### INTRODUCTION

#### *Pilot plant:*

“Defined as a part of the pharmaceutical industry where a lab scale formula is transformed into a viable product by the development of liable practical procedure for manufacture.”

R & D Production

**Pilot Plant**

A pilot plant is a pre-commercial production system that employs new production technology and/or produces small volumes of new technology-based products, mainly for the purpose of learning about the new technology. The knowledge obtained is then used for [design](https://en.m.wikipedia.org/wiki/Design) of full-scale production systems and commercial products, as well as for identification of further research objectives and support of investment decisions. Other (non-technical) purposes include gaining public support for new technologies and questioning government regulations.Pilot plant studies must includes a close examination of formula to determine its ability to withstand batch- scale and process modifications; it must includes a review of range of relevant processing equipment also availability of raw materials meeting the specification of product and during the scale up efforts in the pilot plant production and process control are evaluated, validated and finalized.

#### *Why conduct Pilot Plant Studies?*

* A pilot plant allows investigation of a product and process on an intermediate scale before large y are committed to full-scale production.
* It is usually not possible to predict the effects of a many-fold increase in scale.
* It is not possible to design a large complex food processing plant from laboratory data alone with any degree of success.

#### *A pilot plant can be used for*

* Evaluating the results of laboratory studies and making product and process corrections and improvements.
* Producing small quantities of product for sensory, chemical, microbiological evaluations, limited market testing or furnishing samples to potential customers, shelf-live and storage stability studies.
* Determining possible salable by-products or waste stream requiring treatment before discharge.
* Providing data that can be used in making a decision on whether or not to proceed to a full-scale production process; and in the case of a positive decision, designing and constructing a full-size plant or modifying an existing plant.

#### *Considerations in pilot plant development*

* Kind and size – depends on goals; evaluating product and process; producing samples of product for evaluation; market testing or furnishing to potential customers.
* Location: near R&D facility? At an existing plant? Close liaison between R&D and pilot plant staff is essential.
* Labor requirements and costs: engineering staff, skilled operations and maintenance staff- pilot plant costs may exceed those of usual plant production costs. The pilot plant may be used for training personnel for a full- scale plant.

### Objective

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 with stand 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.

### Significance of Pilot Plant[3]

* + Standardization of formulae.
  + Review of range of relevant processing equipments.
  + Optimization and control of production rate.
  + Information on infrastructure of equipments during the scale up batches physical spacerequired.
  + Identification of critical features to maintain quality of a product.
  + Appropriate records and reports to support GMP.

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