PlantaCORP
advanced liposomal technology

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Title of the study:

Improvement and Verification of the Effectiveness of a CIP System in a Production Tank: Influence of the Spray Ball Alignment and Pump Settings on Cleaning Efficiency

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List of Contents

I List of Abbreviations

Abbreviation	Meaning
ATP	Adenosine Triphosphate
CIP	Cleaning-in-Place
EHEDG	European Hygienic Engineering & Design Group
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis of Critical Control Points
ISO	International Organization for Standardization
MP	Measuring Point
Ra	Roughness Average
RLU	Relative Light Units
Rz	Mean Peak-to-Valley Height
Sa	Areal Surface Roughness
SNR	Signal-to-Noise Ratio
SCNR	Signal-to-Carrier-and-Noise Ratio
TSA	Tryptic Soy Agar
UV	Ultraviolet
VDMA	Verein Deutscher Maschinen- und Anlagenbau (German Engineering Federation)

II Abstract

This study examines the cleanability of stainless steel production tanks used in the manufacture of liposomal dietary supplements, with a focus on the effectiveness of the existing Clean-in-Place (CIP) procedure. The investigation was conducted on-site at Plantacorp GmbH's production facilities to ensure the practical relevance and applicability of the results. To ensure hygienic conditions in compliance with food safety standards such as ISO 22000 and Hazard Analysis and Critical Control Points (HACCP), various experimental methods were applied, including riboflavin spray shadow testing, ultrasonic flow rate measurements, surface roughness analysis, and microbiological as well as Adenosine triphosphate (ATP) swab tests. The results showed that feed pump pressure and spray ball orientation significantly influence the cleaning performance. A minimum feed pump pressure of 9 bar was identified as necessary to achieve sufficient mechanical cleaning action and spray coverage, especially in geometrically complex areas. However, due to the current technical limitations of the CIP system in place, production cleaning is still performed at 7 bar, which leads to visible residue at certain points. Despite this, microbiological and ATP tests remained within acceptable limits. The study also identified potential design-related hygiene risks, such as liquid retention in unused outlet cavities and persistent residues on the stirrer. Based on a structured risk assessment following DIN EN ISO 12100:2011, targeted recommendations were proposed, including system upgrades to enable higher flow rates, improved spray ball positioning, and further verification under real CIP conditions.

The approach and methodology presented in this thesis not only provide practical value for internal optimization at PlantaCorp GmbH but also serve as a transferable model for other companies seeking to validate and enhance their CIP processes in hygienically critical applications.

III List of Figures

IV List of Tables

1 Introduction

The production of liposomal dietary supplements requires strict adherence to hygiene standards to ensure product safety and compliance with regulatory requirements. Liposomal formulations of dietary supplements often contain phospholipids and bioactive compounds that may leave residues difficult to remove and could support microbial growth if not cleaned properly. At PlantaCorp GmbH, these products are manufactured in closed stainless steel tanks with volumes of 250L, 500L, and 1000L. After each filling process, a CIP procedure followed by chemical disinfection is used to remove product residues and eliminate microbial contamination inside the stainless steel tank. A critical factor in the effectiveness of CIP processes is ensuring that all inner surfaces of the tanks are reached by the cleaning fluid with adequate mechanical force. This is achieved using spray balls, which distribute the cleaning chemical through a 360° spray pattern. The manufacturer's specifications for spray ball operation typically require a defined minimum flow rate and pressure to ensure sufficient impact force and complete wetting of the tank surfaces. Due to the complex geometry of the tanks, including multiple inlets, outlets, and additional components like stirrers, there is a risk of spray shadows, which are areas that do not get covered properly with cleaning solution.

Since the tanks are customized and modified on-site, standardized spray ball alignment recommendations from the manufacturer are not applicable. Therefore, individual optimization and verification of the spray ball orientation are necessary. Additionally, it must be ensured that the spray balls operate effectively and achieve 360° coverage inside the tank. To address this, spray shadow tests, volumetric flow rate measurements, and microbiological as well as ATP-based surface testing must be performed.

This study investigates whether the current CIP process achieves the required level of hygiene throughout the tank and which factors influence cleaning efficiency with the goal of identifying potential areas for optimization.

2 Objective

The objective of this thesis is to evaluate and verify the effectiveness of the CIP process in a 1000 L stainless steel production tank used for the manufacture of liposomal dietary supplements.

Firstly, the required feed pump pressure for full 360° spray ball coverage is determined by measuring the volumetric flow rate in the supply pipes that transport the cleaning solution from the CIP unit to the spray balls. This helps establish the hydraulic baseline for effective mechanical cleaning.

Secondly, a riboflavin spray shadow test is conducted to identify critical areas inside the tank that may not be sufficiently cleaned due to geometric constraints. Based on these results, the orientation of the spray balls is optimized to improve coverage and eliminate shadowed zones.

Thirdly, the effectiveness of the cleaning process, including the new spray ball configuration, is verified through ATP testing and microbiological surface swabs. These evaluations are performed after standard cleaning and disinfection cycles and under realistic production conditions, where normal manufacturing takes place between CIP procedures.

Fourthly, the surface roughness of selected stainless steel areas within the tank is measured to assess its influence on cleanability and to support the interpretation of the microbiological and ATP results.

Finally, the entire cleaning process is evaluated using a structured, risk-based approach. This assessment considers both the mechanical limitations of the CIP system and the microbiological safety requirements, aligning with hygienic design and food safety standards.

3 Theoretical Background

3.1 Contamination in the Context of Food Production and Cleaning Processes

In food-producing facilities, contamination in general refers to the unwanted presence of substances or microorganisms that have the potential to affect the product´s safety, quality, or conformity to hygienic norms. Such contaminants can originate from raw materials, equipment, and environments and can be substances that are organic and/or inorganic residues, microbial entities, and physical particles. Managing contamination is critical to ensuring food safety, preventing spoilage, and complying with regulatory requirements such as those set by HACCP, the U.S. Food and Drug Administration (FDA), or the European Food Safety Authority (EFSA).

In the context of cleaning, two main types of contamination are particularly relevant:

- Soiling includes leftover food particles, fats, proteins, carbohydrates, and minerals that accumulate on equipment surfaces during production. Such residues can be difficult to remove from surfaces, especially if subjected to heat, and can provide a food source for microorganisms if not thoroughly removed.
- Microorganisms such as bacteria, yeasts, and molds can attach to surfaces and form biofilm, which is protected by an extracellular matrix. Biofilms are especially problematic because they are more resistant to standard cleaning and disinfection processes and therefore need special treatment. Due to their increased resistance to cleaning agents and disinfectants, they often require mechanical force for effective removal.

In the context of CIP processes, spray shadows, rough surfaces, and geometrically complex areas can provide favorable conditions for biofilm development if not properly cleaned. Biofilm not only compromises product safety but can also lead to recurrent contamination issues if not effectively addressed through validated cleaning protocols [1]. ATP tests and microbial swabs are designed to detect sources of nutrients for bacterial growth and biofilm formation. These methods serve as sensitive indicators of insufficient cleaning, even in areas that may appear visually clean, and are therefore essential tools in evaluating the hygienic effectiveness of CIP procedures [2].

3.2 Cleaning and Disinfection in the Food Industry

Ensuring the hygienic integrity of equipment is a fundamental aspect of food safety. In the food industry, machines and storage tanks that come into direct contact with food must be cleaned and disinfected regularly to prevent microbiological contamination, ensure product quality, and comply with food safety regulations. Cleaning is the process of removing visible dirt, organic matter, and residues from surfaces using water and detergents. Followed by that, sanitization uses chemical or physical agents to reduce microorganisms to safe levels. These are defined by the AOAC as a 5-log (99.999%) reduction within 30 seconds on food contact surfaces. Without effective cleaning, disinfectants cannot work efficiently, as residues can shield microorganisms and reduce disinfectant penetration [3].

3.2.1 General Cleaning Procedures

In general, it is common to have certain steps for removing dirt in the most efficient way without using too many resources, such as water or chemicals. The first step often involves pre-rinsing the equipment surface with water to remove loose dirt and debris.

The water applied has a moderate pressure and temperature. This step is also necessary to prepare the surface for contact with chemicals.

The second step is the application of the cleaning agent, which may be an alkaline cleaner, an acid cleaner, or an enzymatic cleaner, depending on the composition of the soil or the product to be removed from the surface. Key factors that influence cleaning efficiency include temperature, contact time, mechanical force, and turbulence, all of which can significantly enhance the removal of residues and microorganisms.

To prevent an interaction between the cleaning chemical and the disinfectant, an intermediate rinse has to be performed to flush out the cleaning agent before disinfectant is applied.

To eliminate the microbial contaminants as the last step, the disinfectant is applied to the surface. Some commonly used disinfectants are peracetic acid, chlorine-based compounds, and hydrogen peroxide. To ensure a sufficient reduction of microbial load, the contact time has to be around 5-15 minutes.

Depending on the disinfectant used, a final rinse is required to flush out the chemical and prevent chemical contamination of the product produced after. In some cases, disinfectants are food safe in trace amounts and don't have to be rinsed off as long as they're not affecting the product [4].

3.2.2 CIP - Systems

The most common cleaning system for closed processes in tanks or pipes is CIP. This automated system allows for efficient sanitation without the need to disassemble machine parts and with minimal human intervention. Typically, CIP involves controlled conditions such as the correct temperature, concentration, time and flow rate. CIP also allows the use of a consistent and validated procedure, which can be customized for different tank designs or contamination levels [4].

3.2.2.1 Advantages of CIP-Systems

CIP systems offer numerous advantages that make them an essential part of modern food production, particularly in facilities where hygiene, efficiency, and product consistency are critical. One of the primary benefits of CIP is its ability to deliver consistent and repeatable cleaning results**.** Because CIP processes are automated, they minimize the risk of human error and ensure that cleaning parameters such as time, temperature, chemical concentration, and flow rate are

precisely controlled. This guarantees uniform sanitation across all cleaning cycles, which is especially important in maintaining food safety standards. Another key advantage is efficiency.

CIP systems significantly reduce cleaning time and resource consumption compared to manual cleaning. The automated nature of the process minimizes equipment downtime between production batches and reduces the need for disassembling complex machinery. In addition to optimizing cleaning performance, CIP systems enhance operator safety by containing the cleaning process within closed systems, reducing exposure to hazardous chemicals and high temperatures [4].

Additionally, the system allows for automated documentation and monitoring, which simplifies compliance with quality assurance standards and regulatory frameworks such as HACCP, ISO 22000, and FDA guidelines. Records of each cleaning cycle can be reviewed and validated, providing clear evidence of hygienic maintenance for inspections or audits [5].

