GMP compliance in a pharmaceutical-company

Industrial Pharmacy Laboratory

Industrial Pharmacy

- A branch of pharmaceutical sciences which is concerned with the conversion of raw materials into a certain dosage form and in a large scale.

- It includes manufacturing, development, marketing and distribution of drug products including quality assurance of these activities.

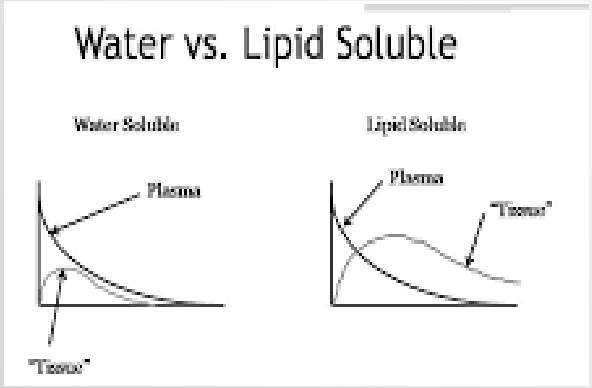
Aims of Industrial Pharmacy

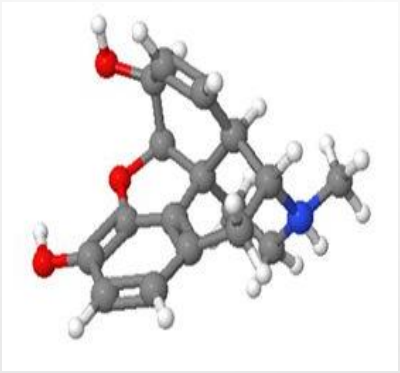
1. Preparation and evaluation of different pharmaceutical dosage forms

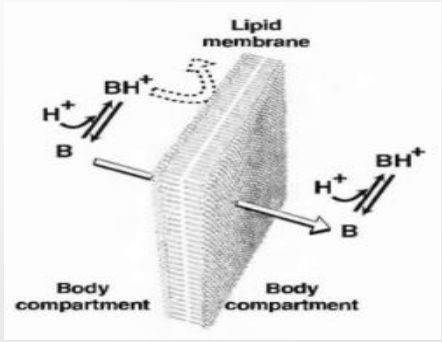
Prepared dosage form should be:

- ✓ Safe
- ✓ Stable
- ✓ Effective
- ✓ Bioavailable

2. Studying the physicochemical properties of pharmaceutical compounds like chemical structure, solubility, permeability, polymorphism, melting point, etc.







Pharmaceutical company departments

1. Pharmaceutical research department

This department is concerned with the formulation of the most suitable dosage form, taking into consideration all factors affecting stability, solubility and mode of action and convenience of administration.

It includes multiple divisions:

chemical research

biological research

pharmacy research, and others

2.Product development department (pilot plant)

It is the part of the pharmaceutical industry where a lab scale formula is transformed into a viable product by development of liable and practical procedure of manufacture

This department is responsible for

- Developing formula: try the process on a model of proposed plant before committing large sum of money on a production unit
- Evaluation and validation for process and equipment
- Confirmation of product uniformity
- Scale up requirements: examination of the formula to determine it’s ability to withstand batch-scale and process modification

3. Production department

This department includes all operations which are involved in conversion of raw materials into final product. The department is divided into dosage form based areas, e.g. tablets, capsules, ampoules ….etc.

4. Quality control department

This department is responsible for evaluation of dosage form before going to the market, and following up the product in the market.

- Evaluation of dosage forms before going to the market.
- Perform checking during the entire process of production from RAW material to FINISHED products.
- Following up the product in the market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والنتيجة دواء صالح للاستهلاك البشري .
Iraqi Ministry of Health
National Center for Drug Control and Research

Quality control vs. quality assurance

- Quality Assurance is **process** oriented and focuses on defect prevention. Quality Assurance is a set of activities for ensuring quality in the processes by which products are developed. Quality assurance is concerned with how a process/product is performed/made.

- Quality Control is **product** oriented and focuses on defect identification. Quality Control is a set of activities for ensuring quality in products. The activities focus on identifying defects in the actual products produced. Quality control is the inspection aspect of quality management

These two practices make sure that the end product or the service meets the quality requirements and standards defined for the product or the service

5. Marketing department

Responsible for product advertisement and marketing

$$ROI = \frac{(\text{Gain from Investment} - \text{Cost of Investment})}{\text{Cost of Investment}}$$

Return on investment (ROI) is a financial ratio used to calculate the benefit an investor will receive in relation to their investment cost. It is most commonly measured as a net income divided by the original capital cost of the investment. The higher the ratio, the greater the benefit earned.

Good Manufacturing Practice (GMP)

Good manufacturing practice is that part of quality assurance which ensures that product is consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

GMP is aimed primarily at reducing the risks inherent in any pharmaceutical production. Such risks are essential of two types: cross contamination (in particular of unexpected contaminants) and mix-ups (confusion) caused by, for example, false labels being put on containers


Materials
Equipment
Buildings
Personal training
Hygiene
GMP

PRINCIPLES OF GMP:

- Design and construct the facilities and equipment properly
- Follow written procedures and Instructions
- Document work
- 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

Why GMP

- Ensure the quality of the medicinal products are consistently produced and controlled according to quality standards.

- Minimize the risk involved in pharmaceutical production that can't be eliminated through testing the final product.

Risk Involved in Pharmaceutical Production

1.Unexpected contamination →

damage to health or even death

2.Incorrect labelling on containers →

patients receive the wrong medicine

3.Insufficient or too much active ingredients →

ineffective treatment or adverse effects

From the previous video we can summarize the following important points:

- The pharmaceutical company should be constructed in area located faraway from town to prevent the risk of contamination from the company to the town and vice versa.
- The company is specialized in the production of tablets
- The processing starts from the raw materials, weighing, homogenization, granulation then tablet pressing and coating.
- Quality control for tablets to ensure good manufacturing

Also we can see

- After tablet preparation, packaging is made containing the correct label involves the name of medicinal compound with its dose and the name of company.

- All the requirements of GMP was taken in consideration like :
- Materials
- Building
- Hygiene
- Personal training

Thank you