KERONE
Kerone Engineering Solutions Limited

PILOT PLANT
SCALE UP
TECHNIQUES

In Association with SVCH-Technologii, Moscow (Russia)

ISO 9001:2015 | ISO 14001:2015 | ISO 45001:2018

ABOUT US

KERONE is now renowned for serving the specialized needs of customers with the best quality and economical process of Heating /cooling and drying products, manufactured in a high-quality environment by a trained and qualified workforce (special purpose machinery)

KERONE is a pioneer in application and implementation engineering with its vast experience and team of professionals.

KERONE is devoteded to serve the industry to optimize its operations both economically and environmentally with its specialized heating and drying solutions.

KERONE is having immense expertise in manufacturing and implementing various types of engineering solutions.

KERONE is possessing employee strength of more than 280+ experts continuously putting efforts for happy industrial engineering solutions.

WHY CHOOSE US

> Enhance the value of customer operation through our customer need centric engineering solution.

With decades of expertise, cutting-edge technology, and a customer-centric approach, Kerone Engineering offers tailor-made heating solutions that prioritize quality, flexibility, and cost-effectiveness. Benefit from our commitment to excellence, post-sales support, and innovative solutions for your unique heating needs. Choose Kerone Engineering for reliability, performance, and unmatched value.

MISSION

- To enhance the value of customer operation throughi our customer need centricengineefing solution
- We are cominitted to provide our customers, unique arid best in class products in Industrial heating drying and cooling segment with strategic tie-up for the technical know-how with renowned leader in the industry specific segment

VISION

- Turn into a world leader in providing specialized, top-notch quality and ecological industrial heating, cooling, and drying solutions across the globe.
- To attain global recognition as the best of quality and environment-friendly engineering solution company.

Introduction

The pilot scale is an intermediate phase between the laboratory (or bench scale) and full-scale production. It involves producing smaller quantities of a product using processes that are representative of full-scale manufacturing. The goal of this phase is to test the scalability of the process, identify any potential issues, and optimize parameters to ensure the process is viable for larger production.

R & D → **Pilot Scale** → **Scale-Up** → **Large Scale Production**

What Do Pilot Scale and Scale- Up Mean?

Pilot Scale	Intermediate Batch Scale	Manufactures drug product by a procedure fully representative of and stimulatory to that of manufacturing scale
Scale-up	Next to pilot scale	Process of increasing the batch size (mixing) / procedure for applying the same process to different output volumes (tableting)

Why Pilot Scale?

- Increasing compliance with regulations as product moves through testing and evaluation
- Animal studies (toxicology, pharmacokinetics-ADME, efficacy)
- Bench studies (product characterization, purity)
- Clinical studies
- Increasing knowledge about the product
- Ultimately facilitates the transfer of product from laboratory into production
- Increasing knowledge about the possible problems, snags, pitfalls with manufacturing, processing, packing, storing (and installing) the product

Why Scale-Up?

- A well defined process
- A perfect product in laboratory and pilot plant
- But may fail in QA tests
- Because processes are scale dependent
- Processes behave differently on a small scale and on a large scale
- Scale-Up is necessary to determine the effect of scale on product quality

Objectives of The Scale-Up

- Formulation related Identification and control of critical components and other variables
- Equipment related Identification and control of critical parameters and operating ranges
- Documentation Records and reports according to cGMP
- Production and Process related Evaluation, validation, and finalization of controls
- Product related Development and validation of reprocessing procedures

Examination of the Formula to Determine

- Ability to withstand batch scale
- Process Modification
- Compatibility of the equipment with the formulation
- Market requirement
- Cost factor
- Physical space required
- Availability of the raw materials meeting the specifications

Pilot Plant Design

Formulation and Process Development

Clinical supply manufacture

Technology evaluation, Scale-Up and Transfer

Attributes Required

- Equipment to support multiple dosage form development
- CGMP Compliance
- A flexible highly trained staff
- Portable equipment
- Restricted access, regulated personnel flow and material flow
- Multipurpose rooms
- Low maintenance and operating costs
- Equipment at multiple scales based on similarly operating principles to those in production (Intermediate sized and Full scale equipment)

