

Indena 30

Quality you can count on





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More than 30 quality controls from starting material to finished product: it's Indena's pivotal 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.





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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.

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.





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Facts and figures

Our quality system is the **foundation**.

Every production site has a quality system.

The application of **GMPs** starts at the cultivation, with growing and harvesting stage.

More than **30 distinct quality controls** are performed for every batch.

All products are manufactured according to the principles of **GMPs**.

Regular internal and external **audits** are performed to maintain and improve the standard of quality.

The whole process is documented from starting plant material to finished product, through a **Master Batch Record** to ensure consistency of the process and full **traceability** back to the cultivation and growing stage.





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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:

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 - supplier inspection and qualification, according to **GAP** (Good Agricultural 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
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Only after all of these controls will the botanical raw material be **released** for further processing or **rejected** due to non conformance with our strict requirements.



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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, every critical procedure and parameter is 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

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PROCESSING



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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 including:

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- MBR documentation review
 - Analytical controls including:
 - content of active principles
 - content of impurities
 - heavy metals
 - pesticides
 - residual solvents
 - Physical analysis
 - microbiological analysis of the final product

30+ Additionally laboratory equipment qualification and periodical maintenance is assured.





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All these activities guarantee the **quality**, **safety** and **efficacy** of a product, together with the consistency and traceability of **every single batch**.

Accurate **biomass** selection, qualified and validated manufacturing **processes** and state of the art **analytical** methods guarantee the standardization and reproducibility of a product time after time, batch after batch.

Only after taking **all these steps** are we confident that our products are ready to enter the **market**.



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