3.2.2.2 Challenges of CIP-Systems

CIP systems also face several challenges that can impact the effectiveness, efficiency, and regulatory compliance of cleaning processes in industrial environments.

A major challenge is achieving complete cleaning, particularly in equipment with complex geometries. Spray shadows, where surfaces are obstructed from direct contact with the cleaning solutions, can prevent effective removal of residues and therefore provide favorable conditions for biofilm development. Furthermore, maintaining appropriate flow velocity within the system is essential; insufficient flow rates can lead to inadequate mechanical cleaning forces, resulting in residual contamination. System design plays a crucial role in the success of CIP operations. Poorly designed equipment with dead ends, shadowed areas, or insufficient spray coverage increases the risk of incomplete cleaning. The detection of these residual contaminations is challenging and often requires advanced analytical methods such as ATP testing. Moreover, the risk of cross-contamination must be carefully controlled, particularly in multiproduct facilities. Cleaning agents must be compatible with the materials of construction to prevent equipment degradation or corrosion, and must fit the residues that should be removed. Different soils require different cleaning strategies; for example, alkaline cleaners are effective against organic residues such as fats and proteins, whereas acidic cleaners are necessary to remove inorganic contaminants like mineral deposits. Therefore, the use of an unsuitable cleaning agent can result in ineffective cleaning [4].

3.2.2.3 Validation and Verification of CIP Systems

The validation and verification of CIP systems represent essential components to ensure process reliability and regulatory compliance. Through these measures, it is demonstrated that the cleaning procedures consistently fulfill the required quality standards as well as the regulatory requirements, including those outlined in Good Manufacturing Practice (GMP) and ISO 22000. Incomplete or inadequate validation and verification can lead to deviations from compliance standards, increased risk of contamination, and unplanned downtimes, which may significantly compromise both production efficiency and product integrity. A central aspect of validation is the verification that all residues, such as inorganic or organic soils, have been completely removed and that microorganism have been effectively eliminated, typically through chemical tests, microbiological analysis, or ATP testing [6].

ATP tests measure the presence of ATP, which serves as an indicator for organic material, potentially signaling insufficient cleaning. In addition to these analytical methods, ensuring the correct function and alignment of CIP spray balls is crucial, as improper spray ball performance can result in spray shadows, areas that receive insufficient cleaning due to poor coverage. These undetected zones pose a significant contamination risk. Therefore, spray coverage testing, such as using riboflavin, is often part of validation and verification protocols. The German Mechanical Engineering Industry Association (VDME) provides guidelines for spray coverage tests with riboflavin for CIP processes [7].

3.3 Surface Characteristics and their Role in Contamination Control

In food processing environments, the ability of microorganisms and soils to adhere to equipment surfaces is a critical factor influencing contamination of the product produced and the effectiveness of the cleaning procedure. Several physical and chemical surface characteristics, including roughness and material composition, directly impact the adhesion of contaminants and the performance of cleaning procedures. This thesis focuses exclusively on surface roughness, as the material composition is not subject to further analysis due to the fixed installation of the production tanks. Consequently, material changes are not feasible. However, if surface roughness is identified as a critical factor, the evaluation of subsequent surface treatment measures may be considered as a viable approach.

3.3.1 Surface Roughness and the Influence on Contamination

Surface roughness is a critical parameter influencing microbial adhesion and the hygienic design of food processing equipment. Ra (arithmetical mean roughness) is defined as the average deviation of the roughness profile from the mean line over a given measurement length. It represents the overall roughness in a simplified, averaged manner and is the most commonly used roughness parameter in the food industry. The calculation of Ra is shown in Figure 1.

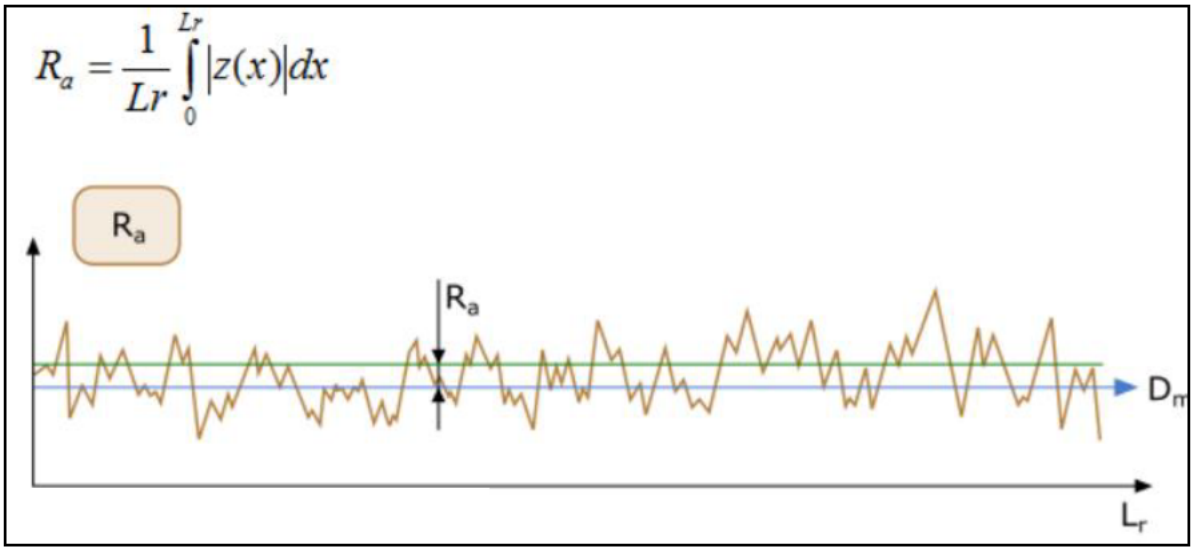


Figure 1: Graphical representation of the arithmetical mean surface roughness (Ra). Ra is calculated as the average absolute deviation of the surface profile from the mean line (Dm) over the evaluation length (Lr), as shown in the integral formula. This parameter provides a simplified measure of overall surface irregularity. Source: www.technisches-zeichnen.net

Rz (mean roughness depth), on the other hand, is the average of the individual heights between the five highest peaks and five lowest valleys over the measurement length. It is more sensitive to occasional deep scratches or pits and, thus, is better suited to reflect the extremes in surface irregularity [8]. The calculation of Rz is shown in Figure 2.

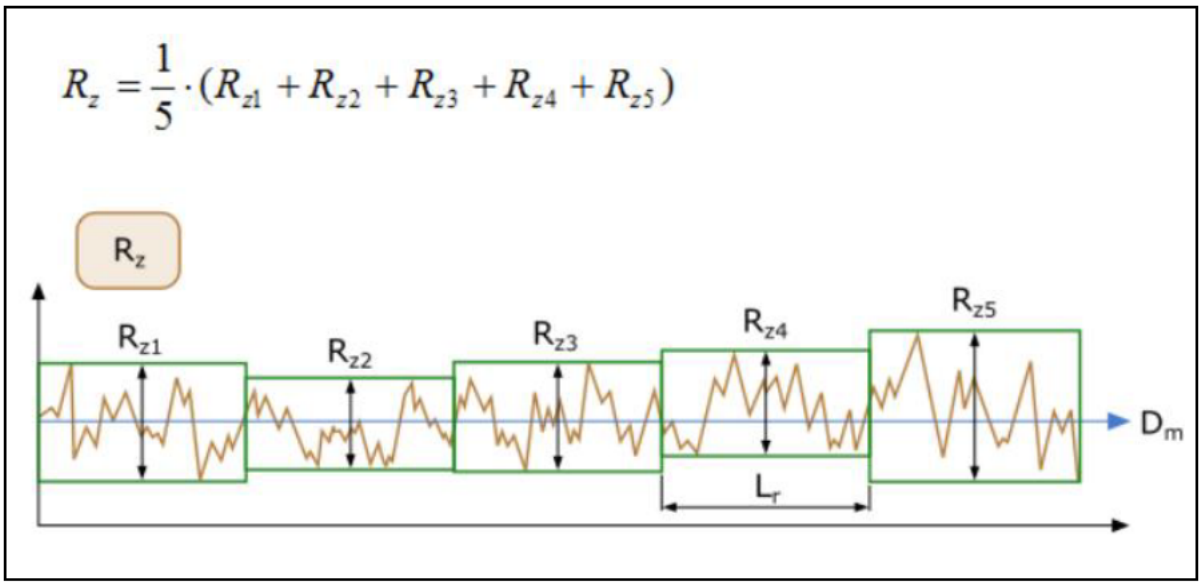


Figure 2: Graphical representation of the mean roughness depth (Rz). Rz is calculated as the average of the vertical distance between the highest peak and lowest valley in each of five consecutive sampling lengths within the total evaluation length (Lr). This parameter is more sensitive to isolated surface defects than Ra. Source: www.technisches-zeichnen.net

Irregularities on material surfaces provide niches where microorganisms can adhere, proliferate, and potentially develop into biofilms. To mitigate this risk, the European Hygienic Engineering & Design Group (EHEDG) recommends that all product-contact surfaces in the food industry should have a surface roughness (Ra) of $\leq 0{,}8$ µm. This threshold is considered sufficient to minimize microbial retention and ensure cleanability under typical industrial cleaning conditions. Surfaces with an Ra below this value tend to have fewer microscopic crevices that can trap soil or bacteria [9]. However, research and industry standards also emphasize that achieving an Ra $\leq 0{,}8$ µm is not sufficient by itself to guarantee hygienic performance. Surface finish alone cannot fully account for the cleanability of a material. Other factors such as surface geometry, waviness, and the absence of pits or scratches also play essential roles. In some cases, materials with roughness values slightly exceeding 0,8 µm may still be adequately cleanable if the surface design prevents fluid stagnation and allows sufficient mechanical action during cleaning [9].

In addition to Ra, the parameter Rz is relevant as well, as it captures isolated deep scratches or pits that may not significantly affect the mean roughness but can still promote microbial retention and impair cleanability.

3.3.1.1 Surface Roughness Measurement

When it comes to measuring surface roughness, various methods are available. One method is contact-based stylus profilometry, and the other is a non-contact method using optical measurements, which was applied in this thesis, as the corresponding device was available.

Optical measurement methods use the reflection of light to analyze surface properties. When light hits a surface, it reflects according to the law of reflection. This means the angle of the incidence equals the angle of the reflection. By measuring the reflected light´s intensity, angle, or spectral changes, characteristics such as surface roughness can be determined. Typically, a monochromatic light source, like a laser, directs light onto the sample, and a detector captures the reflected beam [10].

