

Basics

Quality Assurance in Herbal Drug Industry: Understanding cGMP, GAP, GMP, and GLP in Traditional Systems of Medicine

- Quality assurance is a process to make sure that herbal products are safe, effective, and of good quality before they reach the consumer.
- In the traditional system of medicine (like Ayurveda, Siddha, Unani), herbal drugs are prepared from plants.
- To maintain the **quality, safety, and consistency** of these herbal products, the following guidelines are followed:



cGMP

Current Good Manufacturing Practices ensure product quality.



GAP

Good Agricultural Practices ensure safe and sustainable farming.



GMP

Good Manufacturing Practices ensure consistent production.



GLP

Good Laboratory Practices ensure reliable research results.

cGMP – current Good Manufacturing Practices

- “**Current**” means up-to-date. Manufacturing methods and practices should follow the **latest scientific knowledge** and technology.
- cGMP ensures that the product is **consistently produced and controlled** according to quality standards.
- Involves **everything from raw material to finished product**, including:
 - Proper equipment
 - Clean production area
 - Trained staff
 - Written procedures (Standard Operating Procedures - SOPs)
 - Documentation of every batch

- Example: If a company is making an Ayurvedic cough syrup, cGMP makes sure that:
 - Herbs are cleaned properly
 - Syrup is made under hygienic conditions
 - The same method is followed for every batch
 - Final product is tested before packaging

GAP – Good Agricultural Practices

- Focuses on the cultivation and collection of medicinal plants.
- Ensures that the plants used for making herbal drugs are grown safely and properly.
- Includes:
 - Use of good quality seeds or planting materials
 - Avoiding harmful pesticides and chemicals
 - Harvesting the plant at the right time when it has the highest medicinal value
 - Storing the raw herbs properly to prevent damage or contamination
- Example: Growing Tulsi (Holy Basil) for medicinal use under GAP means:
 - Using organic farming methods
 - Protecting the crop from pests using natural methods
 - Harvesting when the plant has the most active medicinal ingredients

GMP – Good Manufacturing Practices

- Similar to cGMP, but refers to basic manufacturing practices.
- It ensures the minimum standard needed to make herbal drugs safely and of good quality.
- GMP includes:
 - Clean production environment
 - Proper hygiene of workers
 - Using suitable tools and machines
 - Checking the quality of materials and products
- While cGMP is a more modern and detailed version, GMP is the foundation for safe manufacturing.

GLP – Good Laboratory Practices

- Focuses on how testing and quality control of herbal drugs is carried out in laboratories.
- Ensures that:
 - Testing is done accurately and reliably
 - Instruments are calibrated

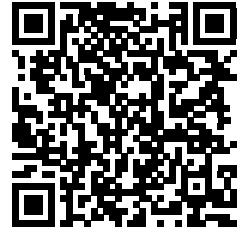


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