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A COMPREHENSIVE REVIEW OF PILOT PLANT SCALE-UP TECHNIQUES IN PHARMACEUTICAL MANUFACTURING

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ABSTRACT

This review examines the critical aspects of pilot plant scale-up, emphasizing its role in bridging the gap between small-scale research and large-scale manufacturing. The transition from laboratory-scale to industrial-scale pharmaceutical manufacturing is pivotal in drug development. Pilot plants serve as hybrid facilities that integrate early development activities, clinical supply manufacture, technology evaluation, scale-up, and transfer to production areas. Key considerations include optimizing process parameters such as mixing time, drying techniques, granulation methods, and coating procedures to ensure product durability, reproducibility, and commercial viability. The data obtained from pilot plant studies are essential for designing efficient production processes, ensuring regulatory compliance, and minimizing risks during commercial manufacturing. Additionally, the review discusses the significance of SUPAC (Scale-Up and Post-Approval Changes) guidelines in maintaining product quality during scale-up and post-approval changes. The review concludes by highlighting the importance of pilot plant scale-up in the successful development of pharmaceutical dosage forms and its role in the regulatory framework.

KEYWORDS: Pilot plant scale, personnel and space requirements, raw materials, SUPAC guidelines, Documentation, platform technology.

INTRODUCTION TO PILOT PLANT SCALE-UP TECHNIQUES

What is pilot plant scale-up?

Pilot plant is a part of the pharmaceutical industry and is defined as the process of developing a reliable, feasible manufacturing process from a lab scale formula to a marketable product. Pilot plant scaleup is a vital phase in pharmaceutical development, serving as the bridge between laboratory research and full-scale commercial production. It involves translating lab-scale formulations into processes that are feasible, reproducible, and compliant at a larger scale, ensuring the product quality and regulatory compliance.[1,2,3]

GENERAL CONSIDERATIONS IN SCALE-UP

Significance of

- Pilot plant scale-up
- Personnel requirements
- Space requirements
- Raw materials

SIGNIFICANCE OF PILOT PLANT SCALE-UP

Purpose of Pilot Plants

Pilot plants serve as an essential bridge between laboratory research and full-scale commercial manufacturing. Their primary purposes include:

- **Evaluation and Optimization of Processes**: Pilot plants enable the testing and refinement of manufacturing processes under conditions that closely mimic commercial production. This helps in identifying the most efficient and robust process parameters.
- **Identification of Production Issues:** By simulating scaled up production, potential challenges such as equipment bottlenecks, material handling issues, or process variability can be detected and resolved early.
- **Generation of Regulatory Data:** Pilot plant operations generate critical data on process performance, product quality, and reproducibility. This data is vital for regulatory submissions to agencies like the FDA, supporting claims of safety, efficacy, and quality.[4,6]

Scope of Pilot Plant Activities

The scope of pilot plant operations is broad and includes variuos key activities:

- **Process Development:** Refining and validating manufacturing processes to ensure they are scalable, reproducible, and compliant with Good Manufacturing Practices (GMP).
- **Technology Transfer:** Facilitating the smooth transfer of processes and knowledge from R&D to commercial manufacturing, ensuring all critical parameters are well documented

and understood.

- **Clinical Supply Manufacture:** Producing batches for clinical trials, ensuring that the investigational product is representative of the final commercial product.
- **Regulatory Preparation:** Generating comprehensive documentation and data to support regulatory inspections and submissions, demonstrating process control and product quality.[5,7]

Flexibility of Pilot Plants

Pilot plants are designed to be adaptable, enabling modifications in equipment and processes as needed during development

- **Adaptable Equipment:** Pilot plants are designed with modular and interchangeable equipment, allowing for quick modifications to accommodate different products or processes.
- **Process Modifications:** The setup enables easy adjustment of process parameters, batch sizes, and configurations, supporting iterative optimization.
- **Support for Multiple Projects:** Flexibility allows the pilot plant to handle various products and formulations, maximizing resource utilization and supporting innovation.[6,7]

SIGNIFICANCE OF PERSONNEL REQUIREMENTS

The success of pilot plant operations in pharmaceutical manufacturing heavily depends on the competence and coordination of its personnel. Effective scale-up requires a blend of technical expertise, practical skills, continuous training, and robust teamwork.

