Good Manufacturing Practices (GMP) for Traditional Medicines: Prospects and Problems

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GMP is a system for ensuring that products are consistently produced and controlled according to quality standards.

- **A set of principles and procedures, which when followed by manufacturers for therapeutic goods, helps to ensure that the products manufactured will have the required/expected quality.**

Objectives of GMP Guidelines

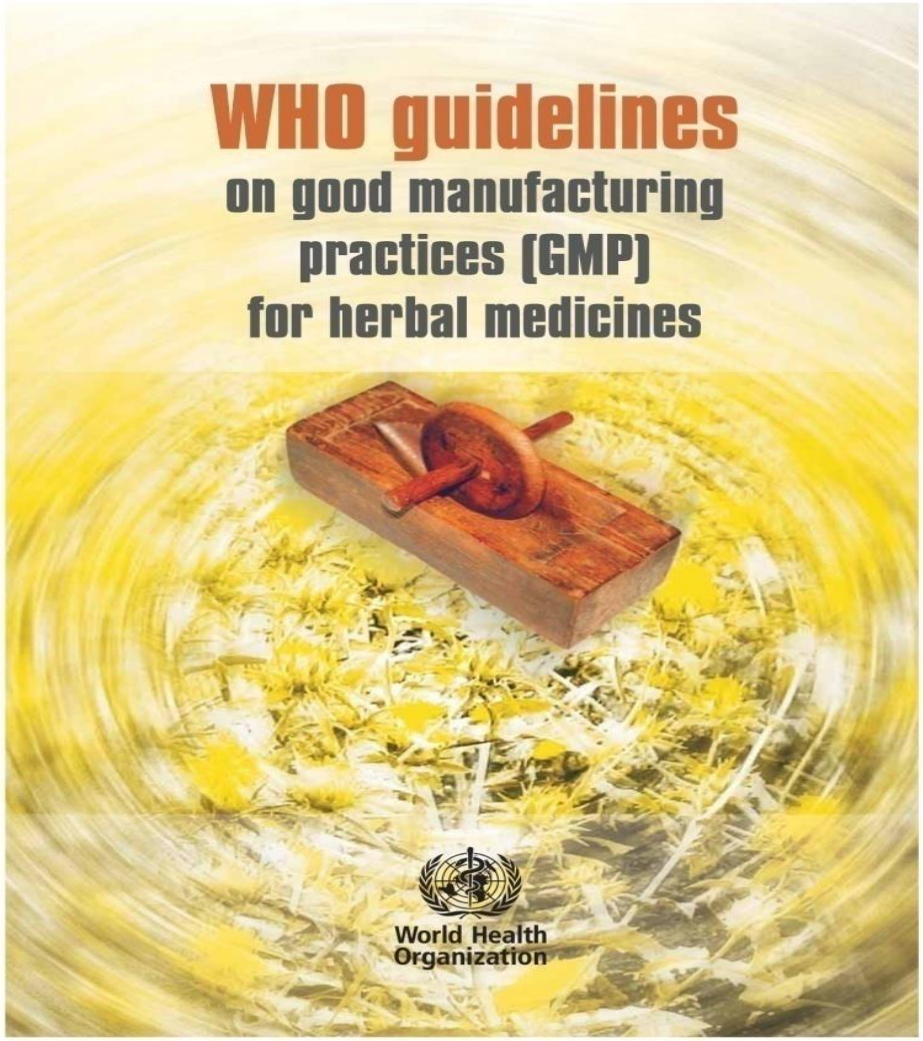
- ✓ Raw materials are authentic, of prescribed quality and are free from any contamination.
- ✓ Manufacturing processes are standardized and are adhered to.
- ✓ Adequate quality control measures are adopted from the starting materials to the end of manufacturing .
- ✓ The manufactured medicine released for sale is of acceptable quality.

WHO Definition of GMP

WHO defines Good Manufacturing Practices (GMP) as “that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required for the marketing authorization.”

Domain of GMP

- GMP covers all aspects of the manufacturing process: defined manufacturing process; validated critical manufacturing steps; suitable premises, storage facility, transport; qualified and trained personnel for production and quality control; adequate laboratory facilities; approved written procedures and instructions; maintenance of records to show all steps of defined procedures; full traceability of a product through batch records and distribution records; and systems for recall and investigation of complaints.


WHO guidelines
on good manufacturing
practices (GMP)
for herbal medicines
World Health
Organization

GMP Covers Quality of 5 Ms

M- Materials

M- Machines

M- Manpower

M- Methods

M- Manufacturer’s/Manager’s Mindset and Mentality

Adoption of GMP leads to-

The Quality of a formulation or a bulk drug depends on the Quality of those producing it. GMP is the magic key that opens the door of the Quality.

In the matter of GMP, swim with the current and in the matter of Quality stand like a rock!