In some cases, direct surface roughness measurement is not feasible due to complex component geometry or the lack of portability of the measurement device. In such cases, indirect methods using surface replication provide a viable solution. One widely accepted approach involves using silicon-based, addition-curing impression materials, commonly employed in dental and precision industrial applications. These materials, such as polyvinyl siloxane, offer high dimensional stability, fast curing, and excellent reproduction of microscopic surface details. This allows for the creation of a negative replica of the original surface, which can then be analyzed outside the production environment. Such replicas are particularly well-suited for capturing the fine topography of technical surfaces, including weld seams and product-contact areas in food and pharmaceutical environments [11].

The resulting negative replica can be analyzed externally using the optical, non-contact profilometry, a technique which scans the surface profile and measures deviations in height across a defined measurement area without physical contact. Key roughness parameters such as arithmetical mean roughness (Ra) and maximum height (Rz) are determined in accordance with the standard, such as DIN EN ISO 4288 [12].

In addition to these traditional profile-based parameters, areal surface roughness parameters such as arithmetical mean height (Sa) can be obtained using modern optical measurement techniques [13]. Although Sa is not yet referenced in most hygienic design standards like EHEDG, which primarily focus on Ra (profile-based), Sa provides valuable three-dimensional information about the surface texture. This can offer deeper insight into the surface characteristics relevant for cleaning efficiency and risk assessment, even if it is not a regulatory requirement.

3.3.2 Mechanical Forces during Cleaning with Spray Balls in CIP Systems

Mechanical forces are a central component of CIP processes and play a critical role in the removal of soils and microorganisms from internal surfaces in food processing equipment. Spray balls, whether static or dynamic, are integral components that apply these mechanical forces through fluid dynamics.

3.3.2.1 Function and Types of Spray Balls

Spray balls are fixed or rotating cleaning devices installed within tanks and pipelines to deliver cleaning solutions under pressure. They are categorized into static spray balls and dynamic (rotary) spray balls.

Static spray balls disperse cleaning chemicals in all directions but rely heavily on gravitational flow and chemical action for cleaning because the spray ball itself is not rotating. The mechanical impact is limited due to low shear forces.

Dynamic spray balls, in contrast, rotate under the force of the fluid and create concentrated jets that deliver significantly higher mechanical energy through shear stress and impact force. Their 360° coverage improves cleaning efficiency due to the rotation of the spray ball, especially on surfaces with biofilm contamination [14].

Figure 3: Comparison between the spray coverage of a dynamic Turbo SSB 75 spray ball from Breconcherry (left) and a static spray ball from Breconcherry (right).

3.4 Hygienic Design

Hygienic Design plays a crucial role in ensuring food safety and process efficiency in the food industry. The core principle of hygienic design is to create equipment and systems that do not harbor contaminants, are easy to clean, and prevent the formation of biofilms or the accumulation of residues that can lead to foodborne illnesses.

The key features of hygienic design include smooth, non-porous surfaces, seamless joints, and easy-to-access components that allow thorough cleaning and inspection. A critical aspect of hygienic design is maintaining the surface roughness of equipment to Ra ≤ 0,8 µm. Moreover, equipment should be designed to prevent the accumulation of dirt or liquids in difficult-to-reach areas, such as dead end, crevices, or sharp corners [15].

In addition to the physical design of the equipment, hygienic design also involves process considerations, such as proper airflow and drainage, which prevent the buildup of moisture and contaminants. The implementation of hygienic design principles is often guided by standards such as the EHEDG guidelines and ISO 14159, which outline best practices for the design of food processing equipment [8], [16].

3.5 Application of Risk Assessment Principles to the Hygienic Design of CIP-Enabled Process Tanks

According to DIN EN ISO 12100:2011-03, conducting a risk assessment for the hygienic design of a production tank involves a systematic evaluation of potential hazards that could compromise product safety due to inadequate cleanability or design flaws. According to DIN EN ISO 12100:2011-03, a risk assessment involves identifying and evaluating potential hazards that could impact the safety and integrity of the final product. In hygienic production environments, particular attention must be paid to microbial risks, residue retention, and cross-contamination.

The process begins with defining the limits of the machine, which includes understanding its intended use, foreseeable misuse, operating conditions, and all phases of its lifecycle. For CIP systems, this means specifying parameters such as temperature, pressure, flow rate, and cleaning agents used. It also involves identifying product contact surfaces and areas that are not easily accessible or visible.

Once the limits are clearly defined, the next step is the identification of hazards related to hygienic design. These may include poorly welded seams, dead legs in pipe connections, shadow areas not reached by spray balls, inappropriate gasket materials, or surfaces that are too rough to clean effectively. Such flaws can lead to microbial growth, residue accumulation, or cross-contamination.

The third step is risk estimation, in which each identified hazard is evaluated based on the severity of potential contamination and the likelihood of its occurrence. For example, a dead leg

near an outlet valve that is not covered by CIP spray patterns poses a high risk due to stagnant product and microbial persistence.

If the risk is deemed unacceptable, risk reduction measures must be taken. Where design solutions are not possible, technical controls (e.g., automated verification of cleaning parameters) and procedural controls (e.g., regular microbiological testing of critical areas) can be used to reduce the remaining risk.

Finally, the residual risk is assessed and justified, and the entire process is documented [17].

4 Investigation

4.1 Equipment and Materials

Table 1: Material which was used in the methods described in chapter 4.2. Data that is not available is marked with "-".

Material	**Supplier**	**Batch number**
Riboflavin powder (vitamin B12)	Changsha Huir Biological-Tech Co., LTD.	107-23021408
Deionized water	CHEMICA GmbH	2.6.047.8
Safety gloves (Nitrile)	Ampri mbH	220010546
Agar plates: Tryptic Soy Agar (TSA)	Thermo Fisher Scientific Inc.	6273696
Swap test: Quick swap	NeoGen Corporation	10524
ATP test stick: Ultrasnap	Hygiena, LLC	116324
Correction of impression material R-SI-LINE UltraLight SH	R-dental Dentalerzeugnisse GmbH	62204926
Static mixing nozzle	R-dental Dentalerzeugnisse GmbH	-
Ultrasonic Coupling paste Ceran XM220	Emerson Electric Co.	99 07309-1

Table 2: Equipment which was used in the methods described in chapter 4.2. Data that is not available is marked with "-".

Equipment	**Supplier**	**Series number**
Clamp-on flow meter FLUXUS F532 WD	FLEXIM GmbH	53204372
Variofix C mounting fixture rail	FLEXIM GmbH	-
Digital camera Redmi	Xiaomi GmbH	-
UV lamp 365 nm	Lekia AB	-
Production tank 1000L stainless steel	-	-
Dynamic Turbo SSB 75 spray ball	Breconcherry GmbH	-
Pump MG 71-160 (Pump pressure: 1-10 bar in 0,5 bar increments)	Grundfos Holdings A/S	A96122679P10807
ATP device	Hygiena, LLC	132230
Measuring cylinder	VitLab GmbH	-
Hand-operated spray bottle	Kraftus GmbH	-
Magnetic stirrer SH3	Dormole Limited	201704282582
Inkubator	Thermo Fisher Scientific Inc.	40947823
Cartidge mixing gun	Omnident Dental-HandelsGmbH	
Safety googles	Univet S.r.l.	-

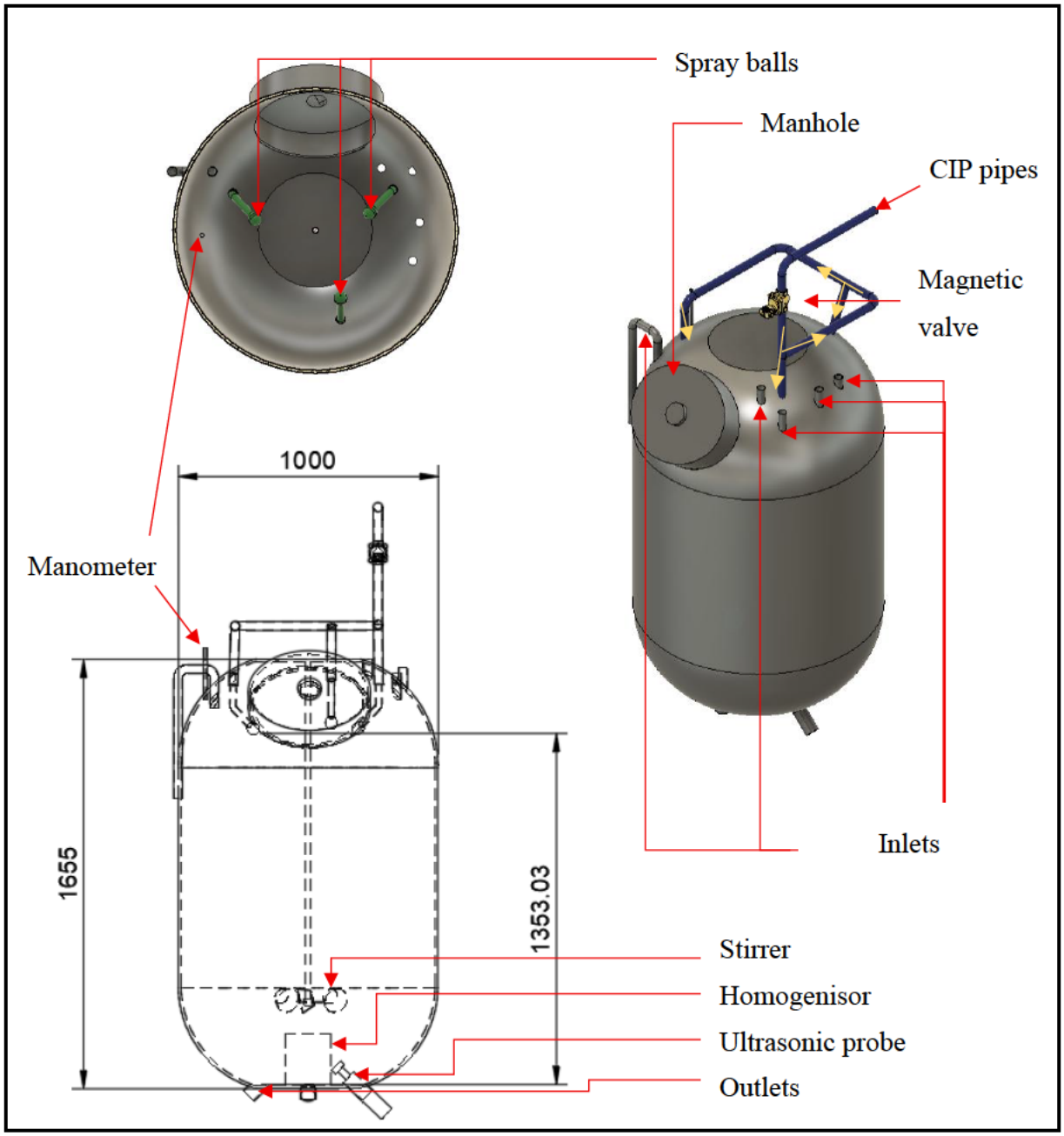


Figure 4: Three-view schematic of the investigated stainless steel production tank (Volume=1000L), showing relevant dimensions and key hygienic design features. Critical components such as the spray balls (colored in green), stirrer and outlet valves are marked for reference in the context of CIP verification. The pipe installation which is delivering water/chemicals to the spray balls is colored in blue. All measurements are given in Millimeters.

