

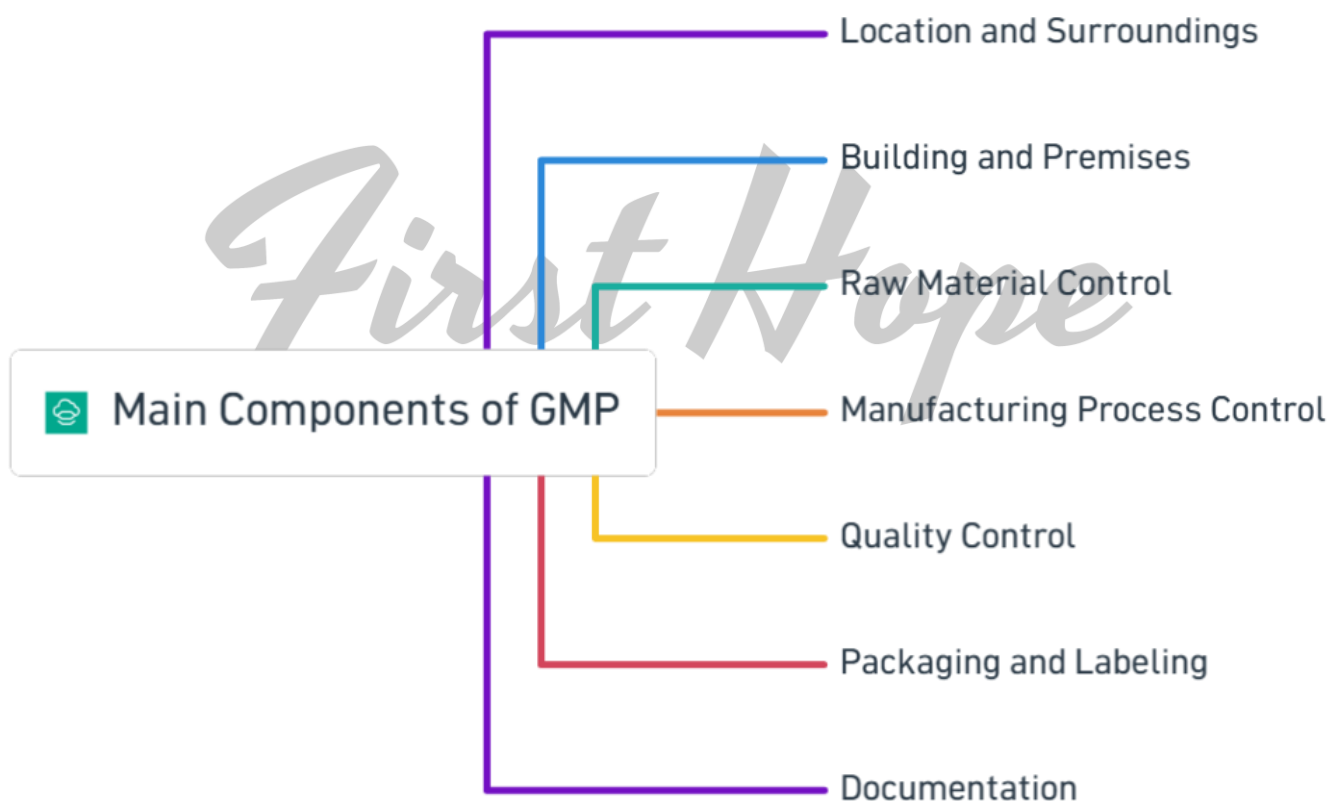
Schedule T – Good Manufacturing Practice of Indian Systems of Medicine

Components of GMP (Schedule – T)

Introduction

- Schedule T is a part of the Drugs and Cosmetics Act related to Good Manufacturing Practices for Ayurvedic, Siddha, and Unani medicines.
- It provides guidelines for proper manufacturing, quality control, storage, hygiene, and documentation.
- In phytochemistry, GMP is important because herbal medicines contain active phytochemicals that must be protected from contamination and degradation.

Main Components of GMP



A. Location and Surroundings

- The manufacturing unit should be located in a clean and hygienic area.
- The surroundings should be free from dust, smoke, bad odor, insects, and waste materials.

B. Building and Premises

- The building should have proper ventilation, lighting, drainage, and water supply.
- Different sections should be arranged properly for manufacturing, packaging, storage, and quality control.

C. Raw Material Control

- Raw materials should be properly identified and tested before use.
- Medicinal plants should be free from adulteration and contamination.

D. Manufacturing Process Control

- Manufacturing should follow approved procedures and standard methods.
- Proper processing helps maintain phytochemical stability and medicinal value.

