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Yield Improvement Strategy in a Pharmaceutical Company in Central Mexico

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ABSTRACT

This study analyzes yield variability in the aseptic manufacturing of oncological injectable drugs within a Mexican pharmaceutical company, emphasizing the critical role of particle contamination control in Class A (ISO 5) environments. Drawing on industrial engineering principles and pharmaceutical quality management frameworks, the research evaluates process performance across twelve production stages, identifying the filling and stoppering phase as the primary source of yield loss.

A comparative analysis of production data from 2024 and 2025 for the product Foavil revealed a significant improvement in yield, increasing from an average of 67.36% to 92.19% following targeted process interventions. These interventions included stricter personnel gowning protocols, validation of garment cleaning cycles, elimination of particle-generating materials, and

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enhanced cleaning and verification of critical equipment such as transfer hoses and glass containers.

The findings confirm that deviations in aseptic practices and environmental control directly impact operational efficiency and product losses. The study highlights that robust adherence to regulatory standards, particularly NOM-059-SSA1-2015, combined with engineering-driven continuous improvement strategies, is essential to achieving high yields in sterile pharmaceutical manufacturing.

This work contributes to the growing body of knowledge on yield optimization by demonstrating that operational discipline and contamination control in critical environments are decisive factors for improving productivity, ensuring product sterility, and safeguarding patient safety in oncological treatments.

KEYWORDS

Aseptic manufacturing, pharmaceutical industry, Process optimization, Contamination control, Cleanroom environments, Oncology pharmaceuticals

INTRODUCTION

The pharmaceutical industry has undergone significant transformation over recent decades, driven by advances in manufacturing technologies, regulatory frameworks, and process optimization methodologies. In emerging markets such as Mexico, the sector has experienced sustained growth, particularly in the production of high-value therapeutics such as oncological drugs. Within this context, achieving high process yields while ensuring product quality and patient safety remains a central challenge for pharmaceutical manufacturers. Yield optimization is not only a matter of economic efficiency but also a critical determinant of supply reliability and access to life-saving treatments.

From an industrial engineering perspective, the application of systematic management principles and advanced analytical tools has been widely recognized as essential for improving productivity in pharmaceutical manufacturing. Recent studies have emphasized the role of process optimization across upstream, downstream, and fill-and-finish operations, highlighting the potential of emerging technologies such as machine learning to enhance process control and reduce variability. However, in the case of sterile injectable products, particularly oncological formulations, the fill-and-finish stage remains one of the most critical and risk-sensitive phases of production.

Aseptic processing is inherently complex and requires strict control of environmental conditions, personnel behavior, and equipment performance. According to NOM-059-SSA1-2015, Class A (ISO 5) environments represent the highest level of control, where operations such as aseptic filling must be conducted under conditions that virtually eliminate particulate and microbiological contamination. Despite these stringent requirements, deviations in aseptic practices—particularly those associated with human intervention—continue to be a leading source of contamination risk and process inefficiency.

Process variability in pharmaceutical manufacturing directly affects the gap between theoretical and actual yields, often resulting in significant product losses and increased production costs. In sterile manufacturing, such variability is frequently associated with contamination events, especially during critical operations such as filling and stoppering. Particle contamination, in particular, represents a major quality concern, as it not only compromises product sterility but also leads to batch rejection during visual inspection, thereby reducing overall process yield.

In the Mexican pharmaceutical context, limited empirical studies have addressed the relationship between aseptic process control and yield performance in commercial manufacturing settings. This gap is particularly relevant for oncological injectables, where the complexity of formulations and the strict regulatory requirements amplify the consequences of process deviations. Therefore, there is a need for applied research that integrates operational analysis with quality management principles to identify critical control points and propose effective improvement strategies.

This study aims to analyze yield variability in the aseptic manufacturing of an oncological injectable drug within a Mexican pharmaceutical company, with a specific focus on the identification and mitigation of particle contamination during critical process stages. By conducting a comparative analysis of production performance between 2024 and 2025, this research evaluates the impact of targeted engineering interventions on yield improvement. Furthermore, it seeks to demonstrate that rigorous adherence to regulatory standards, combined with disciplined operational practices and continuous improvement strategies, can significantly enhance process efficiency in sterile pharmaceutical manufacturing.

