# An Assignment on

# Industrial Pharmacy - II

Topic - Pilot Plant scale up techniques - General Considerations

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# Pilot Plant Scale up Techniques.

- A pilot plant can be define as the pre-commercial production system which includes new production technology and produces small volume of new technology-based-products
- Scale-up - is the process of increasing the batch size or a procedure for applying the same process to different output volumes.

## General Considerations

### (1) Personnel Requirements

→ The Qualification requirement for a person to work in pilot plant Organization are.

- Good theoretical knowledge on blending
- Pharmaceutical industry experiences.
- Good communication skill (writing and speaking)
- Practical Experience in production areas about formulation, process and equipment.

## (2) Reporting Responsibility -

- The objective of the reporting responsibility in Pilot plant is to facilitate the transfer of a product from the laboratory into production.
- The effectiveness of pilot plant is determined by the case with which the new product or process is brought into routine production.
- This could be possible if a good relationship exists between the pilot plant group with other groups (Research & Development, Processing, Packaging, Engineering, Quality Assurance, Quality Control, Regulatory and Packaging of the company.

## (3). Space requirement

The space requirement in pilot plant is divided into 4 areas that are as follows -

(A) Administration and Information area.

(B) Physical testing area.

(c) Standard equipment and floor space.

(d) Storage area.

(4) Traning:-

The various departments that are responsible for compliance of GMP are

- Engineering
- Quality control
- Material handling
- Warehousing and distribution
- Purchasing.

→ Depending on complexity of the job, each person involve in manufacturing, Processing, packaging and holding of a drug product, must receive the GMP and other specific training.

(5) Review of the formulation

The objective of each ingredient and its contribution to the final product manufactured on small scale

equipment must be throughly understood.

- The modification in formulation during the scale up is possible to be done in phase III trial, so that sufficient time could be available for generation of meaningful long term stability data in support of a proposed New Drug Application (NDA)

## ⑥ Relevant Processing Equipment

- The selection criteria for one equipment to produce effective product within the proposed specification are equipment must be economic, simple (In-installation, handling, cleaning and maintenance), efficent and most capable of consistently producing a product.

## (7) Process Evaluation.

- Things that should be critically examined during the Process Evaluation are-

→ Order of addition of the components including adjustment of their amount.

- Mixing speed and time.
- Rate addition of granulating agent, solvents and drug solutions.
- Heating and cooling rates.
- Filter size for liquids.
- Types of filter media used for liquids.
- Fan speed etc.

(8) Preparation of Master Manufacturing Procedure.

The Master Manufacturing Procedure includes followings.

- The process of Manufacturing Direction.
- The chemical Weight Sheet.
- The Sampling Direction.
- The Batch record direction
- The in-Process specification.
- The finished Product specification

➡ The periodic revalidation, GMP and monitoring of finished product test results via contral charts are essential to maintaining consistent product quality.

## ⑨ GMP Consideration

- The check list of the GMP items that should be a part of the scale-up or new products or process introduction including following-

- Equipment qualification
- Process Validation
- Regulatory schedule preventive maintenance
- Regular process review and revalidation.
- The use of competent, techically qualified personnel.
- A well-defined technology transfer system
- Arrangement of material to avoid cross contamination.