Pilot Plant Operation

Operational Aspects

- Validation
- Training
- Material control
- Inventory, Orders, Labelling
- QA & QC
- Process & Manufacturing Activities
- Maintenance and Calibration
- Engineering support

Validation

- Design specifications
- Installation Qualification
- Operational Qualification
- Performance Qualification
- Compliance with CGMP and FDA standards

Training

- Compliance with GMP
- Technical skills and knowledge
- Compliance with SOPS
- Safety and environmental responsibilities

Quality Assurance

- Auditing pilot plant
- Auditing and approval of component suppliers
- Reviewing, approval and maintaining batch records for clinical supplies
- Sampling and release of raw materials and components required for clinical supplies
- Release of clinical supplies
- Maintaining and distributing facility and operating procedures (SOPs)
- Review and approval of validation and engineering documentation

Quality Control

- Release Testing of finished product
- Physical, Chemical and Microbiological testing of finished clinical products, components required for clinical supplies
- Testing for validation and revalidation programs
- QC in-process testing during development, Scale-Up and Technology transfer activities

Industries Using Pilot Plants

- Pharmaceutical: Testing new drug synthesis methods.
- Chemical: Developing new chemical processes.
- Food: Testing recipes and processing methods.
- Energy: Optimizing energy production techniques.
- Textile Industry: For coating clothes

Benefits of Pilot Plants

- Cost Savings: Identify issues early, reducing expensive modifications later.
- Quick Development: Rapid testing and iteration of processes.
- Improved Understanding: In-depth insights into process variables.

What are Metal-Organic Frameworks (MOF)

Metal-Organic Frameworks (MOFs) are a class of highly porous materials that are constructed by linking metal ions or clusters with organic ligands through coordination bonds. These materials have a unique structure where metal nodes or clusters are interconnected by organic linker molecules, forming a three-dimensional lattice-like framework. The resulting structure has a high surface area and well-defined pores, which can lead to exceptional properties and various applications.

Metal–organic frameworks (MOFs) are a class of compounds consisting of metal clusters (also known as SBUs) coordinated to organic ligands to form one-, two-, or three-dimensional structures. The organic ligands included are sometimes referred to as "struts" or "linkers", one example being 1,4-benzenedicarboxylic acid (BDC).

In most cases for MOFs, the pores are stable during the elimination of the guest molecules (often solvents) and could be refilled with other compounds. Because of this property, MOFs are of interest for the storage of gases such as hydrogen and carbon dioxide. Other possible applications of MOFs are in gas purification, in gas separation, in water remediation, in catalysis, as conducting solids and as super capacitors.

Why Pilot Plants

Pilot plants are intermediate-scale facilities that bridge the gap between laboratory research and full-scale industrial production. They play a crucial role in the development and optimization of new processes, technologies, and products before they are implemented on a larger, commercial scale. There are several reasons why pilot plants are used

- Process Validation and Optimization
- Scale-Up Challenges
- Cost Savings
- Regulatory Compliance and Safety
- Market Testing and Product Development
- Feasibility Studies
- Research and Development
- Training and Skill Development
- Customization and Adaptation

Process Design and Flow Diagram

Process Design

Process design is the systematic and creative process of defining how a process will work, including selecting equipment, specifying operating conditions, and determining the sequence of steps. It involves considering factors such as efficiency, safety, sustainability, and cost-effectiveness.

Key steps in process design

- Optimization
- Defining Objectives
- Process Flow Analysis
- Equipment Selection
- Material and Energy Balances
- Safety and Environmental Considerations

Flow Diagram

Flow diagrams are visual representations that illustrate the sequence of steps, components, and interactions within a process. They come in various forms, depending on the complexity of the process and the level of detail needed.

Some common types of flow diagrams include

- Process Flow Diagram (PFD)
- Piping and Instrumentation Diagram (P&ID)
- Block Flow Diagram (BFD)
- Functional Flow Block Diagram
- Flowcharts
- Sankey Diagrams

TRUSTED PARTNERS

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TOYO ENGINEERING

EIL

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ZEPPELIN WE CREATE SOLUTIONS

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THANK YOU

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