Expertise

Staff should possess both theoretical knowledge and practical experience in pharmaceutical manufacturing, particularly in the dosage forms being scaled up (solids, liquids, semisolids).[8,9]

- **Theoretical Knowledge:** Staff must have a strong foundation in pharmaceutical sciences, especially in the specific dosage forms being scaled up—whether solids, liquids, or semisolids. This includes understanding formulation principles, process engineering, and regulatory requirements.[6,7]

- **Practical Experience:** Hands-on experience with manufacturing equipment, troubleshooting, and process optimization is essential. Personnel should be adept at translating laboratory procedures to pilot-scale operations, anticipating and resolving scale-dependent issues.[5]

Training

Continuous training in equipment operation, safety protocols, cGMP, and emergency procedures is essential.[10,9]

- **Continuous Training:** Ongoing education is vital to keep staff updated on the latest equipment, cGMP (current Good Manufacturing Practices), and evolving safety protocols. Training should cover:
  - Equipment operation and maintenance
  - Standard operating procedures (SOPs)
  - Emergency response and safety drills
  - Regulatory compliance and documentation practices
- **Competency Assessments:** Regular evaluations ensure that staff maintain the necessary skills and knowledge to operate effectively and safely.[6,7]

Cross-Functional Teams

Collaboration among R&D, engineering, quality control, and production departments is critical for successful scaleup.[10]

- **Interdepartmental Collaboration:** Successful scale-up relies on seamless communication and cooperation between R&D, engineering, quality control, and production departments. Each brings unique expertise:
  - R&D: Provides process knowledge and formulation expertise.
  - Engineering: Ensures equipment suitability and process scalability.
  - Quality Control: Oversees analytical testing and compliance.
  - Production: Manages day-to-day operations and process execution.
- **Problem-Solving:** Cross-functional teams facilitate rapid identification and resolution of technical or operational challenges.[4,5]

Responsibility

Clear reporting relationships and defined responsibilities ensure accountability and smooth operation.[1,2,9]

- **Defined Roles and Reporting:** Clear organizational structure, with well-defined roles and reporting relationships, is essential for accountability. Each team member should understand their responsibilities and authority within the scale-up process.

- **Documentation:** Proper assignment of documentation duties ensures that all process changes, deviations, and outcomes are accurately recorded and traceable.
- **Leadership**: Experienced supervisors or managers should oversee pilot plant operations, ensuring adherence to SOPs, safety, and regulatory requirements.[4,7]

SIGNIFICANCE OF SPACE REQUIREMENTS

An efficiently designed pilot plant is essential for the safe, flexible, and compliant development of pharmaceutical products. Space planning must consider functional needs, safety, adaptability, and storage, all of which directly impact operational efficiency and regulatory compliance.

1. Functional Areas

Pilot plants are generally organized into distinct functional zones to streamline workflow and ensure compliance,[4,6,7]

- **Administration Area:** Houses offices for management, documentation, and coordination activities.
- **Physical Testing Area:** Dedicated space for in-process and finished product testing, equipped with analytical instruments and quality control tools.
- **Equipment Floor**: The main area where manufacturing equipment is installed and operated. This space must accommodate various process units for solids, liquids, and semisolids.
- **Storage Areas:** Segregated zones for raw materials, intermediates, finished products, and waste, each with appropriate environmental controls (e.g., temperature, humidity).

2. Safety

Safety is a paramount consideration in pilot plant design.[6,7]

- **Equipment Spacing:** Sufficient space between equipment is mandatory to allow safe operation, routine maintenance, and emergency access.
- **Clear Pathways:** Unobstructed aisles and exits ensure rapid evacuation and facilitate the movement of personnel and materials.
- **Emergency Provisions:** Incorporation of safety showers, fire extinguishers, alarms, and first-aid stations at accessible locations.

3. Flexibility

Pilot plants must be adaptable to accommodate evolving processes and new technologies,[6]

- **Modular Layout:** The design should allow for easy reconfiguration of equipment and process lines as development needs change.
- **Utility Access:** Flexible connections for utilities (water, steam, compressed air, power) support equipment relocation and process modifications.
- **Scalability:** The space should support incremental expansion or contraction based on project demands.