E. Quality Control

- Quality control tests should be performed for raw materials and finished products.
- Physical, chemical, and microbial tests are necessary.

F. Packaging and Labeling

- Packaging materials should protect formulations from moisture, light, and contamination.
- Labels should contain product name, batch number, expiry date, and storage instructions.

G. Documentation

- Proper records should be maintained for all manufacturing and testing activities.
- Documentation helps maintain traceability and quality assurance.

Objectives of GMP

Introduction

- GMP guidelines are followed to ensure that medicines are consistently produced and controlled according to quality standards.

Objectives of GMP

A. To Ensure Quality Medicines

- GMP helps produce safe, pure, and effective herbal formulations.
- It maintains proper quality of medicinal products.

B. To Prevent Contamination

- GMP prevents contamination by dust, microbes, chemicals, and foreign matter.

C. To Maintain Uniformity

- GMP ensures batch-to-batch consistency in formulation quality and phytochemical content.

D. To Ensure Safety and Efficacy

- Proper manufacturing methods help maintain therapeutic effectiveness and patient safety.

E. To Maintain Proper Documentation

- GMP requires proper records for manufacturing, testing, packaging, and storage.

F. To Improve International Acceptance

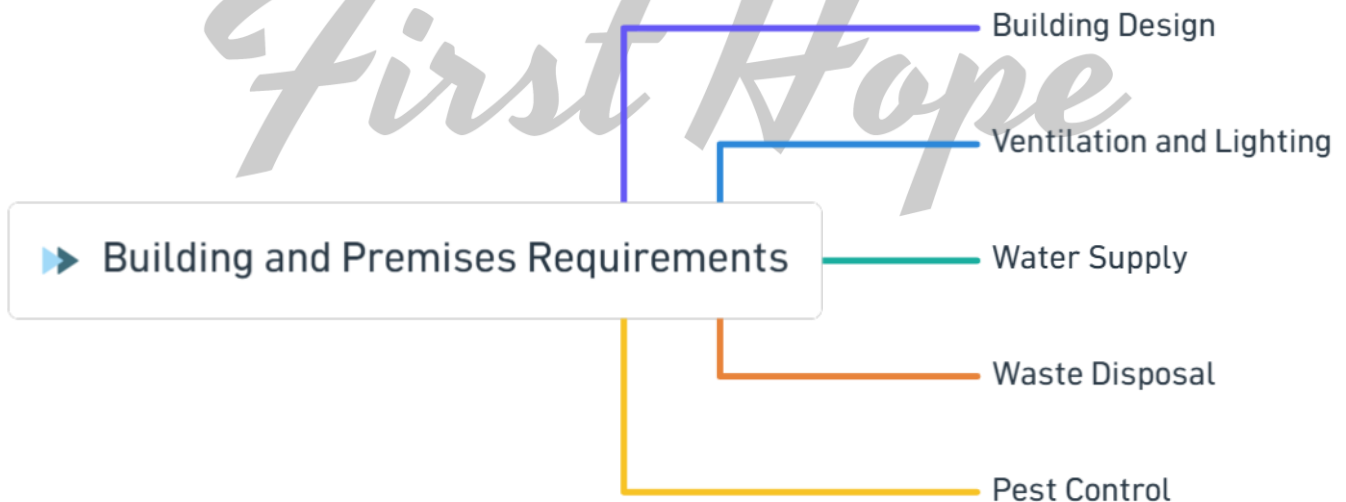
- Standardized manufacturing practices increase global acceptance of Indian traditional medicines.

Infrastructural Requirements

Introduction

- Proper infrastructure is necessary for manufacturing quality herbal medicines.
- The manufacturing area should support safe and hygienic processing.

Requirements



A. Building Design

- The building should be spacious and properly planned.
- Separate areas should be available for raw materials, manufacturing, packaging, storage, and quality control.

B. Ventilation and Lighting

- Proper ventilation should be provided to remove dust and fumes.
- Adequate lighting helps proper manufacturing and inspection.

C. Water Supply

- Clean and safe water should be available for washing, processing, and cleaning purposes.

D. Waste Disposal

- Waste materials should be removed safely to prevent contamination and pollution.

E. Pest Control

- Proper measures should be taken to control insects, rodents, and pests.