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Ultimately, this work contributes to the field by providing empirical evidence on the importance of contamination control in Class A environments and by reinforcing the role of industrial engineering approaches in achieving operational excellence within the pharmaceutical sector.

DEVELOPMENT

Pharmaceutical industry in Mexico has been developed its methods and products along the years. As rough out by [3], management principles can be adopted in the pharmaceutical industry to optimize manufacturing processes and to improve yield and productivity.
[4] reveals the importance on ensuring high yields and minimal product loss in pharmaceuticals and biologicals. In pharma, it is very important to develop methods or strategies to ensure high yields or improving them.
Yields improvement can be performed or researched on Upstream Processing, Downstream Processing and/or Fill & Finish. [6] state that applications of ML (Machine Learning) algorithms for upstream processing and downstream processing can help on yields improvement. [7] suggested the importance of using strategies for enhancing yield through strain improvement and fermentation condition optimization.
Process variations in the production process generate a difference between planned yield and actual yield, affecting operational efficiency and production costs [2]. Aseptic filling is the handling of sterile components in a strictly controlled environment, using careful (aseptic) techniques to produce a sterile product [1]. Contamination of parenteral solutions can be mainly attributed to inadequate practices during preparation and administration, as well as to failures in the aseptic behavior of the responsible personnel [5].

GENERAL OBJECTIVE AND SPECIFIC OBJECTIVES

To analyze and optimize process yield in the aseptic manufacturing of an oncological injectable drug through the identification, evaluation, and mitigation of particulate contamination in critical process stages—particularly during filling and stoppering—by applying industrial engineering principles, regulatory compliance criteria, and continuous improvement strategies.

Specific objectives:

1. Analyze the relationship between particulate contamination and process yield variability
2. Identify critical stages of the sterile manufacturing process associated with contamination risk
3. Evaluate the impact of operational deviations in Class A environments on product quality and batch rejection
4. Implement contamination control measures in aseptic operations (gowning, cleaning validation, equipment control)

OBJECT OF STUDY

The object of study is the process yield variability in the aseptic manufacturing system of an oncological injectable drug, specifically within the fill-and-finish stage (filling and stoppering) conducted under Class A (ISO 5) conditions in a Mexican pharmaceutical company.

METHODOLOGY

Present study was developed under a non-experimental, descriptive, and longitudinal approach, based exclusively on the analysis of a pharmaceutical manufacturing process within a company dedicated to oncological injectable drugs.
The analysis focuses on the sterile manufacturing process, particularly on the stages associated with aseptic filling operations (fill-and-finish). The study is limited to the evaluation of process performance through yield behavior and its relationship with contamination by particles.
The temporal scope corresponds to a comparative analysis between 2024 and 2025, using production data from the product Foavil.
The study is based on internal operational information described in the text, specifically: Production yield data; Description of the manufacturing process; Identification of operational issues related to particle contamination; and Regulatory framework.
No external data sources or additional measurement instruments are incorporated beyond those described.

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A sequential process analysis was conducted, based on the twelve defined stages of sterile manufacturing: Raw material dispensing; Washing and sterilization; Bulk production; Bulk filtration; Primary packaging material supply; Washing and depyrogenation of vials; Filling and stoppering; Capping and cleaning; Visual inspection; Secondary packaging material supply; Labeling and coding; and, Secondary packaging

Each stage was described according to its function and operational controls, with particular emphasis on environmental conditions and contamination risks. Its important to mention that the images on each stage described, was taken prom the process and re-pixel on a cartoon style.

Through the analysis described in the text, the critical issue affecting yield was identified in Stage VII (Filling and Stoppering). This identification is based on: The occurrence of particulate contamination; The classification of the area as Class A; The operational sensitivity of the stage, where the product is exposed prior to sealing; Yield Analysis

A descriptive comparison of production performance was conducted using the reported indicators: Average yield; Maximum yield; Minimum yield; and, Range

The comparison between 2024 and 2025 allows the observation of changes in: Overall efficiency; Process variability (reduction in range); and, Evaluation of Process Improvements.

The study considers the implementation of specific operational adjustments described in the text: Reinforcement of gowning and personnel behavior; Validation of garment cleaning; Cleaning and verification of hoses and glass containers; and, Elimination of paper use in aseptic areas

The impact of these actions is evaluated indirectly through the observed improvement in yield between the two periods.