4. Storage

Proper storage is critical for efficient workflow and regulatory compliance,[4,6]

- **Raw Materials**: Secure and controlled storage for APIs, excipients, and packaging materials to prevent contamination and degradation.
- **Intermediates and Finished Products**: Designated areas for holding in-process materials and finished batches, with environmental monitoring as required.
- **Waste Management**: Separate, well-ventilated areas for temporary storage of process waste, ensuring safe and compliant disposal.

SIGNIFICANCE OF RAW MATERIALS

Raw materials form the foundation of any pharmaceutical manufacturing process. Their quality, quantity, handling, and procurement significantly influence the success of pilot plant operations and the eventual scale-up to commercial production.

1. Quantity

- **Intermediate Scale:** Pilot plant production requires a larger quantity of raw materials than laboratory-scale experiments but significantly less than full commercial manufacturing.[6,74]
- **Batch Size Considerations:** The quantity must be sufficient to produce representative batches that mimic commercial scale, enabling accurate process evaluation and optimization.
- **Cost and Waste Management:** Balancing quantity is crucial to minimize material wastage and manage costs effectively during development.

2. Quality

- **Consistency with Commercial Production:** Raw materials used in pilot plants should be identical in quality and specifications to those intended for commercial manufacturing to ensure process relevance and product consistency.[4,5]
- **Early Identification of Challenges:** Using commercial-grade materials early helps uncover potential issues related to raw material variability, compatibility, and sourcing, allowing for timely mitigation.
- **Compliance:** Materials must meet pharmacopeial standards and regulatory requirements to guarantee safety and efficacy.

3. Storage and Handling

- **Proper Storage Conditions:** Raw materials require controlled environments (temperature, humidity, light) to maintain their integrity and prevent degradation or contamination.[6,7]
- **Inventory Management:** Efficient systems for tracking material quantities, batch numbers, and expiry dates are essential to ensure traceability and avoid stockouts or overstocking.
- **Waste Disposal:** Robust procedures for the segregation, handling, and disposal of expired or rejected materials must be in place to comply with environmental and safety regulations.

4. Procurement

- **Bulk Purchasing**: Pilot plant scale may introduce bulk procurement practices, necessitating careful supplier evaluation to ensure consistent quality and supply reliability.[7.5]
- **Supplier Quality and Traceability:** Suppliers should be qualified, and raw materials must be traceable through documentation to comply with GMP and regulatory standards.
- **Risk Mitigation:** Multiple sourcing strategies and quality agreements help reduce risks associated with supply chain disruptions.

PILOT PLANT SCALEUP CONSIDERATIONS FOR DOSAGE FORMS

- Solids
- Liquid Orals
- Semisolids

SOLIDS (Tablets, Capsules)

Blending

Uniform mixing is critical to ensure dose uniformity. Equipment must be scalable and capable of handling increased batch sizes without segregation. Achieving uniform mixing is paramount to ensure consistent dose uniformity in pharmaceutical formulations. As batch sizes increase during scale-up, the risk of segregation—where components separate due to differences in particle size or density—becomes more pronounced. To mitigate this, equipment must be selected based on its ability to handle larger volumes without inducing segregation. Continuous mixers, for instance, offer enhanced homogeneity by maintaining consistent residence times and controlled shear forces, effectively reducing the likelihood of component separation. Additionally, optimizing mixing parameters such as impeller speed and batch size is crucial to maintain blend uniformity during scale-up,[2,3]

Granulation

Wet or dry granulation processes must be optimized for larger volumes, considering factors like mixing time, binder addition, and drying. Granulation processes, including wet and dry methods, are employed to improve the flowability and compressibility of powders. In wet granulation, the addition of a binder solution to the powder mixture facilitates particle agglomeration. Critical factors during this process include the rate of binder addition, mixing time, and the speed of the granulator's impeller and chopper. These parameters influence the granule's size distribution, moisture content, and overall quality. Dry granulation, on the other hand, involves compacting the powder mixture under high pressure without the use of a binder solution, making it suitable for moisture-sensitive ingredients. The scale-up of these processes requires careful calibration of equipment and process parameters to ensure consistent granule quality and performance.[2]