The CIP system in use is a semi-automated unit with a separate tank installed at PlantaCorp GmbH, designed for recirculating cleaning agents through dedicated supply lines (marked in blue) and return lines (outlet from the tank) to the production tanks (Figure 4). The system operates with a Grundfos MG 71-160 pump and is configured to clean production tanks of up to 1000 L via three top-mounted dynamic spray balls. It includes programmable steps for rinsing, alkaline and acid cleaning, as well as final disinfection.

4.2 Methods

To improve and verify the effectiveness of the existing CIP system in a production tank, several targeted tests were carried out. First, the optimal pump pressure was determined based on flow rate measurements, which is necessary to verify the spray balls' effective reach. Then spray shadow formation was evaluated under different spray ball orientations to verify the spray coverage. Microbial and ATP tests were used to assess cleaning performance, followed by surface roughness measurements to examine the cleanability of product contact surfaces inside the tank.

4.2.1 Determination of an effective Pump Pressure based on the Flow Rate

To determine the effective pump pressure required for the CIP process, a clamp-on flow meter was used to measure the volumetric flow in real time. This measurement should determine the pump pressure that is needed to get enough spray coverage to effectively clean the tank. Figure 5 gives information about the volumetric flow needed to reach a specific pressure at the spray ball. In addition to that, the graph in Figure 6 gives information about the required pressure to reach a specific distance in the tank. Therefore, measuring the volumetric flow rate is necessary to determine the pressure, which in turn indicates the reach of the water inside the tank while cleaning.

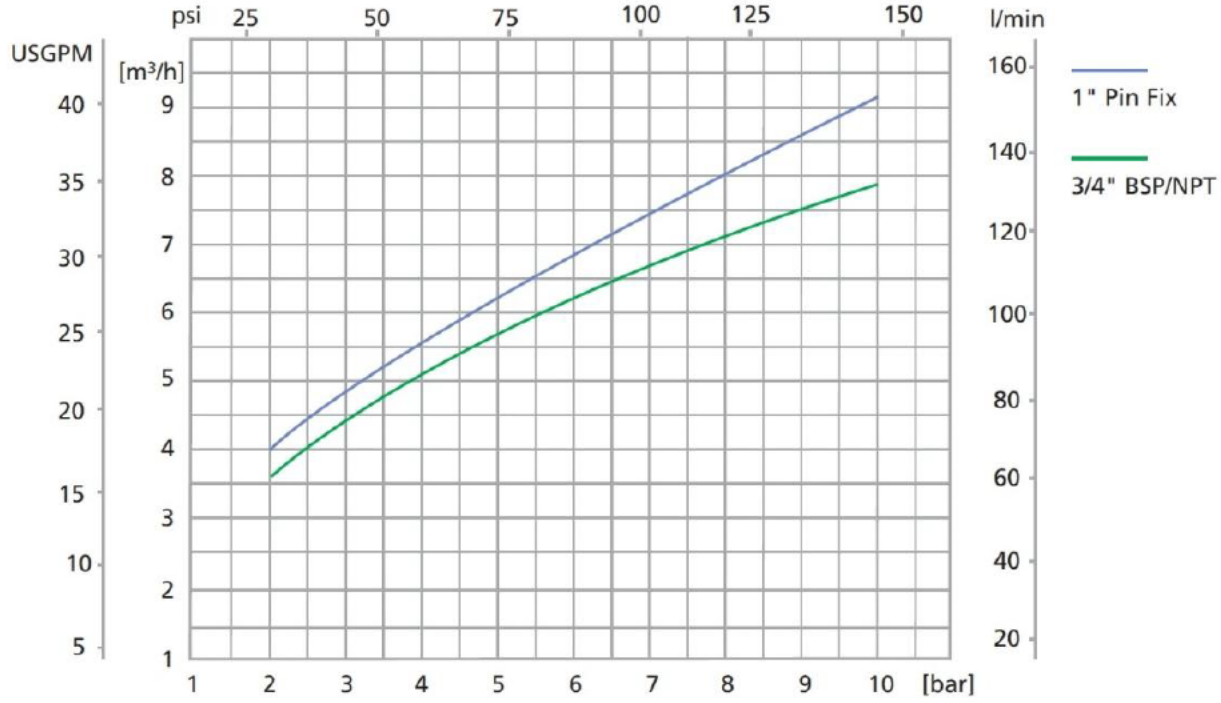


Figure 5: Comparison of flow rates for 1" Pin Fix and ¾ BSP/NPT spray balls as a function of inlet pressure. The analysis in this thesis focuses on the ¾" BSP/NPT as this is installed in the tank (lower curve in green).

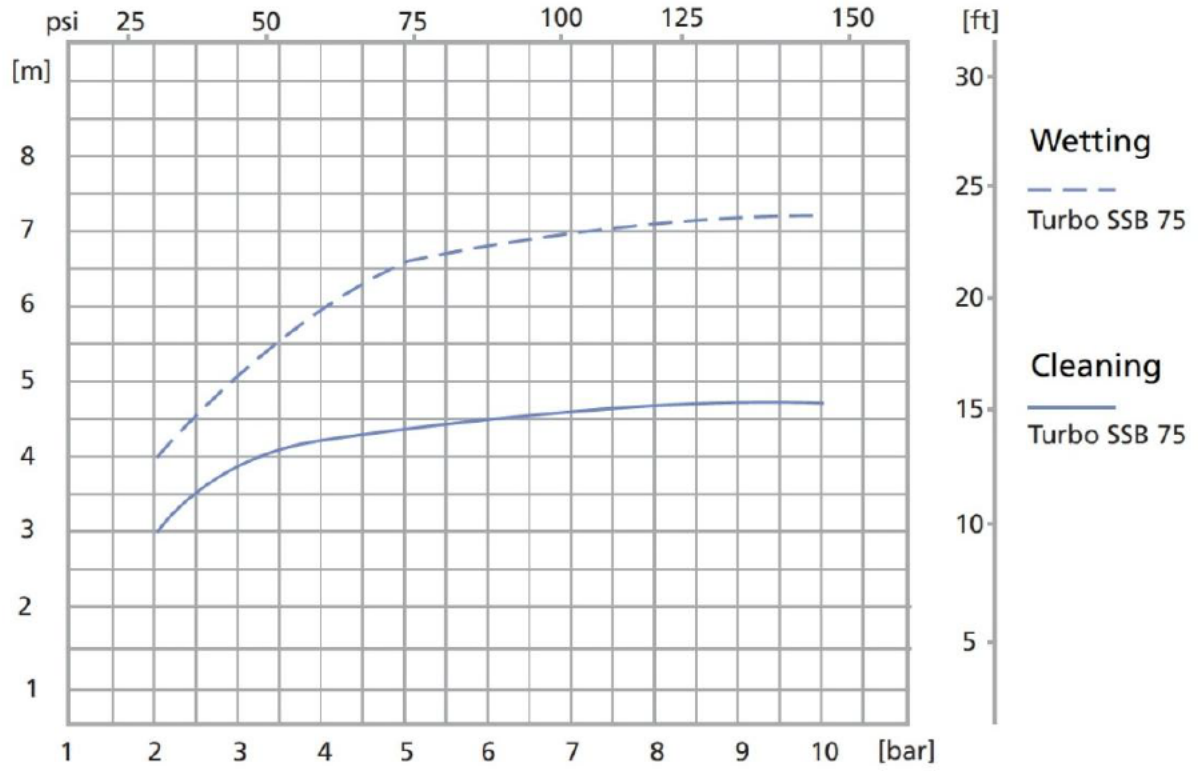


Figure 6: Flow rate and cleaning/wetting diameter as a function of nozzle inlet pressure. The upper graph (wetting diameter) is not relevant for this evaluation, as the focus is on effective mechanical cleaning.

To determine the required feed pump pressure to reach all areas of the tank, the pressure at the inlet of the spray ball was estimated. This was done by measuring the volumetric flow rate in the pipe section directly upstream of each spray ball using a clamp-on ultrasonic flow meter. Based on the manufacturer´s data for the spray balls shown in Figure 5, which relates volumetric flow rate to required inlet pressure for the spray ball type used, the pressure at each spray ball was derived using the measured flow rates. The size of the tank is 1,55 meters with a radius of 0,5 meters, so the farthest point from the spray balls is about 1,35 meters. This means that it is necessary to have at least 2 bars at each spray ball for a cleaning diameter of 3 meters and therefore a volumetric flow from about 60 l/min per spray ball to reach all parts of the tank (Figure 6).

To determine the volumetric flow rate with the clamp-on flow meter from FLEXIM GmbH, it was necessary to first clean the outside of the pipe, as the method is based on the transit-time difference method using ultrasonic signals. Any dirt, rust, or paint that may interfere with the signal transmission had to be removed. As the second step, the mounting fixture rail was attached to the pipe section. Before placing the transducers on the rail, it is necessary to apply coupling gel to the contact surfaces of the transducers to ensure optimal sound transmission.

After that, the transducers were connected to the transmitter unit. The transmitter got connected to the software FLEXIM FluxDiag, which automatically calculated the signal path and the spacing between the sensors with parameters like pipe material, wall thickness, inner and outer pipe diameter, fluid type, and temperature. In this case, the sensors were placed 25 mm away from each other. The placement of the sensors is illustrated in Figure 7. To ensure the measurement accuracy, the installation also adhered to the manufacturer's recommended minimum distance from flow disturbance, which is ten times the pipe diameter upstream and five times downstream [18]. In case there is a flow disturbance like a 90° elbow or a reduction in front or behind the measurement point, and the sensors cannot be placed further away from it, this also has to be added in the software.