PHASES OF DEVELOPMENT

The development of this research was structured in sequential phases aligned with the defined methodological approach. In the first phase, a delimitation of the study was carried out, focusing on the aseptic manufacturing process of oncological injectable drugs, specifically within the fill-and-finish stage. This was followed by the collection and organization of internal production data corresponding to the 2024–2025 period, ensuring consistency and comparability of yield indicators.

In the second phase, a detailed characterization of the twelve stages of the sterile manufacturing process was performed. Each stage was analyzed based on its operational function, environmental conditions, and potential sources of particulate contamination, emphasizing critical control points.

The third phase consisted of the identification of the main source of variability through a sequential process analysis. Stage VII (filling and stoppering) was determined as the most critical due to its exposure conditions and sensitivity to human intervention.

Subsequently, a comparative analysis of yield performance was conducted using key indicators such as average, maximum, minimum, and range values. Finally, in the last phase, improvement actions were evaluated based on their impact on yield behavior, establishing a direct relationship between contamination control measures and process efficiency enhancement.

RESULTS AND DISCUSSION

The company under study is a pharmaceutical company located in the central region of the country, dedicated to the manufacturing of oncological drugs. The company was established in 2004, obtained its sanitary license in 2007, and by 2013 had consolidated itself as one of the fastest-growing manufacturers of oncological products in the country. Subsequently, in 2016, it carried out its first export to Latin America, marking an important step in its international expansion.

The company has two authorized drug manufacturing lines. The first corresponds to solid oncological products, in which tablets, compressed tablets, coated tablets, hard gelatin capsules, and soft gelatin capsules are produced. The second line corresponds to sterile oncological products, where injectable solutions, lyophilized solutions, suspensions, and emulsions are manufactured.

The Quality Assurance Department is the area responsible for ensuring that drugs are manufactured safely, effectively, and in compliance with current health regulations. Within the Documentation area, the preparation, review, control,

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storage, and distribution of the documentation that comprises the Quality Management System are carried out, ensuring that all documents and records comply with the guidelines established in the Good Documentation Practices Policy.
In addition, the development, review, updating, and control of Standard Operating Procedures (SOPs), master production orders, and primary and secondary packaging orders are performed, as well as the review, distribution, and storage of work instructions, formats, and records, ensuring that they are maintained in their current and duly approved version. Likewise, batch manufacturing records are reviewed, verifying that the information is complete, legible, and properly documented, with the objective of ensuring process traceability and timely detection of any deviation.
The pharmaceutical industry in Mexico is a highly important sector. For companies in this sector, it is essential to ensure that this technology operates efficiently, reducing losses that affect company profitability, without affecting the health of the population.
In the company under study, the manufacturing of the oncological drug has faced significant challenges due to particulate contamination. In this article, the analysis of yields between 2024 and 2025 allows understanding how process control, process improvement, and regulatory compliance are the only paths to achieving excellence in the production of injectables.
According to NOM-059-SSA1-2015, Class A (ISO Class 5) is the area of highest risk and strictest requirements. It is the environment where aseptic filling is performed and where practically no particles are allowed that could compromise product sterility.
The following describes each stage of the aseptic filling process.

Section I: Raw material dispensing
In this first phase, the warehouse operator, production supervisor, and quality inspector work together to dispense raw materials. This stage is of utmost importance, since each input must be verified to exactly match what is specified in the production order in order to avoid formulation errors (Figure 1).

Figure 1.
Dispense the raw materials

Note: Source, self-made based on a picture taken from the production process

Section II: Washing and sterilization of materials
Subsequently, the analysis of water for injection is performed. Only upon obtaining satisfactory results in microbiological and physicochemical control tests does the preparation and sterilization of materials in the autoclave proceed, ensuring that the equipment is free of microorganisms (Figure 2).