Compression

Tablet presses should be selected based on batch size, and parameters like compression force and speed must be validated. Tablet compression involves the transformation of granules into solid dosage forms under high pressure. During scale-up, it's essential to select tablet presses that can accommodate increased batch sizes while maintaining consistent tablet weight and content uniformity. Key parameters to validate include compression force, tablet hardness, and ejection speed. Adjustments may be necessary to account for differences in material behavior at larger scales, ensuring that tablets meet the required specifications for strength and dissolution characteristics.[2]

Coating

Scaleup requires assessment of pan size, spray rate, and drying conditions to ensure consistent coating quality Tablet coating is applied to protect the active pharmaceutical ingredient (API) from environmental factors and to control the release of the drug. During scale-up, it's crucial to assess parameters such as pan size, spray rate, and drying conditions to achieve uniform coating thickness and consistency. The number of spray guns and their positioning, along with the airflow and temperature settings, must be optimized to ensure that the coating process is efficient and reproducible at larger scales.[2]

LIQUID ORALS

Mixing

Equipment must provide adequate agitation to ensure uniformity, with attention to air entrapment and uniform mixing is crucial for ensuring consistent dose uniformity in pharmaceutical formulations. During scale-up, equipment must provide adequate agitation to handle increased batch sizes without causing segregation. It's essential to address issues like air entrapment and foaming, which can compromise product quality. Strategies to mitigate these issues include adjusting impeller positions, utilizing bidirectional mixing, incorporating baffles, optimizing mixing speeds, and employing vacuum mixing techniques.[8,9]

Homogenization

For emulsions or suspensions, homogenizer selection and operating parameters are crucial. Homogenization is vital for producing stable emulsions and suspensions. The selection of appropriate homogenizers and the optimization of operating parameters are crucial during scale-up. High shear homogenizers, such as rotor-stator systems, are commonly used to achieve uniform droplet sizes. It's important to calibrate equipment settings to ensure consistency between laboratory and industrial scales.[9]

Storage

Tanks and transfer lines should be compatible with the formulation and easy to clean. Proper storage of pharmaceutical products is critical to maintain their stability and efficacy. During scale-up, it's essential to ensure that storage tanks and transfer lines are designed to prevent contamination and degradation of the product. This involves selecting materials that are compatible with the product, ensuring proper sealing to prevent leaks, and implementing monitoring systems to track storage conditions.[8,9]

SEMISOLIDS (Ointments, Creams, Gels)

Mixing

Equipment must handle high-viscosity products, ensuring thorough mixing and heat transfer. High-viscosity pharmaceutical formulations, such as pastes or gels, demand specialized mixing equipment capable of delivering adequate shear and heat transfer. Traditional agitators may not suffice due to their limited shear capabilities. Advanced mixers like double-arm kneaders, planetary mixers, and hybrid planetary mixers are designed to handle materials with viscosities ranging from several hundred thousand to over a million centipoise. These mixers employ dual-motion agitators and high-shear blades to achieve uniform blending and efficient heat transfer.[11,8,9]

Homogenization

Uniform dispersion of active ingredients and excipients is essential; specialized mixers may be required. Homogenization is crucial for dispersing active pharmaceutical ingredients (APIs) and excipients uniformly, particularly in emulsions and suspensions. High-shear homogenizers, such as rotor/stator systems, apply intense mechanical shear to reduce droplet sizes and enhance dispersion. This process improves emulsion stability and bioavailability of the drug. For large-scale operations, inline high-pressure homogenizers offer continuous processing capabilities, ensuring consistent quality and scalability.[11,8]

Heating/Cooling

Controlled temperature profiles are necessary for product stability and texture. Methods such as jacketed vessels, dynamic scraped surface heat exchangers (DSSHEs), and heat exchangers are employed to regulate temperatures during processing. DSSHEs are particularly effective for high-viscosity materials as they prevent fouling and ensure efficient heat transfer by continuously scraping the heat exchange surface.[11]

Pumping

Pumps should be selected based on viscosity and compatibility with the product to avoid degradation or contamination. Pumping high-viscosity pharmaceutical formulations requires careful selection of pump types to prevent degradation and contamination. Positive displacement pumps, such as gear or diaphragm pumps, are commonly used for their ability to handle viscous materials without compromising integrity. It's crucial to ensure that the selected pumps are compatible with the formulation's chemical properties and can maintain sterile conditions if necessary.[11]

RELEVANT DOCUMENTATION

Proper documentation is a basis of pharmaceutical manufacturing, especially during pilot plant scale-up. It ensures traceability, regulatory compliance, process reproducibility, and effective technology transfer.

