

# AUTHENTICITY and TRACEABILITY: key parameters for quality botanicals

Indena provides genomic identification solutions for both plants and extracts

It has been estimated that approximately 30% of the biomass of materials sold for human consumption is not what it's claimed to be. The market for botanical products is full of adulterated items and being able to guarantee the quality and safety of your own products provides a competitive edge. Indena ensures the reliability and consistency of its extracts' composition with a process that involves every stage of production — from cultivation to the finished ingredient.

The first quality control step during the preparation of botanicals is to correctly identify the plants being used. Currently, there are two mandatory tests: botanical identification (macroscopic and microscopic) and chemical identification (analytical “fingerprint” techniques to characterise secondary metabolites). The two main reference points are the *European Pharmacopoeia*'s general monograph, “Herbal,” and the *United States Pharmacopoeia*'s general chapter on the “Identification of Article of Botanicals Origin,” which are accepted all around the world as key guidances.

Most plants can be unequivocally identified by macroscopic and microscopic analysis. In



some cases, however, it is necessary to resort to DNA-based methodologies to precisely define the identity at the species or variety level. As such, it can be said that one of the most effective methods is to verify the authenticity of botanical raw materials according to its genomic identification.

Managing the genomic identification of plants is somewhat challenging because, although we know a great deal about animals and their DNA, the same cannot be said for plants. Indeed, our knowledge regarding animals and, in particular, their DNA, is relatively extensive, whereas the authentication of herbs and botanicals is more complex and requires the expertise of different scientific disciplines, including botany, biology and chemistry.

Initiating a programme of research on the topic in 2010, Indena has since developed some sophisticated DNA sequencing-based tests (DNA barcoding) that ensure the traceability of the medicinal plants being used. And, considering that there is no universal DNA barcoding methodology for plants — because each one requires a dedicated method to be developed according to its specific genome —

Indena has been mapping the genetic identity of the raw materials it uses for its botanical extracts for years: this knowledge has allowed the company to develop species-specific DNA identification analytical tools.

Since 2011, Indena has been able to guarantee the identification of the plants being used with species-specific DNA barcoding. In addition, the company has added DNA analysis to the many quality control procedures it performs to guarantee the high standards of its products, such as botanical and chemical identification, purity and the absence of contamination. With plant DNA analysis, Indena has added a fundamental element of certainty about the quality and authenticity of its products. Moreover, Indena is able to apply the appropriate technology on case-by-case basis.

DNA testing generally comprises three stages:

- extraction using an established protocol to extract the DNA
- amplification, which is usually achieved by PCR (Polymerase Chain Reaction) to provide a consistent amount of DNA to be analysed
- measurement by analysis of the DNA sequences.

However, Indena's approach to genomic identification is more well-structured and based on the following pillars:

- DNA barcoding is orthogonal: one technique may not be enough
- an in-depth botanical background to structure the DNA methodologies
- the ability to use the whole range of available DNA techniques
- the availability of authenticated plant material to develop highly reliable DNA tests
- knowing where, when and how to collect the reference species to be used as “certified” controls to validate DNA methods
- the ability to identify unknown species.

Thanks to the DNA sequencing-based tests, which are part of Indena's quality protocols, the company is able to identify the species and varieties of the medicinal plants it uses and guarantee the quality, traceability and authenticity of its ingredients.

## FROM PLANTS TO EXTRACTS: FACING THE NEW CHALLENGE OF DNA TESTING

As a matter of fact, what Indena clients buy and use is a botanical extract. That's why applying DNA analysis to our extracts provides an additional level of quality and safety assurance. After years of research and investment, Indena's quality system now delivers a reliable method of genomic analysis for a wide range of extracts.

The first product on which Indena successfully performed a DNA test is its bilberry extract, Mirtoselect. Bilberry (*Vaccinium*

*myrtillus*) extracts are largely used in pharmaceutical and nutraceutical products because of their known benefits in eye health and microcirculation applications. It is important to guarantee that bilberry extracts meet required specifications in terms of chemical components, purity and botanical origin.

The method Indena has developed comprises four crucial phases: extraction, purification, amplification and identification. After the bilberry extract has been obtained, its DNA is purified using an off-the-shelf kit. The third phase is amplification: a fragment of DNA is processed using a real-time PCR-probe, which amplifies a specific region of the DNA and allows researchers to determine — exactly, with no uncertainty whatsoever — if the plant used to make the extract is actually *Vaccinium myrtillus*. Identification of the extract is then the final step of the whole process.

The method has two great strengths. First of all, it gives robust results: 20 lots of bilberry extract have been tested independently, in triple-blind experiments, and the analyses were always positive — even considering that the results of DNA purification were very variable. The outcome was also confirmed using sequence analysis. The second point of strength is the speed of the process: Indena's patented extract testing method is fast because amplification with a real-time PCR-probe takes only about 1 hour.

Indena, however, wants to go further and enable its clients to experience the same levels of absolute certainty about the quality of plants and extracts they use themselves. Through an exclusive agreement with Hyris Ltd, and drawing on Indena's decades of accumulated knowledge, DNA fingerprint analysis of plant samples can now be done in the field by almost anyone.

The easy-to-use device that makes this possible is the bCUBE, produced by Hyris, which can analyse raw material samples in the field in roughly an hour. Even when done thousands of miles away from Indena's labs, the test results can be shared on a proprietary cloud-based platform in real-time. In addition, GPS data can also be recorded to enable precision tracing. Indena holds preferential access to this breakthrough technology for the on-site identification of botanical species for the dietary supplement ingredient industry. 📍

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