Quality is the denominator of the value in terms of -

- ✓ Practitioner's confidence in the product
- ✓ Consumer's confidence in the product
- ✓ Regulator's confidence in the product

- **Quality can never be attained accidently or by chance or by luck.**

- **Quality is always the result of intelligent thinking and continuous efforts.**

- **There must be a will to produce superior things. Adopting GMP is the key for manufacturing quality medicines.**

Essentials of GMP

- Quality assurance of all aspects of production from the starting materials, premises and equipment to the training and personal hygiene of staff.
- Detailed written procedures for each process that could affect the quality of the finished product.
- Systems to provide documented proofs that correct procedures are consistently followed at each step in the manufacturing process - every time a product is made.

Manufacturing Aspects Vs Quality Assurance Aspects

Provisions of GMP for Ayurvedic, Siddha and Unani (ASU) Medicines

- Rule 157 of the Drugs and Cosmetics Rules, 1945 provides the requirement of GMP compliance for grant or renewal of license to manufacture ASU medicines since March, 2003 and amended in May, 2010. (Earlier Factory premises and hygienic conditions were prescribed in February, 1970.

- Schedule “T” under Rule 157 prescribes the GMP guidelines.

- Supplementary guidelines for manufacturing of mineral/metal based formulations included in Schedule “T” since March, 2009.

Provisions of Schedule ‘T’ PART- I

Factory Premises (Receiving & Storing Raw Materials, Manufacturing process areas, quality control section, finished goods store, rejected goods/drugs store, office)

General Requirements: Location & surroundings; Buildings with proper hygienic conditions, fire safety measures, free from insects/rodents, drainage system; Water supply; Disposable of Wastes; Containers’ cleaning; Stores for Raw Materials, Packing Materials and Finished Goods; Working Space, Health Clothing, Sanitation and Hygiene of Workers; Medical Services; Machinery and Equipment; Batch Manufacturing Records; Distribution Records; Records of Market Complaints; Quality Control Section.

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Requirements for Sterile product manufacturing

- Separate enclosed manufacturing area, Packing Material, Finished Goods Store, Working Space, Medical Services, Precautions against contamination and Mix.

PART- II

A. List of recommended machinery, equipment and minimum manufacturing premises required for the manufacture of various categories of medicines of Ayurvedic and Siddha systems.

B. List of machinery, equipment and minimum manufacturing premises required for the manufacture of various categories of medicines of Unani system.

C. List of equipment recommended for in-house QC section.

Principles of GMP

- Design and install the facilities and equipment properly.
- Follow written procedures and Instructions
- Document work and Validate work.
- Monitor facilities and equipment.
- Write step by step operating procedures and work on instructions.
- Design ,develop and demonstrate job competence.
- Protect against contamination.
- Control components and product related processes.
- Conduct planned and periodic audits.

Cost of effective GMP

Positive cost benefits of GMP/QA are-

- Good plant lay out, Smooth work flows, Efficient documentation systems, well controlled process, good stores lay outs and stores records- These are Good manufacturing practices.

- Reduction in work in process and inventory holding costs.

- Avoidance of cost of Quality failure (cost of waste, of rework, of recall, of consumer compensation and of loss of company reputation)

Documents for GMP Compliance

- Policies
- SOPs
- Specifications
- Master Formula Record
- Batch Manufacturing Records
- Manuals
- Master plans/ files
- Calibration and Validation protocols
- Forms and Formats
- Records

Qualities of good documentation

1. Accurate
2. Clear
3. Complete
4. Consistent
5. Indelible
6. Legible
7. Timely
8. Direct
9. Authentic
10. Authorized

How can Quality be Achieved?

- By practice
- By following professional guidance
- By keeping records
- By adopting corrective measures
- By regular monitoring
- By complying with the Regulations
- By culturing the right attitude/priority.

Benefits of Adhering to GMP

GMP boosts	Confidence
GMP reduces-	Re-work
GMP makes -	Good Business Sense
GMP improves-	Working Conditions
GMP enhances-	Prestige
GMP ensures-	Quality
GMP augments-	Trade
GMP accords-	Overall socio-economic value of the product and manufacturer.

Constrains & Challenges in Complying to GMPs

1. Optimal investment for creation and maintenance of required infrastructure- Micro, Small and Medium Scale Entrepreneurs may fail in or shirk from investing.

2. Lack of qualified & trained technical and regulatory manpower- Pharmacy education of Traditional Medicine not developed to the desired extent nor the regulatory capacity/auditor's role to the mark.

3. Inconsistent quality of plant raw materials- varied resources of medicinal plants, varied geo-climatic conditions, asymmetrical harvesting practices, storage and transportation.

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4. Agro-technology for cultivation of all medicinal plants not developed- constraint for getting quality raw material from cultivated source.

5. Limitations of conventional manufacturing technology and quality testing tools- principles of manufacturing & quality check of traditional medicines are compromised.

6. Reference standards and objective parameters of quality assurance not prescribed – outcome products of manufacturing may not have reliable evidence of quality owing to subjective bias.

Thanks

For any query or guidance, please write to-

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Manufacturer's Responsibility for GMP Compliance

- The licensed manufacturer is expected to evolve methodologies and procedures for following the prescribed process of manufacturing of medicines, which should be documented as a manual and kept for reference and inspection.

- Adherence to Reference Standards and SoPs