Below are the key documentation types required

1. Batch Records

- **Purpose**: Batch records provide a detailed, step-by-step account of each batch manufactured in the pilot plant.
- **Contents**
    - List of all raw materials (with batch numbers and quantities)
    - Detailed description of each processing step
    - In-process control results (e.g., pH, temperature, viscosity, tablet hardness)
    - Equipment and personnel involved
    - Any deviations, corrective actions, and investigations
- **Significance**: These records are essential for troubleshooting, process validation, and regulatory audits.[7,4]

2. Standard Operating Procedures (SOPs)

- **Purpose**: SOPs ensure that all operations are performed consistently and in compliance with cGMP.
- **Contents**
    - Procedures for equipment operation, cleaning, and maintenance
    - Stepwise instructions for each unit operation (e.g., blending, granulation, mixing)
    - Safety protocols and emergency procedures
    - Documentation practices and record-keeping requirements
- **Significance**: SOPs minimize variability, facilitate training, and support regulatory inspections.[7]

3. Technology Transfer Reports

- **Purpose:** These documents facilitate the transfer of manufacturing processes from R&D to the pilot plant and eventually to full-scale production.

- **Contents**
  - Detailed process description and rationale for chosen parameters
  - Critical process parameters (CPPs) and critical quality attributes (CQAs)
  - Equipment and scale-up considerations
  - Lessons learned and troubleshooting guidance
- **Significance**: Technology transfer reports ensure knowledge continuity and help prevent errors during scale-up.[4,7]

4. Regulatory Submissions

- **Purpose:** Documentation prepared for submission to regulatory authorities (e.g., FDA, EMA) to demonstrate process control, product quality, and compliance.
- **Contents**
  - Validation protocols and reports (process, cleaning, analytical methods)
  - Stability data supporting shelf-life and storage conditions
  - Product specifications and certificates of analysis
  - Risk assessments and change control documentation
- **Significance**: These documents are critical for gaining approval to progress from clinical to commercial manufacturing.[4,7]

SUPAC GUIDELINES

The **Scale-Up and Post-Approval Changes (SUPAC) guidelines a**re a set of regulatory recommendations issued by the U.S. FDA to guide pharmaceutical manufacturers in managing changes to approved drug products after initial regulatory approval. These changes may involve formulation, manufacturing process, equipment, batch size, or manufacturing site.[12,4,17,18,19]

Purpose of SUPAC Guidelines

- Ensure that any post-approval changes do not negatively impact the identity, strength, quality, purity, or potency of the drug product.[14,17]
- Provide a structured approach for evaluating and documenting changes, maintaining product consistency and patient safety.[17,18]

Scope of SUPAC Guidelines

SUPAC guidelines apply to a variety of post-approval changes, including:

- Changes in components and composition of the drug product

- Changes in manufacturing site
- Scale-up or scale-down of batch size
- Changes in manufacturing process or equipment
- Changes in packaging.[14,16,17]

SUPAC guidance is categorized by dosage form

- SUPAC-IR: Immediate-release solid oral dosage forms
- SUPAC-MR: Modified-release solid oral dosage forms
- SUPAC-SS: Non-sterile semisolid dosage forms (e.g., creams, ointments, gels)[17,18]

Levels of Change

SUPAC classifies changes into three levels, each with different regulatory requirements.

Level	Description	Regulatory Requirement
Level 1	Minor changes unlikely to impact quality or performance (e.g., minor equipment changes)	Annual Report
Level 2	Moderate changes that could impact quality/performance (e.g., moderate batch size increase)	Supplement with supporting data (e.g., dissolution testing)
Level 3	Major changes likely to impact quality/performance (e.g., major process or site changes)	Prior Approval Supplement (PAS), may require bioequivalence studies and stability data

[14,16,17,18,19]

Documentation and Evaluation

- **Chemistry, Manufacturing, and Controls (CMC)**: All changes must be supported by updated CMC documentation, including revised batch records and validation data.
- **Testing**: Depending on the level of change, additional testing (e.g., dissolution, stability, bioequivalence) may be required to demonstrate continued product quality and performance.[14,17,18]
- **Submission:** The type and extent of documentation submitted to the FDA depend on the change level—ranging from annual reports for minor changes to full supplements for major changes.[14,16,17]