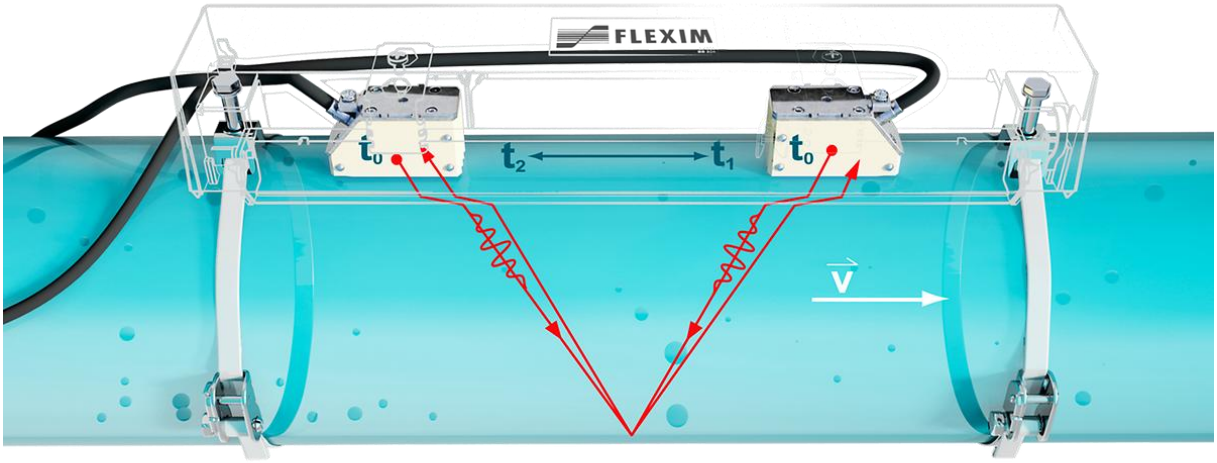


Figure 7: Operating principle of ultrasonic flow measurement using the transit-time method. Two sensors alternately transmit and receive ultrasonic signals. The difference in transit times (t_1-t_2) is used to calculate the flow velocity of the medium. Source: www.flexim.com

After that, the measurement and the monitoring for the volumetric flow rate were started, and a flushing cycle was started to run water through the pipe at a set pump pressure until a stable volumetric flow rate was achieved. For quality assurance of the flow measurements, additional signal parameters such as the signal-to-noise (SNR), signal-current-to-noise (SCNR), and the amplitude were recorded and evaluated by the measurement software. If the signal quality is insufficient, the system provides warnings and suggestions for improvement.

After the cycle ended, the measurement and monitoring were turned off, and the results were saved.

All measurements were conducted by the use of water without chemicals at a temperature of 20-25°C. This approach ensures that the software receives consistent and well-defined fluid

parameters for accurately calculating the signal path and transducer spacing. Additionally, by avoiding chemical additives and maintaining a stable temperature range, the influence of varying viscosity, density, and acoustic properties was minimized. This was essential to obtain comparable and reproducible results across all measurements. To make sure that the measurements are transferable to the CIP cycle, which is used in the daily business, two measurements of the volumetric flow at different pressure settings were taken during the CIP cleaning process (see Appendix I for the process steps). One time with hot water (step 5) and one time with cold water mixed with the chemical (step 6).

The key parameters for this method are listed in Table 3.

Table 3: Key Parameters and Conditions for Ultrasonic Flow Measurement with Clamp-On Flow Meter.

Parameter	**Value/Description**
Sensor distance	25 mm
Recommended installation distances	10 x pipe diameter upstream, 5 x pipe diameter downstream from disturbance
Measurement fluid	Water
Temperature during measurement	20-25 °C
Measured parameter	Volumetric flow rate
Quality metrics	SNR, SCNR, Amplitude
Target spray ball pressure	≥ 2 bar (for a cleaning diameter ~ 3 m)
Required volumetric flow rate per spray ball	Approximately 60 l/min
Parameters added to the system	pipe material, wall thickness, inner and outer pipe diameter, fluid type, and temperature

4.2.2 Determination of Spray Shadows with different Spray Ball Directions

The riboflavin spray shadow test was carried out under VDMA instructions on how to perform a riboflavin test [7]. A 0,2 % riboflavin solution was prepared by dissolving 0,2 grams of riboflavin powder in one liter of deionized water. The solution was stirred on a magnetic stirrer until fully dissolved and used shortly after preparation to ensure consistent fluorescence.

During the application, the internal surface of the clean production tank was uniformly coated with the riboflavin solution using a hand-held spray bottle. It was ensured that all parts of the inside of the tank were covered in the solution by checking with the UV lamp.

According to Table 2 of the information sheet [7], drying of the solution is avoided, which is why the flushing cycle started directly after applying the solution. The test was conducted at ambient water temperature (20-25 °C), without the use of cleaning agents, as the objective was to detect potential spray shadows rather than evaluating cleaning performance. The pump pressure was set to a specific pressure setting, which was supposed to be tested. The flushing cycle was set for 20 seconds, following the test conditions, to ensure consistent rinsing and allow for a representative evaluation of spray coverage. In addition to the visual inspection, the volumetric flow rate in the supply pipe to the spray balls was measured during the test. This measure was carried out to determine the point at which the full target flow rate was achieved at the spray balls, ensuring that the test conditions are the same as during the volumetric flow measurement.

Following the rinsing process, the tank was inspected under UV light with the lid closed to have a dark environment. Areas where riboflavin residues remained fluoresced with a distinct yellow-green color, indicating insufficient spray coverage. All fluorescent areas were documented photographically. The shadow test was first conducted using various pump pressure settings, with the volume flow rates measured at the water supply pipe (MP1 in Figure 4) continuously during the test to ensure consistency with previously recorded values. These initial spray shadow tests aimed to determine the pump pressure level at which no further changes in spray coverage occurred. Subsequently, with the optimal pump pressure setting, additional spray shadow tests were performed while varying the orientation of the spray balls to eliminate the remaining spray shadows identified earlier. The key parameters for this method are listed in Table 4.

Table 4: Key parameters and conditions of the riboflavin spray shadow test

Parameter	**Value/Description**
Riboflavin solution concentration	0,2% (0,2 g riboflavin in 1 L deionized water)
Water temperature	20-25 °C
Measurement fluid	Water
Cleaning agents used	none
Pump pressure	Varied (5,5 bar – 10 bar)
Flushing time	20 seconds
UV wavelength	365 nm

4.2.3 Microbial and ATP Examination

To evaluate the effectiveness of surface disinfection and identify hygiene critical areas, microbiological and ATP sampling were performed at points defined as critical according to the spray shadow test performed earlier. Five of these areas were selected for further hygienic investigation after a cleaning cycle with a pump pressure of 9 bar. In comparison to the critical points inside the tank, one location with confirmed effective spray coverage was also analyzed for ATP residues and microbiological contamination. In total, the six surface samples were taken after each of five cleaning cycles, with normal production occurring in the tank between the cycles. The selected sampling points were visibly soiled after the normal production of liposomal supplements, ensuring that the results were both representative and reliable and that they reflected realistic operating conditions.

The first step for an investigation for ATP was to take a swab sample with a specific test stick. While doing that, the surface must be dry. The stick was then placed in a special solution where cells were broken down to also release the ATP inside the cells. Quickly after that, the stick was placed inside an ATP machine to measure the bioluminescence coming from the sample. On a stainless steel and food contact surface should be a value less than 10 relative light units (RLU).

Microbiological surface testing was carried out following ISO 18593 [19]. For smaller areas or areas that are hard to reach, a pre-moistened sterile swab was used to sample the selected surface

area. The swabbing area was defined (e.g., 10 x 10 cm), and the swab was rubbed across the surface in horizontal and vertical strokes while applying even pressure. The swabs were then placed in the transport media and cultivated on a TSA Agar plate with no dilution. The plates were placed in an incubator (37°C) for 72 hours. The key parameters for this method are listed in Table 5.

Table 5: Key parameters and procedure for ATP and microbial surface testing

Parameter	**Value/Description**
Standard followed for the microbial test	ISO 18593
Sampling tool for the microbial test	Pre-moistened sterile swab
Swabbing area	Defined (e.g., 10 × 10 cm), vertical and horizontal strokes
Cultivation method for the microbial test	Direct streaking onto TSA Agar plate (no dilution)
Incubation conditions for the microbial test	37°C for 72 hours
Acceptable RLU value	< 10 RLU for stainless steel food-contact surfaces
Measurement principle	Bioluminescence after cell lysis and ATP release
Number of sampling points (ATP and microbial test)	6 total (5 critical areas, 1 reference area with confirmed coverage)
Cleaning conditions	Performed after 5 separate cleaning cycles with 9 bar pump pressure
Production context	Normal production took place between cleaning cycles.
Surface condition before cleaning	Visible soiled after production

4.2.4 Surface Roughness: Impression Sampling and Measurement

Due to the confined and complex geometry of the stainless steel tank used for the production of liposomal dietary supplements, an indirect method was used by creating detailed surface replicas using a high-precision correction impression material.

Before impression taking, critical locations inside the tank were identified, especially near inlets, outlets, and areas where the spray shadow test revealed a lack of coverage during the CIP. These surfaces were visually inspected and gently cleaned with sterile wipes to remove any interfering residues or moisture. The impression material, a vinylmethylpolymethylsiloxane-based two-component system, was dispensed using mixing tips that ensured homogeneous blending of both components and a fast application directly after combining them. The compound was applied evenly to the target surface inside the tank using gloves. While applying, it was ensured that no air was trapped between the surface and the compound. After the recommended curing time, which was five minutes, the fully cured impression was removed carefully from the surface and placed onto a clean, labeled metal piece to prevent deformation during storage and transport.

The negative replicas were analyzed externally using an optical, non-contact profilometer. Each replica was analyzed along 5 representative surface areas, ideally aligned with the surface processing direction, like brushed finishes. From the measured data, the surface roughness parameters such as the arithmetical mean roughness (Ra) and the maximum profile height (Rz) were extracted and statistically evaluated. Additionally, the areal surface roughness (Sa) was measured three times per replica, and a picture was taken from the 3D surface to compare the different replicas. After that, the mean of the Sa values was calculated.

4.2.5 Risk Assessment of the Hygienic Design based on Experimental Findings

To implement the risk assessment of the production tank's hygienic design, the structured approach outlined in DIN EN ISO 12100:2011-03 was applied in a practical, test-based manner. The aim was to identify, evaluate, and reduce hygiene-related hazards that may compromise product safety during normal CIP cleaning operations. This was done through a combination of targeted experimental analyses explained earlier and risk-based interpretation of the results.

The assessment focused exclusively on hygiene risks within the stainless steel production tank, especially regarding the tank's cleanability via CIP. The system was evaluated during cleaning with water only, as well as under realistic process conditions.

Through this process, the practical limitations of the current CIP system were also identified and defined, particularly in terms of achievable pump pressure, flow rate, and spray coverage performance.

