

EU and ICH Guidelines for Quality Control of Herbal Drugs

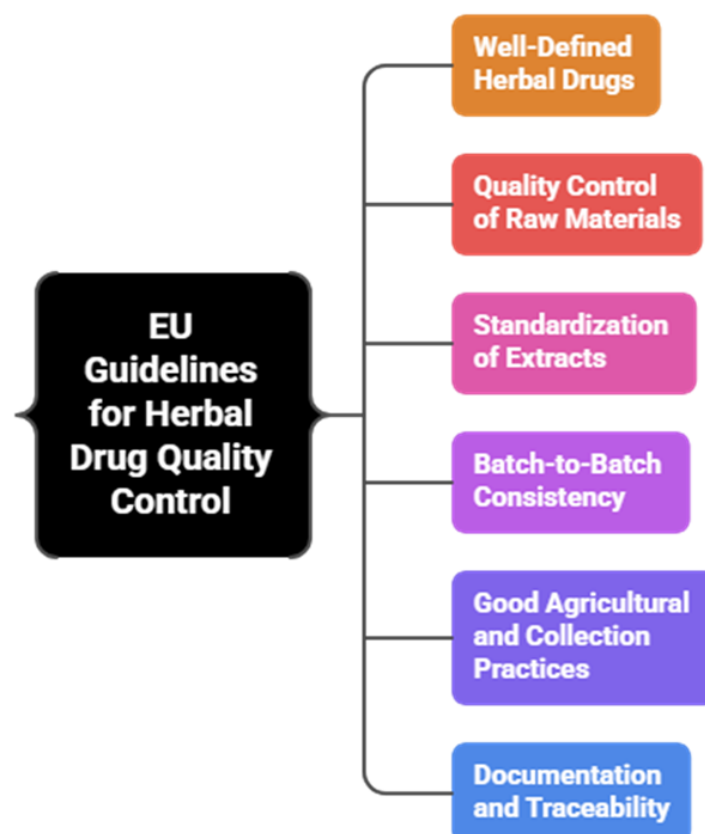
What is the EU and ICH?

- **EU** stands for **European Union** – a group of countries in Europe that follow common laws and regulations.
- **ICH** stands for **International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use**.
- It is a global organization that brings together authorities from the USA, Europe, and Japan (and now others too), and it works to make sure that medicines (including herbals) are safe, effective, and of good quality.

Why are these guidelines important for herbal drugs?

- Herbal drugs come from plants and nature, and they can have a lot of variability due to:
 - Where the plant is grown
 - How it's harvested
 - How it's stored
 - Which part of the plant is used
- Unlike synthetic drugs, herbal drugs may have many active compounds, and the concentration of these compounds can change depending on many natural factors.
- So, to ensure **consistent quality**, the EU and ICH provide **guidelines** for manufacturers.

Key points of EU Guidelines for herbal drug quality control:



1. Herbal Drugs Must be Well-Defined

- The plant name (scientific name) must be properly identified.
- The plant part used (leaf, root, flower) must be clearly mentioned.
- The country and method of cultivation should be recorded.

2. Quality Control of Raw Materials

- Tests should be done to check for foreign matter (like dirt, insects).
- Tests for moisture content, ash content, and extractive values are required.
- Microbial contamination (bacteria, fungi) must be within safe limits.
- Testing for pesticides, heavy metals, and aflatoxins (toxic molds) is necessary.

3. Standardization of Extracts

- When making an herbal extract, the active ingredients must be quantified.
- For example, if an extract contains curcumin (from turmeric), the amount of curcumin must be standardized.

4. Batch-to-Batch Consistency

- Each batch of the herbal product should be similar in terms of appearance, chemical composition, and biological activity.

5. Good Agricultural and Collection Practices (GACP)

- Plants should be cultivated and harvested using proper practices to maintain quality.
- WHO has developed GACP guidelines which EU also recommends.

6. Documentation and Traceability

- Every step in the supply chain should be recorded.
- It should be possible to trace the raw material back to its origin.

Key points of ICH Guidelines relevant to herbal drugs:

- Although ICH was originally focused more on synthetic drugs, many of its principles apply to herbal medicines too.
- Some relevant ICH guidelines include:

1. ICH Q1 – Stability Testing

- Herbal products should be tested under different environmental conditions (heat, humidity, light) to ensure they remain stable during shelf life.

2. ICH Q2 – Validation of Analytical Methods

- The methods used for testing herbal products (like HPLC, TLC) must be validated. That means they should give accurate, reproducible, and specific results.

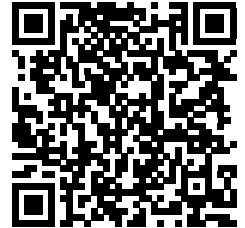


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