Importance in Phytochemistry

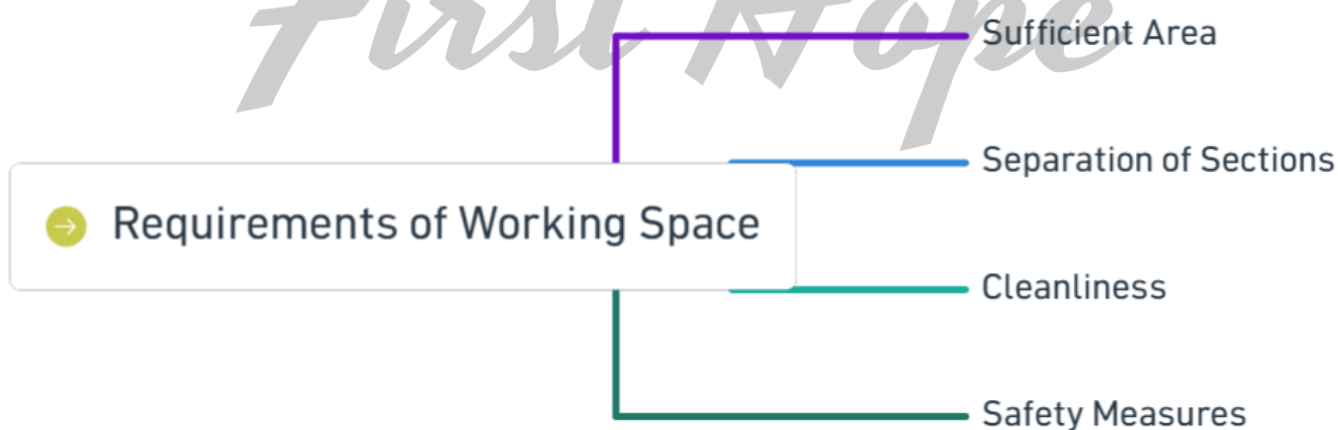
- Proper infrastructure protects herbal drugs from moisture, heat, light, and contamination.
- It helps maintain stability of active phytochemical constituents.

Working Space

Introduction

- Working space refers to the area used for manufacturing and processing medicines.
- Adequate space is necessary for safe and smooth workflow.

Requirements of Working Space



A. Sufficient Area

- Enough space should be available for workers, machines, and movement of materials.

B. Separation of Sections

- Different manufacturing operations should be carried out in separate areas.
- Raw materials and finished products should not mix together.

C. Cleanliness

- The working area should be kept clean and free from dust and waste materials.

D. Safety Measures

- Safety equipment and emergency facilities should be available in the working area.

Importance in Phytochemistry

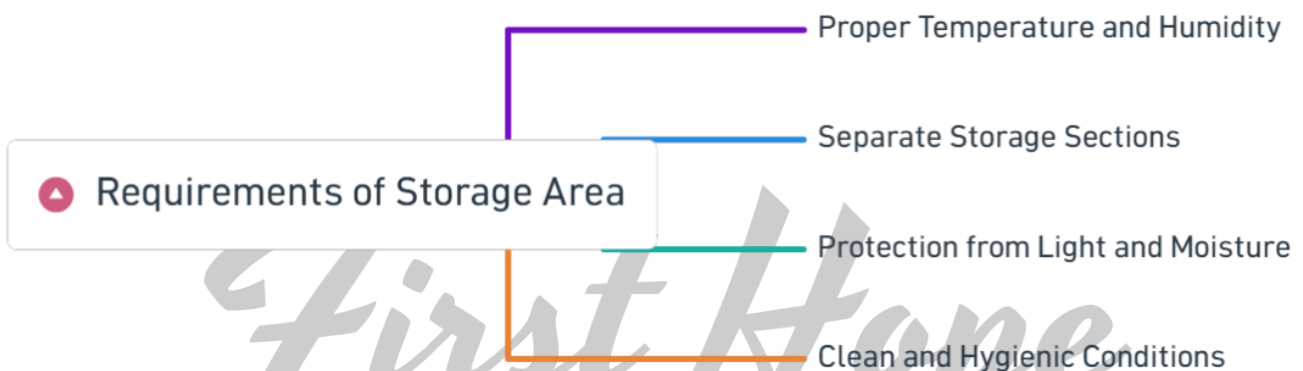
- Proper working space prevents contamination of herbal materials.
- It helps maintain purity and quality of phytochemical constituents.

Storage Area

Introduction

- Storage area is the place where raw materials, packaging materials, and finished products are kept.

Requirements of Storage Area



A. Proper Temperature and Humidity

- Temperature and humidity should be controlled to prevent degradation of herbal drugs.

B. Separate Storage Sections

- Raw materials, finished products, rejected materials, and packaging materials should be stored separately.

C. Protection from Light and Moisture

- Herbal drugs should be protected from direct sunlight and moisture.

D. Clean and Hygienic Conditions

- The storage area should be clean, dry, and free from insects and rodents.

Importance in Phytochemistry

- Proper storage helps maintain stability of active phytochemicals such as volatile oils and alkaloids.
- It prevents microbial growth and spoilage.



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