IMPLEMENTATION OF GMP IN AYURVEDIC PHARMA INDUSTRY

INTRODUCTION

Ayurveda the science of life has both preventive and curative aspect of health and diseases.

Drugs of plant, animal and mineral origin are used for treating diseases and maintaining health.

Among the quadruplet of treatment viz. Physician, Drug, Attendant and Patient the drug is second most important after physician.

In ancient period, drugs were found in abundant quantity. So, physician were not depended upon pharma companies . They were able to collect the drugs from near by and dispense to their patients after proper processing.

But now the scenario is totally changed. Due to massive population, deforestation and commercialization, Ayurvedic physicians more or less totally depends upon pharmaceutical companies .

In this connection WHO has given certain guidelines for preparing various herbal and herbomineral products.

To promote the export of Ayurvedic medicines in the global market the Govt. of India has imposed GMP for the commercial drug manufacturing companies.

The main object of the implementation of GMP is to obtain the products which are reproducible, safe, therapeutically effective and also economic.

GMP FOR ASU DRUGS

It is mentioned in schedule ‘T’ under Rule 157 of Drugs & Cosmetic Act, 1940.

Practitioners of Ayurveda, Unani & Siddha who prepare medicines for their patients are exempted from purview of GMP.

OBJECTIVE OF GMP

The GMP are prescribed to ensure that:-

- Raw material used in the manufacturing of drugs are authentic, of prescribed quality and are free from contamination.

- The manufacturing process is as has been prescribed to maintain the standards.

- Adequate quality control measures are adopted.

- The manufactured drug which is released for sale is of acceptable quality.

- Manual of methodology, procedure maintained for reference and inspection.

COMPONENTS OF GMP

- Receiving and storing raw materials.
- Manufacturing of process areas.
- Quality control section.
- Finished goods store.
- Office.
- Rejected goods/drug store.

GENERAL REQUIREMENTS

- Location and surroundings.
- Buildings.
- Water supply
- Disposable of wastes

- Container cleaning

- Stores
  - Raw material stores
  - Packing materials
  - Finished Goods Stores

- Working Space.

- Health, Clothing, Sanitation & Hygiene of Workers

- Medical Services

- Equipments

- Batch Manufacturing Record
- Distribution Record
- Records of Market Complaints

- **Quality Control**

Facility for quality control section in his own premise or through Govt., approved testing laboratory.

Test should be as per the ASU pharmacopeias standard.

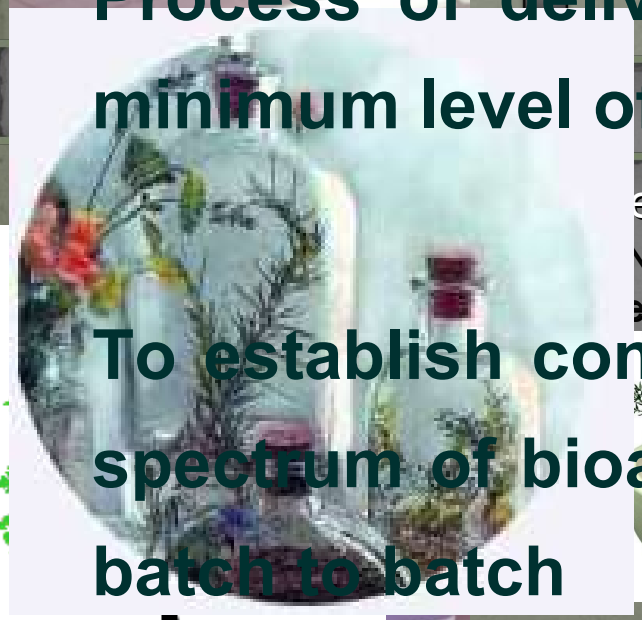
The quality control section should verify all the raw materials, monitor in process, quality checks and control the quality of finished product being released to finished goods store

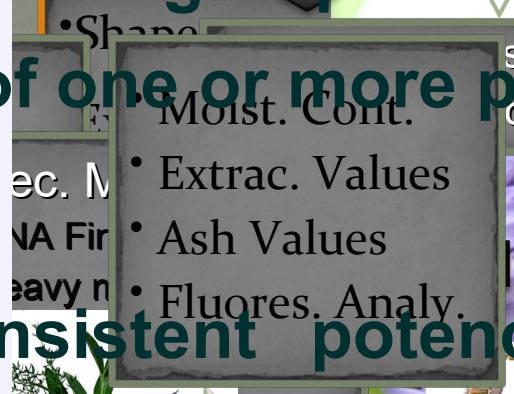
STANDADIZATION / QUALITY CONTROL OF HERBAL DRUGS

- BOTANICAL
- ORGANOLEPTIC
- PHYSICAL
- BIOLOGICAL
- CHEMICAL

Process of delivering a product with a specified minimum level of one or more plant constituents

To establish consistent potency & to ensure full spectrum of bioactive constituents (markers) from batch to batch





Quality control section should have following facilities-

Area should be 150 sq feet ,

References books like AFI, API, Materia medica, D&C Act and other pharmacopeias.

References samples of Raw drug.

Manufacturing records should be maintained.

For verification controlled samples of finished products of each batch will be kept for 3 yrs.

Keep record in establishing shelf life and storage requirements for the drugs.

Raw material should be monitored with a view to reduce fungal and . Bacterial contamination.

Expert of pharmacy, pharmacognosy, chemistry should be added

One person with degree holder in ISM pharmacy

CONCLUSION

At present more than 10000 manufacturing units in India who are preparing ASU drugs.

Most of them are GMP certified without having infrastructure up to the mark.

A lot of research work has been done on standardization of ASU drugs but till today not a single drug is standardized in terms of quality because generally all the Ayurvedic pharma companies have own matter formula and standards method of preparation which varies from pharmacy to pharmacy.

And due to this variation the colour , consistency , shape and size also varies thus it is found very difficult to select the genuine and good quality product from the market.

Therefore observing these things from daily routine life it was decided by Govt. of India to develop SOPs for each and every process which needs uniformity from batch to batch.

Thank You