Potential hygienic design risks were identified through experimental simulation and observation of tank cleaning behavior. Specific testing was performed to investigate design-related

factors that could lead to microbial growth, residue retention, or insufficient cleaning. To support the risk assessment, the tests outlined in Section 4.2 were conducted and are briefly summarised in the following:

- Pump pressure and flow rate testing using a clamp-on ultrasonic flow meter to determine whether the spray balls reached all areas of the tank with sufficient mechanical force. These values provided the hydraulic baseline for the cleaning system.
- Spray shadow analysis using riboflavin testing, which allowed for the visual identification of areas that were not sufficiently covered by the CIP spray pattern. These shadow zones were considered high-priority risk zones for microbial persistence.
- Targeted microbiological swab testing and ATP analysis were carried out after CIP cleaning at locations identified as shadow areas. These tests confirmed whether residue or microbial contamination persisted in those regions and validated the effectiveness of the cleaning process under normal production conditions.
- Surface roughness measurements were conducted using non-destructive impression sampling and 3D profilometry to identify surfaces with potentially inadequate cleanability. Areas with high roughness values above 0,8 µm were classified as hygienically critical.

The test results were used to estimate the hygiene risk for each identified issue based on the extent and consistency of spray shadow formation, flow and pressure conditions at the time of cleaning, microbial/ATP detection rates, and surface roughness values exceeding recommended thresholds.

Each issue was evaluated qualitatively in terms of potential product contamination. For example, a riboflavin-positive zone with confirmed microbial contamination was classified as a high-risk area. In contrast, areas with sufficient spray coverage, low surface roughness, and ATP values <10 RLU were considered to pose low risk.

Where necessary, risk-reducing recommendations were formulated based on the test outcomes, such as re-angling the spray balls to eliminate spray shadows, increasing flow rates, and, where applicable, recommending surface rework or intensified monitoring for rough or difficult-to-reach surfaces.

5 Results

In order to evaluate the effectiveness of the existing CIP system and to identify potential hygienic risks, several tests were performed. The results of these investigations are presented below.

5.1 Determination of an effective Pump Pressure based on the Flow Rate

To determine the volumetric flow rates reaching the individual spray balls, the CIP pipeline configuration was first analyzed. Figure 8 shows the top of the production tank with the relevant piping and spray ball connections. This setup formed the basis for understanding the flow distribution and was essential for calculating the actual flow rates reaching each spray ball.

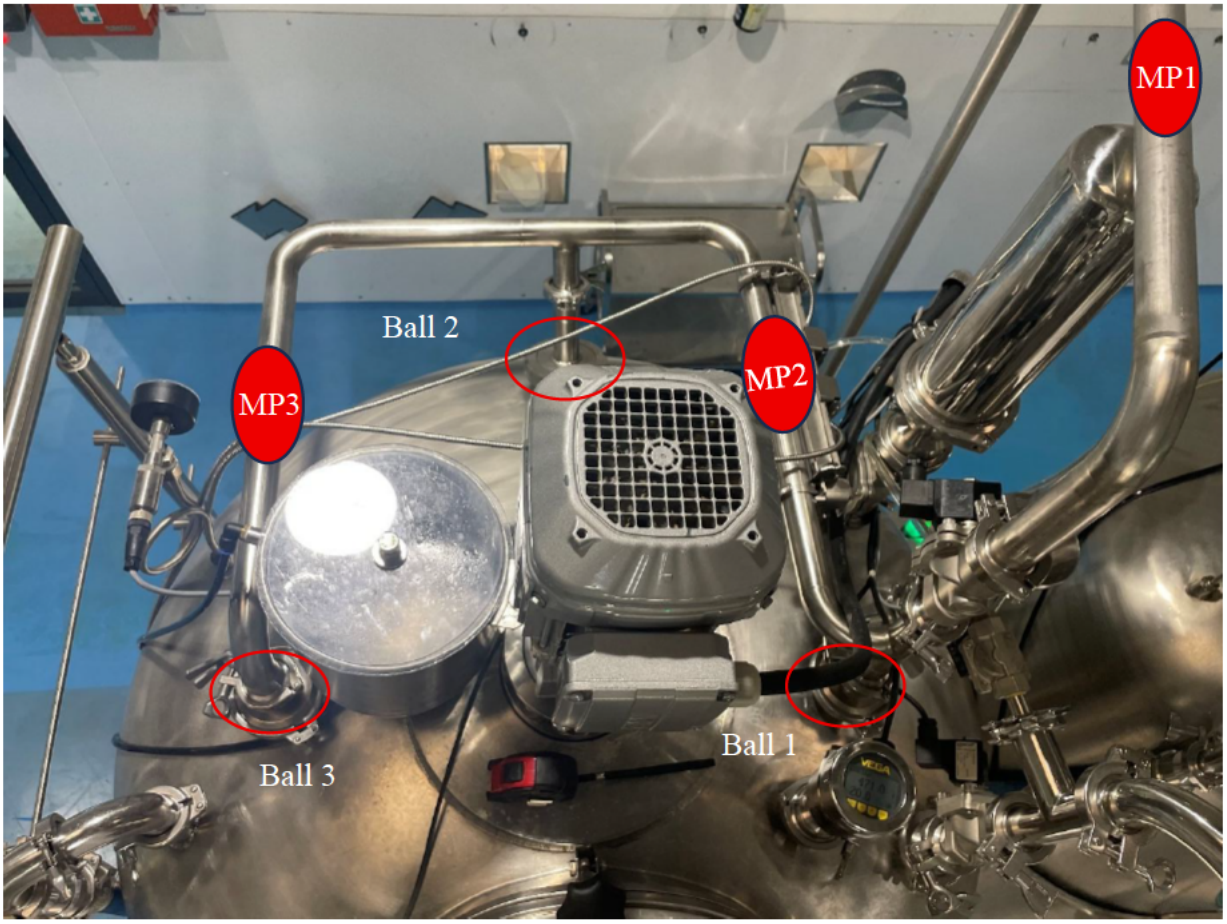


Figure 8: CIP system setup showing the pipeline configuration and the installed spray balls inside the production tank. The different measuring points (MP) for the volumetric flow rate measurement are shown in this picture, as well as the position of the spray balls. The view is from on top of the tank.

To assess the flow distribution within the CIP system, the volumetric flow rates were measured at three measuring points (MP) in the pipeline (MP1-MP3). The actual flow rate reaching each spray ball was calculated by subtraction, and it was assumed that there were no additional branches or losses between the measuring points. The flow rate to spray ball 1 was determined

by subtracting MP2 from MP1 (MP1-MP2), as MP2 represents the flow after spray ball 1. Similarly, the flow rate to spray ball 2 was calculated by subtracting MP3 from MP2 (MP2-MP3). The remaining flow at MP3 corresponds to the flow reaching spray ball 3. The results of the measurements are summarized in Table 6, and the calculated flow at each spray ball is demonstrated in Table 7. Additionally, the SNR, SCNR, and Amplitude were evaluated by the measurement software, and all values were within acceptable ranges.

Table 6: Measured volumetric flow rates in l/min at three different measuring points. The measuring points are demonstrated in Figure 8.

	Volume flow [l/min]		
Feed pump pressure [bar]	**MP1**	**MP2**	**MP3**
10	253	186	93
9	240	176	88
8	225	165	83
7	207	151	76

Table 7: Calculated volumetric flow rates to the individual spray balls at different pump pressures. The spray ball position is demonstrated in Figure 8.

	Volume flow [l/min]		
Feed pump pressure [bar]	**Spray ball 1**	**Spray ball 2**	**Spray ball 3**
10	67	93	93
9	64	88	88
8	60	82	83
7	56	75	76

To assess the transferability of the results to the real CIP operations, additional flow measurements were conducted at MP1 during two different steps of an actual CIP cleaning process. These included one measurement during a hot water rinse and one during a cold cleaning step with chemical additives. Those values got a good signal quality as well as the previous ones.

The flow rates measured at MP1 during the hot water and chemical disinfection step showed only minor deviations from the reference values obtained under standard conditions, as shown in Table 8.

Table 8: Comparison of the volumetric flow rate measurements at MP1 under different conditions.

	Volume flow [l/min]		
Feed pump pressure [bar]	**MP1 – Water (20-25°C)**	**MP1 – Hot Water (90°C)**	**MP1 – Chemical step (1% O33 Aktiv 5, 20-25°C)**
10	253	259 (+2,3%)	247 (-2,4%)
9	240	246 (+2,4%)	233 (-3,0%)
8	225	230 (+2,2%)	219 (-2,7%)
7	207	210 (+1,4%)	201 (-3,0%)

The hot water rinse resulted in a slightly higher volumetric flow (up to 2,4 % increase), and in contrast, the flow rates during the cold chemical step were slightly lower, with a reduction of around 2-3 %. The deviations between the standardized water-based measurement and the measurements under actual CIP conditions are in an acceptable range. This is considered acceptable because the initial flow rate measurements were calculated using a safety buffer, assuming a maximum spray distance of 1,5 m, even though the actual furthest point is only 1,35 m away. This ensures sufficient cleaning performance even with slight flow variations. Therefore, the use of water at room temperature without chemicals can be considered valid for determine the most effective pump pressure for the CIP balls to work.

5.2 Determination of Spray Shadows with different Spray Ball Directions

To support the understanding of the spray coverage of the CIP spray balls within the tank, the results of the spray shadow test are illustrated using 3D model visualization. These models help to identify critical areas that may not be adequately reached by the cleaning fluid distribution during the test, and regions that require special attention in terms of spray ball positioning and cleaning verification were identified.

It should be noted that due to the complexity and limited accessibility of the tank geometry, the 3D model may deviate slightly from the actual tank dimensions. Nonetheless, the model serves as a reliable tool to visualize the spray coverage and to support the interpretation of critical

cleaning zones. For clarity and visual focus, the models shown in this results section are presented without dimension labels. A detailed version of the model with approximate measurements is provided in Figure 4 to support spatial orientation and technical reference.

5.2.1 Comparison of different Pump Pressure Settings

The first four spray shadow tests were performed to evaluate at which pump pressure the spray coverage will not change significantly anymore. The test conditions, as well as the measured volumetric flow during these tests, are stated in Table 9. Additionally, the SNR, SCNR, and Amplitude of the measurement were evaluated from the software and are shown in the table as the general signal quality of the flow rate measurement.

Table 9: Test conditions for the first four spray shadow tests, in which the optimal pump pressure regarding the spray coverage is determined.

Spray shadow test	**Pump pressure (bar)**	**Spray ball orientation**	**Volumetric flow rate measurement MP1 (l/min)**	**The signal quality of the flow rate measurement**
1	5,5	1	169	Good
2	8	1	198	Good
3	9	1	210	Good
4	10	1	222	Good

The spray shadow test performed with 5,5 bar feed pump pressure represents the conditions as they were in the past. The results of the test are shown in Figure 9 and marked in green color.

