PILOT PLANT
SCALE- UP TECHNIQUE

By

Dr. Deepak Choudhary

Department of Pharmaceutical Sciences,
MLSU, Udaipur

CONTENTS

- **Definition**
- **Objectives**
- **Steps in Scale-up**

Definitions

- Plant:- It is a place were the 5 M's like money, material, man, method and machine are brought together for the manufacturing of the products.

- 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.

- Scale-up:- The art for designing of prototype using the data obtained from the pilot plant model.

Objectives

- To try the process on a model of proposed plant before committing large sum of money on a production unit.
- Examination of the formula to determine it’s ability to withstand Batch-scale and process modification.
- Evaluation and Validation for process and equipments.
- To identify the critical features of the process Guidelines for production and process controls.
- To provide master manufacturing formula with instructions for manufacturing procedure.
- To avoid the scale-up problems.

Steps in scale-up

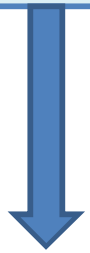
Define product economics based on projected market size and competitive selling and provide guidance for allowable manufacturing costs.

Conduct laboratory studies and scale-up planning at the same time.

Define key rate-controlling steps in the proposed process.

Conduct preliminary larger-than-laboratory studies with equipment to be used in rate-controlling step to aid in plant design.

Design and construct a pilot plant including provisions for process and environmental controls, cleaning and sanitizing systems, packaging and waste handling systems, and meeting regulatory agency requirements.



Evaluate pilot plant results (product and process) including process Economics to make any corrections and a decision on whether or not to proceed with a full scale plant development.

Thank You