Significance

- SUPAC guidelines streamline the regulatory process for post-approval changes, making it more predictable and efficient while safeguarding product quality.[17,18]
- They reduce the regulatory burden by clarifying what documentation and testing are

necessary for different types of changes, supporting continuous improvement and innovation in pharmaceutical manufacturing.[14,17,18]

INTRODUCTION TO PLATFORM TECHNOLOGY

Introduction to Platform Technology in Pharmaceuticals

Platform technology in the pharmaceutical industry refers to a foundational set of standardized processes, methodologies, or equipment that serve as a base for the development, manufacturing, and scale-up of multiple drug products or formulations.[1] This approach enables companies to streamline product development, optimize manufacturing, and accelerate time-to-market by leveraging prior knowledge and proven systems across a range of products.

Key Concepts and Definitions

- **Platform Technology**: A core set of technological tools, processes, or systems that can be applied to develop various products within a single framework. It acts as a "base" upon which other applications, processes, or innovations are built.[20,23]
- **Standardization:** Involves using common protocols, equipment, and methodologies, ensuring consistency and reproducibility across different products or batches.[24,25]
- **Modularity and Scalability:** Platforms are designed to be flexible and scalable, allowing for easy adaptation to new products or increased production volumes.[23,25]

Importance and Benefits

- **Efficiency:** Reduces development time and costs by applying established processes to new products, eliminating the need to "reinvent the wheel" for each formulation.[21,24,26]
- **Regulatory Simplification:** Familiarity with platform processes can simplify regulatory submissions and approvals, as the technology's safety and performance are already well-characterized.[21,23]
- **Facilitates Technology Transfer:** Standardized platforms make it easier to transfer processes from laboratory to pilot plant and then to commercial manufacturing,[24,26]
- **Supports Innovation:** Enables rapid adaptation to new scientific advances or therapeutic needs, such as the quick development of mRNA vaccines for COVID-19.[23]

Applications in Pharmacy[21,23]

- **Drug Delivery Systems:** Liposomes, microspheres, nano-emulsions, and sustained-release formulations serve as platforms for delivering a variety of drugs with similar release or targeting profiles.

- **Biologic Production**: Monoclonal antibody and recombinant protein platforms use standardized cell lines and processes for different therapeutic proteins.
- **Gene and Cell Therapy:** Viral vector and CAR-T cell platforms allow for the rapid adaptation of delivery systems to new genetic therapies.
- **mRNA Technology:** Used in vaccines and adaptable for different diseases with minimal changes to the core platform.
- **Analytical and Process Control**: Robust analytical methods and data management systems are integral to platform technology, ensuring process monitoring and quality control across products.

Platform Technology in Pilot Plant Scale-Up[24,26]

In pilot plant scale-up, platform technology enables

- **Standardized Process Development:** Applying the same process design and control strategies across multiple products.
- **Equipment Standardization**: Using common reactors, mixers, and filtration systems to simplify qualification and validation.
- **Quality-by-Design (QbD):** Integrating QbD principles to focus on critical quality attributes and risk management.
- **Efficient Data Management:** Leveraging digital systems for process monitoring, control, and optimization.

Table: Platform Technology Features.

Feature	Description
Standardization	Common processes and equipment for multiple products
Scalability	Easy adaptation from lab to pilot to commercial scale
Regulatory Efficiency	Simplifies submissions due to proven technology base
Cost & Time Savings	Reduces duplication of development and validation efforts
Flexibility	Supports innovation and rapid response to new product needs

CONCLUSION

Pilot plant scale-up is a critical step in bridging the gap between laboratory innovation and full- scale commercial production in the pharmaceutical industry. It ensures that the formulation developed at the research level can be reliably and reproducibly manufactured at larger volumes while maintaining the same safety, efficacy, and quality standards. awell-planned pilot plant scale-up strategy is not merely a technical requirement—it is a strategic tool that ensures product success in a highly regulated and competitive market. Mastery of scale-up techniques empowers pharmaceutical scientists to bring quality medicines to patients faster, safer, and more reliably.

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