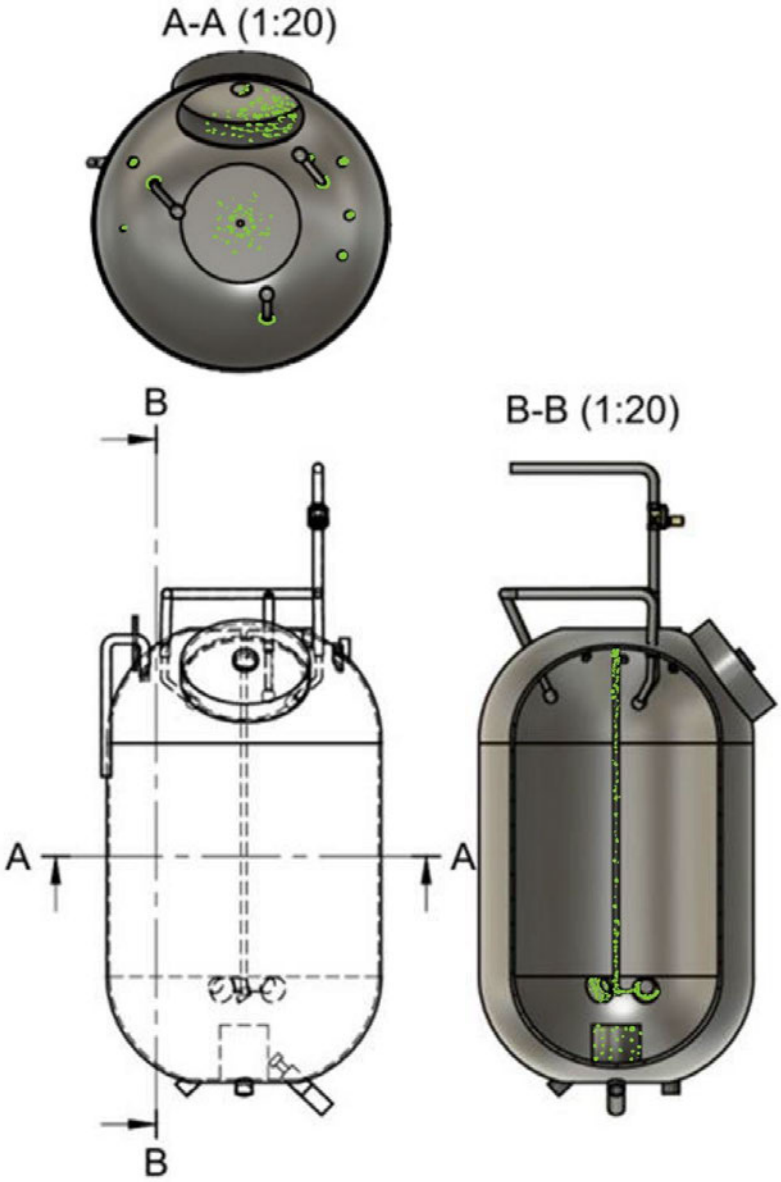


Figure 9: Demonstration of the areas which still had riboflavin (green) after a spray shadow test with 5,5 bar feed pump pressure.

After that, a spray shadow test with a pump pressure of 8 bar was performed. The results of the spray shadows for this test are shown in Figure 10, and the findings are marked in green. In this spray shadow test, riboflavin residues were still detectable on and around the shaft of the stirrer and its cups at the bottom, on the homogenizer, around the spray ball fittings, and on the inner side of the tank lid. There were also residues in all inlets at the top of the tank.

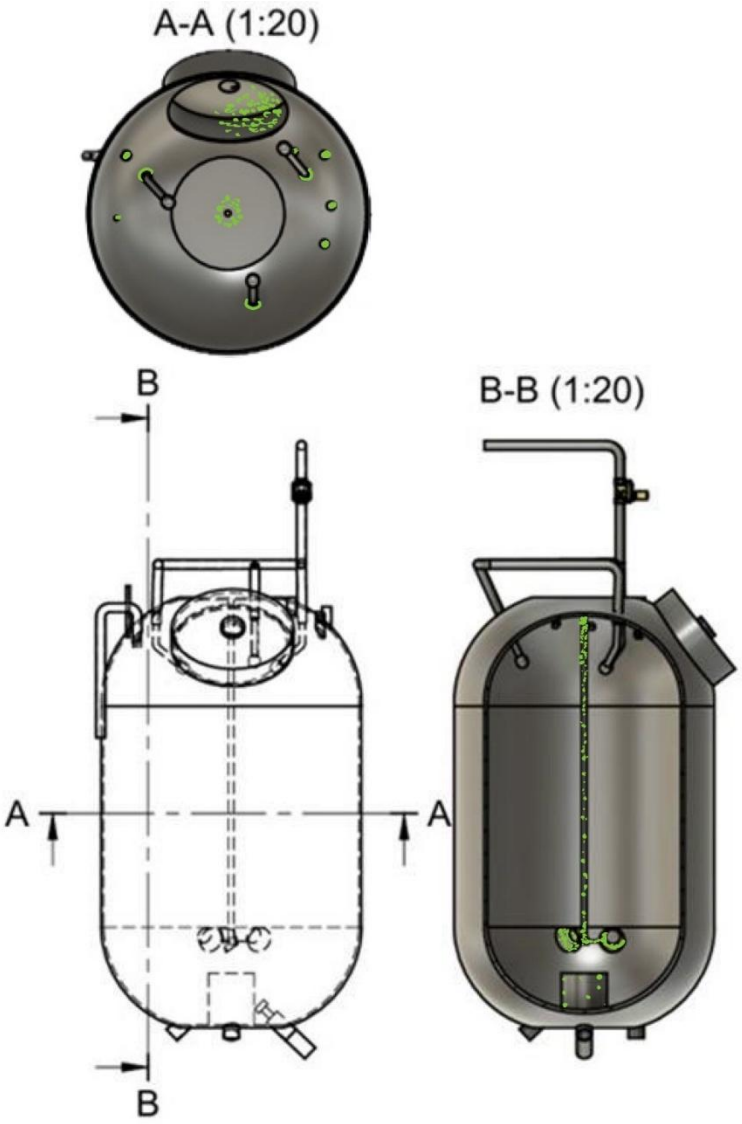


Figure 10: Demonstration of the areas which still had riboflavin (green) after a spray shadow test with 8 bar feed pump pressure.

The results of the spray shadow test performed with 9 bar are shown in Figure 11, and the spray shadows are marked in green color. At 9 bar, not much riboflavin was observed on the stirrer shaft. Only at the very top and at the bottom cups some riboflavin was left. The homogenizer and coverage around the spray balls had improved significantly, and riboflavin traces on the tank lid were also visibly reduced. The inlets still had riboflavin inside after the flush of 9 bar.

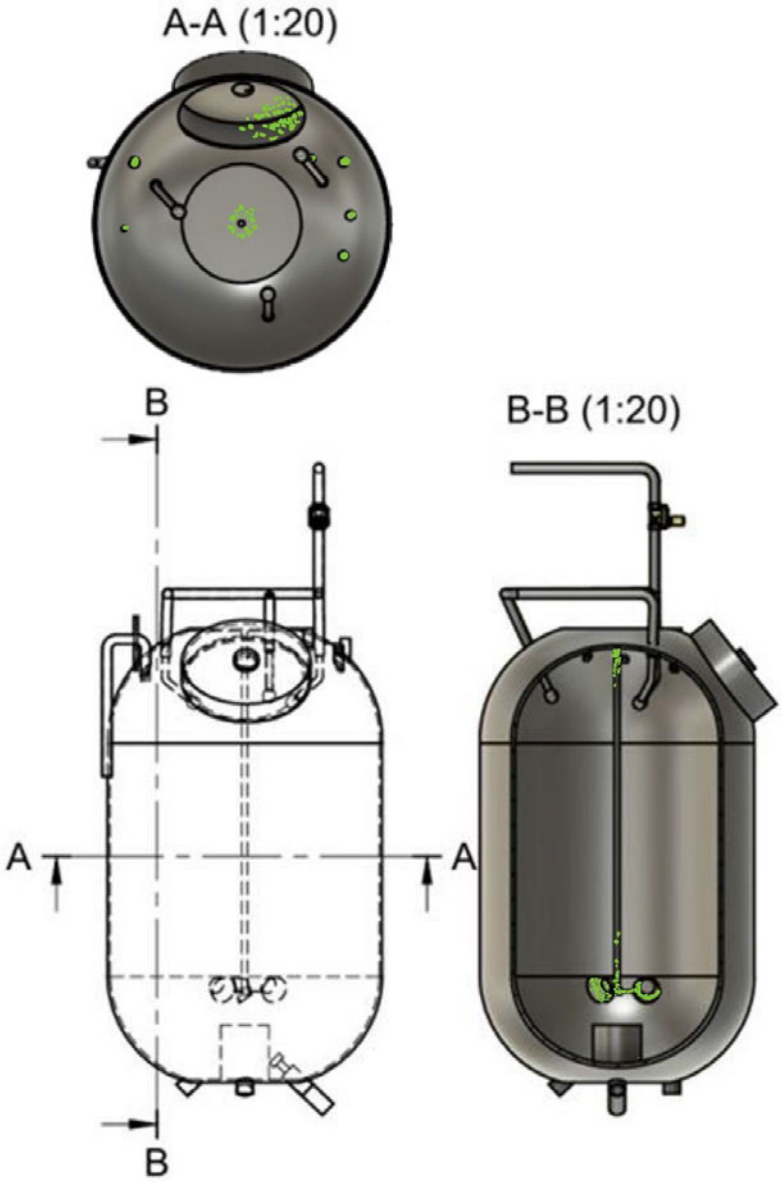


Figure 11: Demonstration of the areas which still had riboflavin (green) after a spray shadow test with 9 bar feed pump pressure.

Afterwards, a spray shadow test with 10 bar was performed, and the results are shown in Figure 12. The spray shadows are marked in green. Compared to 9 bar, a bit fewer riboflavin residues remained on the tank lid. Two inlet fittings that previously showed contamination were now free of riboflavin. In addition, the outer surfaces of the stirrer cups and the shaft's central section were no longer stained.