Figure 2.
Analysis of water for injection

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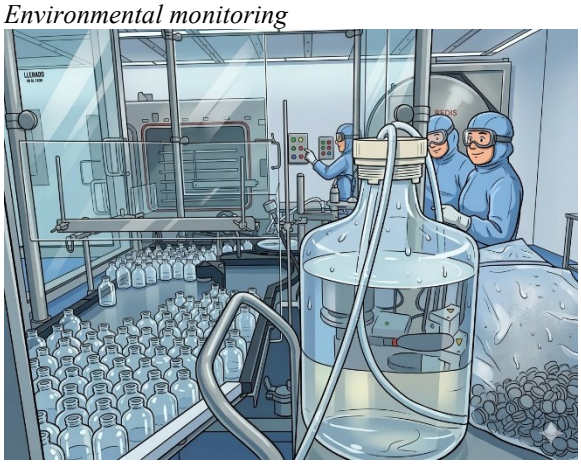
Note: Source, self-made based on a picture taken from the production process

Section III: Bulk production

This stage requires strict environmental monitoring. It begins with microbiological area monitoring and water analysis. During the manufacturing of the drug, the analytical chemist and the operator perform real-time pH adjustments to ensure that the final solution complies with the specifications established in the procedure (Figure 3).

Figure 3.

Environmental monitoring



Note: Source, self-made based on a picture taken from the production process

Section IV: Bulk filtration

Once the bulk is approved, it must undergo a filtration process. To proceed, it is essential to have favorable environmental monitoring results, ensuring that the passage of the product through the filtration membranes occurs in a controlled environment without risk of external contamination (Figure 4).

Figure 4.

Filtration process

Note: Source, self-made based on a picture taken from the production process

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Section V: Primary packaging material supply

The supply of primary packaging materials (such as vials, seals, stoppers, etc.) is managed. Quality Assurance and Production supervise that the materials delivered by the warehouse operator are appropriate to receive the sterile product (Figure 5).

Figure 5.

Supply of primary packaging

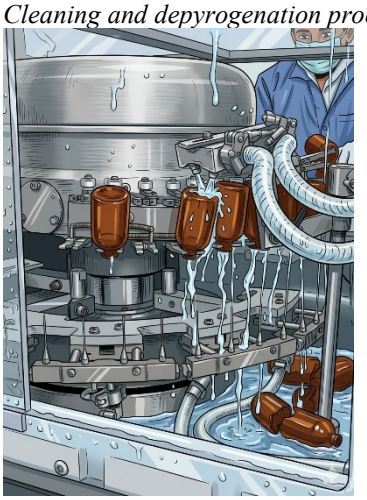
Note: Source, self-made based on a picture taken from the production process

Section VI: Washing and depyrogenation of vials

The vials then undergo a critical cleaning and depyrogenation process in vial washing equipment and a depyrogenation tunnel. As in previous stages, it is necessary to validate water quality and air conditions through environmental monitoring before starting (Figure 6).

Figure 6.

Cleaning and depyrogenation process



Note: Source, self-made based on a picture taken from the production process

Section VII: Filling and stoppering

This is considered the stage of highest risk. During filling, airflow must be continuous to keep particles at the floor level. In addition to strict environmental monitoring, the operator proceeds with filling the vials with the drug and their immediate stoppering. Synchronization at this stage is critical to maintain the sterility achieved in previous stages (Figure 7).

Figure 7.

Filling and stoppering

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Note: Source, self-made based on a picture taken from the production process

Section VIII: Capping and cleaning

As a process control measure, container closure integrity tests are performed at three points (initial, intermediate, and final), validating that the closure protects the drug from any future leakage (Figure 8).

Figure 8.

Capping and cleaning

Note: Source, self-made based on a picture taken from the production process

Section IX: Visual inspection of vials

At this stage, the yield of the sterile process is evaluated. Using an automatic inspection machine, each unit is inspected individually to detect and separate vials with particles or physical defects. It is at this point where the efficiency of the filling and stoppering stages is reflected (Figure 9).

Figure 9.

Visual inspection of vials

Note: Source, self-made based on a picture taken from the production process

Section X: Secondary packaging material supply

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With the product already sealed and inspected, boxes, labels, and inserts required for the final presentation are supplied, under the supervision of the Quality Assurance Department (inspectors) and the warehouse (Figure 10).

Figure 10.
Secondary packaging material supply

Note: Source, self-made based on a picture taken from the production process

Section XI: Labeling and coding
The labeling machinery is adjusted to print and place batch number, expiration date, and technical specifications on each vial, thus ensuring product traceability (Figure 11).

