



uality
you can
count on

 **indena**[®]
INDUSTRIA
DERIVATI
NATURALI



ORIGIN MAKES THE DIFFERENCE

The quality of the starting herbal material is an essential prerequisite, since it may affect all the subsequent phases. Hence **GMPs** are applied already from these early steps to guarantee the characteristics of the final product. At this stage, there are a number of measures we employ:

- √ supplier inspection and qualification, according to **GACP** (Good Agricultural and Collection Practices)
- √ area selection
- √ control of:
 - _ harvesting period and harvesting method
 - _ drying conditions
 - _ storage
- √ botanical identification of the plant and part of the plant
- √ quarantine of the biomass under monitored conditions
- √ microbiological analysis
- √ chemical analysis
- √ control of contaminants, including:
 - _ pesticides
 - _ aflatoxins
 - _ heavy metals

Only after all of these controls the botanical raw material will be **released** for further processing or **rejected** due to non conformance with our strict requirements.

PROCESSING: TIGHT CONTROLS PREVENT ERROR

The whole production process is controlled by **strict adherence to GMPs** with well defined **procedures** and **analysis** at critical steps of production.

All raw data is recorded and every critical procedure and parameter are thoroughly described for workers and double-checked in a **Master Batch Record (MBR)**.

The manufacturing process includes controls on:

- ✓ grinding
- ✓ extraction process parameters including:
 - solvent type
 - extraction conditions (time, temperature and pressure)
- ✓ concentration
- ✓ purification
- ✓ drying
- ✓ packaging/labeling
- ✓ cleaning



CHECK AND THEN CHECK AGAIN

The finished product undergoes **final analysis** and documentation review; this ensures compliance with specifications. **Leading-edge technology** and analytical instrumentation are employed, including **HPLC** and **NMR**, according to suitably validated analytical methods.

Qualified analytical **reference standards** are used, and all data is summarized in the Certificate of Analysis. All analytical data is maintained for future reference.

The **final stage** involves quality assurance/quality control review such as:

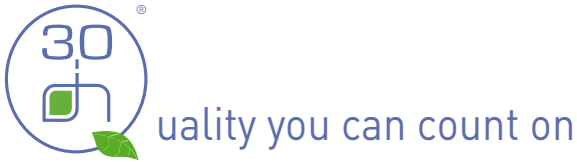
- ✓ MBR documentation review
- ✓ analytical controls such as:
 - _ content of active principles
 - _ content of impurities
 - _ heavy metals
 - _ pesticides
 - _ residual solvents
- ✓ physical analysis
- ✓ microbiological analysis of the final product

Additionally, laboratory equipment qualification and periodical maintenance is assured.



Only when our scientists are **FULLY SATISFIED**, a product is qualified to **ENTER THE MARKET**





More than 30 quality controls from starting material to finished product: it's Indena's prerequisite, the only reliable basis on which the manufacturing process can be established and the way we create a **value difference**.

Indena is committed to continuous improvement of **Quality Assurance (QA)** and is actively engaged in helping to define the **regulatory environment**.

Robust **QA systems** ensure quality is built into the product, starting with **Good Agricultural and Collection Practices (GACP)** during **cultivation, growing and harvesting** of the plant.

The quality of a product is **controlled** during **all stages** of the manufacturing process by adherence to strict **Good Manufacturing Practices (GMPs)** and extensive testing at every stage of manufacturing and following HACCP in case of food products.

Only when our scientists are **fully satisfied** is a product qualified to enter the market.

But the process doesn't stop there. Our scientists are constantly developing **new analytical methods** to ensure the products we offer are state of the art.

Every process that has an impact on product quality is precisely documented, and **available** for review by our customers and regulatory authorities.





HEADQUARTERS

Viale Ortles, 12
20139 Milan - Italy
tel.+39.02.574961
fax+39.02.57404620

PRODUCTION SITES

INDENA S.p.A.
Via Don Minzoni, 6
20090 Settala (Milan) - Italy

BERNETT S.r.l.
Strada Statale dei Cairoli, Km 53
27030 Palestro (Pavia) - Italy

INDENA S.A.S.
30/38, Avenue Gustave Eiffel
BP 37095
Tours Cedex 2, France

INDENA INDIA Pvt. Ltd.
No. 43/3, Sivapura Post,
Raghunathapura,
Doddaballapura,
Bangalore, 561 203, India

i n d e n a . c o m

