, final product, intermediates and starting materials for both small and large molecule drug products.

Sampling

One of the most important aspects for a correct analysis of herbal drugs is the sampling and assessing the homogeneity of the sample. Only a few grams are needed for an analysis of a substance. This small amount is representative for an entire batch. Therefore the sampling is very important.
When the sample arrives in our lab we mill and homogenize the sample according to EP 2.8.20. The amount of required sample depends on the sample batch size. If you need further information we will be glad to assist you.

Testing of full Monograph

We already have experience in the analysis of herbal drugs for more than 90 years.
We can test the microscopical and macroscopical identity of your product according to EP or ChP. We also have a huge variety of methods and references for the identity testing using thin layer chromatography. The European Pharmacopeia also specifies several purity checks for herbal drugs e.g. the testing of foreign matter, ash, acid insoluble ash, swelling index, bitterness value, loss on drying etc. Of course we are also able to offer the complete scope of these tests.

Mycotoxins (Aflatoxins and Ochratoxins)

Aflatoxins are part of the so-called mycotoxins. They are natural, secondary metabolites of moulds, which can show toxic effects towards humans and animals even in low concentrations. Because of the known genotoxic and carcinogenic properties of aflatoxins their dietary intake should be reduced as far as possible. Therefore, analysis of aflatoxins is a vital component of risk management programs.

Aflatoxins are formed by different Aspergillus species, mainly Aspergillus flavus and Aspergillus parasiticus. At least 20 naturally occurring aflatoxins are known, of which the aflatoxins B1, B2, G1 and G2 occur in herbals. Aspergillus species require high temperatures and humidity for the formation of aflatoxins.

Therefore, these toxins are – despite of the worldwide occurrence of toxin-forming fungi – especially prominent in subtropical and tropical areas and less significant in areas of cultivation of the temperate zones.

However, when conditions benefiting the growth (e.g. high temperature and humidity) occur during storage of harvested crops, these products may be also affected and contaminated after the harvest.



We can offer the analysis of aflatoxins B1, B2, G1, G2 and their sum according to EP 2.8.18. Additionally, we can perform the analysis of ochratoxin A according to EP 2.8.22.

Heavy Metals

The heavy metals lead, cadmium, mercury as well as arsenic are omnipresent within our environment – not least due to various industrial processes. They find their way into herbal drugs by intake through water and soil as well as through atmospheric sediments.

The Monograph for herbal drugs describes requirements for Cadmium (<1.0 ppm), Lead (<5.0 ppm) and Mercury (<0.1 ppm) as well as the information, that limits for other heavy metals may be required.

The European Pharmacopoeia describes the analysis of heavy metals in chapter 2.4.27. This chapter recommends the use of ICP-MS or AAS for detection. The ICP-MS method has several advantages; it allows the performance of a screening, the time of analysis is clearly shorter and the limits of detection can be set much lower. We perform both methods on a routine basis.

Pesticides

The term "pesticides" summarizes active agents used for pest control as well as crop and storage protection. These substances control harmful insects or inhibit the growth of moulds. They are applied during crop production, processing and storage of raw materials of plant origin.
Worldwide, more than 1,000 agents are permitted that spread over a wide range of chemical products. These products are applied on soil or plants to avoid yield loss caused by the damage of insects or fungi. But even after proper and recommended use of pesticides, residues may remain on the harvested crop.

Our Eurofins partner laboratory Dr. Specht offers the analysis of pesticides according to EP 2.8.13, under either GMP or ISO 17025 conditions.

Of course, it is also possible to test according to self-determined specifications with individual scopes of testing. Hereby several single or group-methods can be applied to diverse raw materials and products.

Pyrrolizidine Alkaloids

Pyrrolizidine alkaloids are secondary metabolic products, formed to protect against herbivores by a multitude of plant species worldwide. More than 500 different pyrrolizidine alkaloids and corresponding N-oxides are known, some of them being extremely toxic.

However, a majority of the levels of pyrrolizidine alkaloids in pharmaceutical raw materials or their extracts are related to impurities with so-called weeds such as, Heliotropium or Senecio species. The weeds can contaminate the respective batches during the harvest, so that indirectly also products from plants could be affected which are not synthesizing pyrrolizidine alkaloids originally by themselves.

The BfArM (Federal Institute for Drugs and Medical Devices; Bundesinstitut für Arzneimittel und Medizinprodukte) demands the pharmaceutical manufacturers, to classify their phytopharmaceuticals and to check routinely the high risk products with regard to the PA level as part of the release dates of each batch production to ensure that a limit of 1.0 µg PA is not exceeded in relation to a daily dose.

Microbiology

The microbiological status is a key indicator for the quality of a product. As aflatoxins, also high levels of bacteria may be an indication for bad storage conditions or other hygienic problems during their processing. High levels of bioburden, but especially of pathogenics may be harmful to humans and therefore their dietary intake should be avoided.
The European Pharmacopeia regulates the microbiological requirements for herbal drugs in Chapter 5.1.8. We offer the testing of your products according to EP 5.1.8 A – C. Of course we can also offer microbiological testing of non-sterile products according to EP 5.1.4.

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