Figure 11.
Labeling and coding

Note: Source, self-made based on a picture taken from the production process

Section XII: Secondary packaging
The final stage consists of the manual assembly of boxes and insertion of the vial together with its insert. Once completed, the quality inspector and the warehouse personnel coordinate the transfer of the batch to the finished product airlock for final distribution (Figure 12).

Figure 11.
Secondary packaging

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Note: Source, self-made based on a picture taken from the production process

It was identified that the yield problem does not originate in the initial washing stages, but specifically in Filling and Stoppering strage. This stage is carried out under conditions that should correspond to Class A. If personnel do not strictly adhere to behavioral and gowning requirements while operating in these critical areas, the risk of introducing particles into the vial prior to sealing is extremely high.

Foavil Yield Comparison (2024 vs. 2025)

Production data for the product Foavil show a positive evolution after the identification of these operational failures.
2024 Period: The average yield was only 67.36%, with minimum values dropping to 37.16%. This indicates that nearly one-third of production was lost due to deficiencies in particle control during the filling stage.
2025 Period: Following the implementation of improvements, the average yield increased to 92.19%, reaching maximum values of 94.00%.
This increase in efficiency demonstrates that focusing on the establishment of clear controls and improvements in highly critical stages makes process improvement achievable.

Table 1.
Foavil Yield Comparison (2024 vs. 2025)

2024				2025			
Average	**Maximum**	**Minimum**	**Range**	**Average**	**Maximum**	**Minimum**	**Range**
67.36 %	**87.65 %**	**37.16 %**	**50.49 %**	**92.19 %**	**94.00 %**	**88.72 %**	**5.28 %**

Note: Self-made based on the production process analizys

Engineering Strategies for Continuous Improvement

To consolidate the improvements achieved in 2025 and eliminate losses due to contamination in Class A areas, the following actions are proposed:

A Strict Gowning and Behavioral Control
The annex of NOM-059 clearly establishes that Class A areas require full protective clothing, including coveralls, hoods, goggles, and sterile gloves. Careless behavior is not acceptable in these zones; personnel must be highly trained and qualified to minimize particle shedding from their own bodies.

B Validation of Garment Washing Cycles
It must be ensured that the cleaning process effectively removes all particulate matter from antistatic garments before entry into the filling area.

C Cleaning and Verification of Hoses and Glass Containers (Pyrex)

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Transfer hoses and containers such as Pyrex used during the filling process represent critical contact points with the product. Therefore, a rigorous program of cleaning, sanitization, and verification must be implemented, including visual inspection, documented records, and, when applicable, analytical testing to confirm the absence of residues or contaminants prior to use.

D Elimination of Medical-Grade Paper Use

The use of medical-grade paper within the aseptic area was discontinued due to the risk of particle generation.

The case of Foavil in the company under study demonstrates that identifying the critical area (Class A) and correcting deficiencies in the filling stage can drastically change plant yield. The objective is to ensure that every vial produced is an approved vial, guaranteeing that oncological treatment reaches patients without compromising their safety.

CONCLUSION

The analysis of the sterile manufacturing process of the oncological product Foavil demonstrates that process yield is directly affected by particle contamination during aseptic operations, particularly in the filling and stoppering stage.

Based on the process description and yield comparison between 2024 and 2025, it is evident that the main source of performance loss is not located in the initial stages, such as washing or sterilization, but specifically in Stage VII, where the product is exposed before sealing under Class A conditions.

The results show a significant improvement in process performance, with the average yield increasing from 67.36% in 2024 to 92.19% in 2025, accompanied by a substantial reduction in variability (range from 50.49% to 5.28%). This change reflects a more controlled and consistent process after addressing the identified issues.

The findings indicate that inadequate control of personnel behavior and materials within critical aseptic environments contributes to particulate contamination, which directly impacts the number of rejected units during inspection.

The implementation of specific measures—such as stricter gowning practices, validation of garment cleaning, control of equipment cleanliness, and elimination of particle-generating materials—correlates with the observed improvement in yield.

This case shows that focusing on critical control points within the process, particularly in high-risk areas such as Class A environments, allows for substantial improvements in manufacturing efficiency without modifying the entire production system.

The study confirms that process control, adherence to regulatory conditions, and operational discipline are key factors in reducing losses and improving yield in sterile pharmaceutical manufacturing, as reflected in the performance evolution of the analyzed product.

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