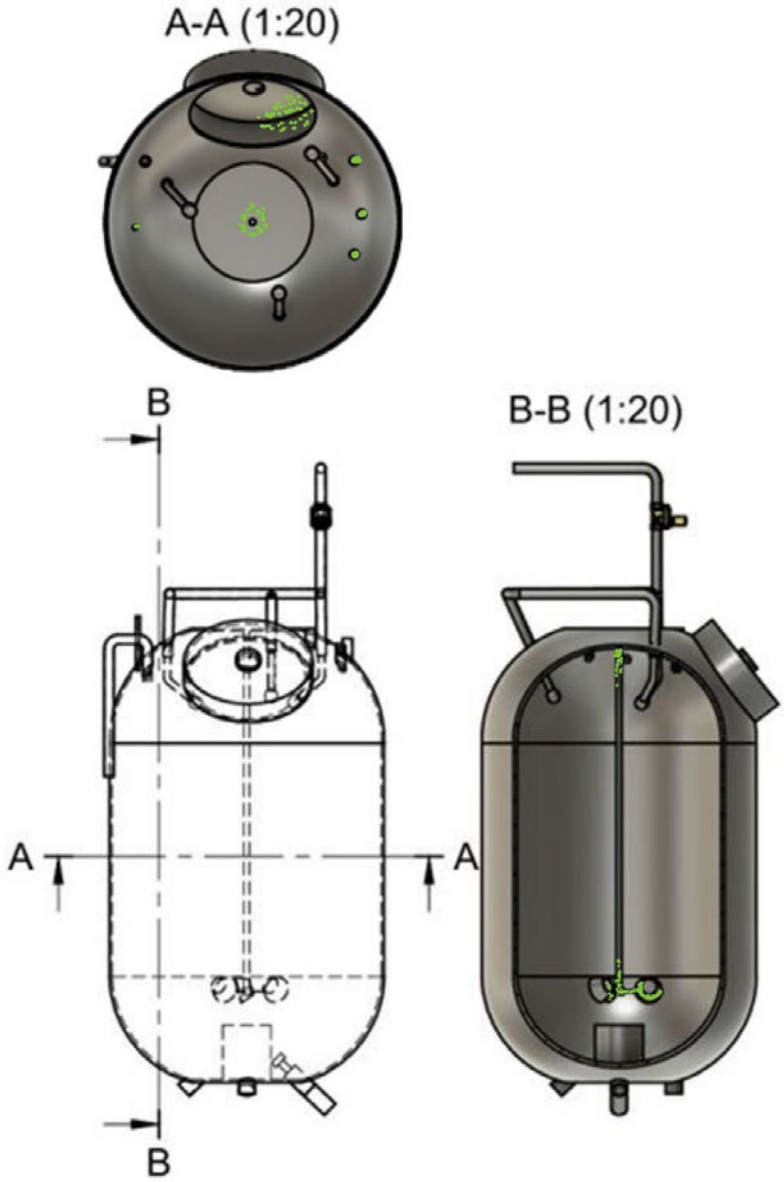


Figure 12: Demonstration of the areas which still had riboflavin (green) after a spray shadow test with 10 bar feed pump pressure.

After each test, approximately 500 mL of water containing riboflavin remained in the tank's outlet area (Figure 13).

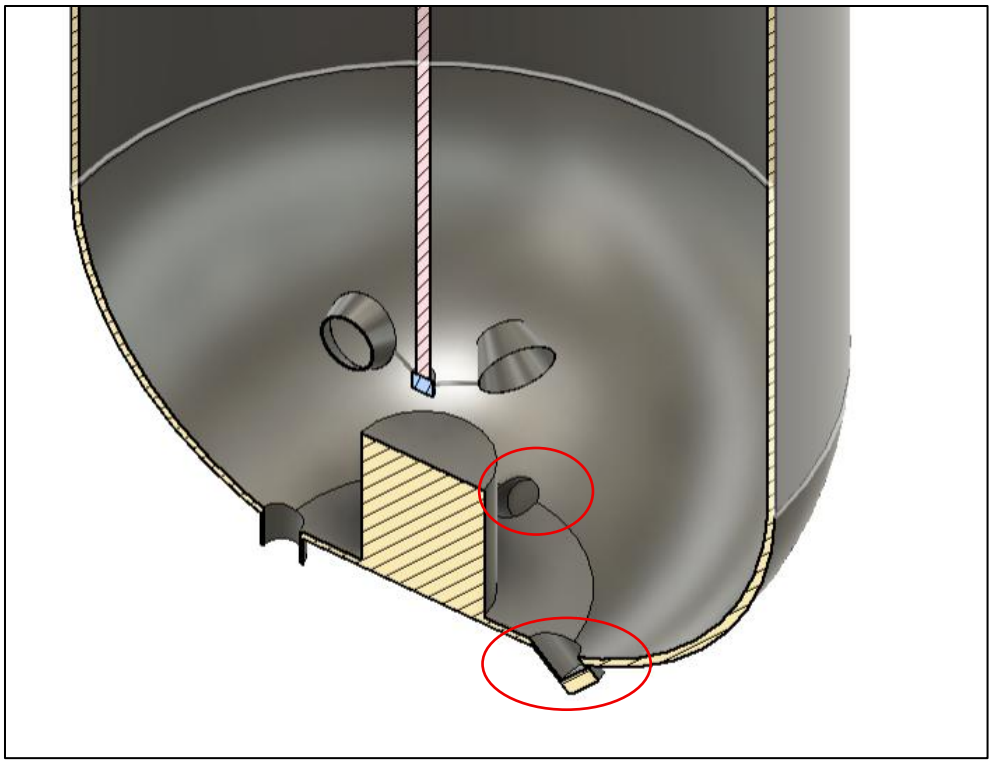


Figure 13: Illustration of the bottom of the tank. Riboflavin residues in the recessed areas of unused outlet sections (red circles), consistently observed after each spray shadow test (5,5 bar, 8 bar, 9 bar, and 10 bar).

5.2.2 Comparison between different Spray Ball Orientations

Following those investigations, an additional series of spray shadow tests was conducted at 9 bar, based on the findings from Figure 9-12. The decision to conduct tests at 9 bar was based on previous visual and flow-related indicators of improved cleaning performance. A detailed justification is provided in the discussion chapter. In subsequent tests, the orientation of the spray balls was varied in order to eliminate the remaining spray shadows. In Table 10, the four different orientations (1, 2, 3, and 4) used during the tests are illustrated. Position 1 got tested previously with test 3. The test conditions, as well as the measured volumetric flow during these tests, are stated in Table 11. Additionally, the SNR, SCNR, and Amplitude of the measurement were evaluated from the software and are shown in the table as the general signal quality of the flow rate measurement.

Table 10: Illustration of the different spray ball settings tested in the spray shadow tests with 9 bar.

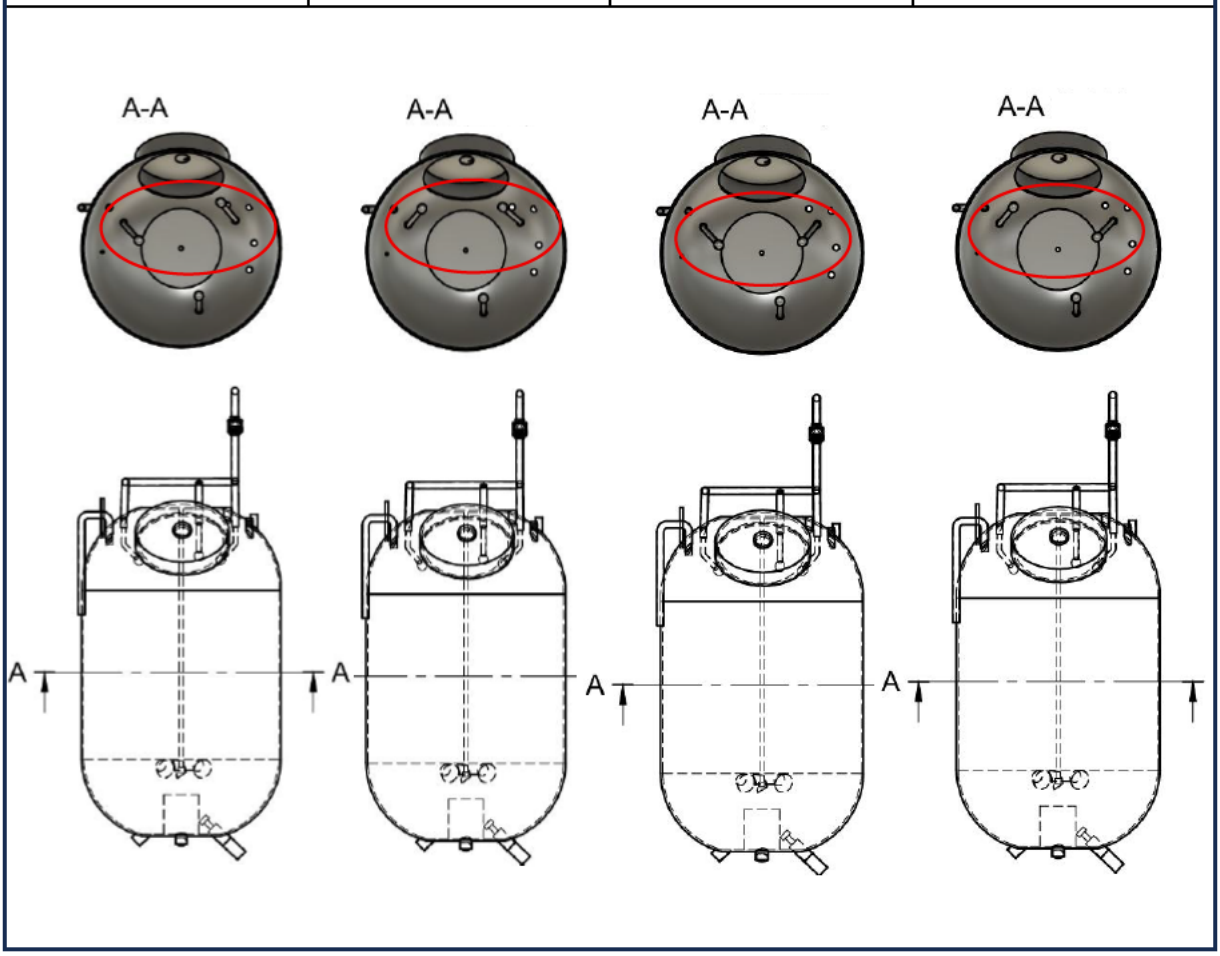
Position 1	Position 2	Position 3	Position 4
			

Table 11: Test conditions for the next three spray shadow tests, in which the optimal spray ball orientation regarding the spray coverage gets determined.

Spray shadow test	**Pump pressure (bar)**	**Spray ball orientation**	**Volumetric flow rate measurement MP1 (l/min)**	**The signal quality of the flow rate measurement**
5	9	2	210	Good
6	9	3	210	Good
7	9	4	210	Good

In Figure 14, the spray shadows of test 5 are illustrated. The spray shadow areas are marked in green.

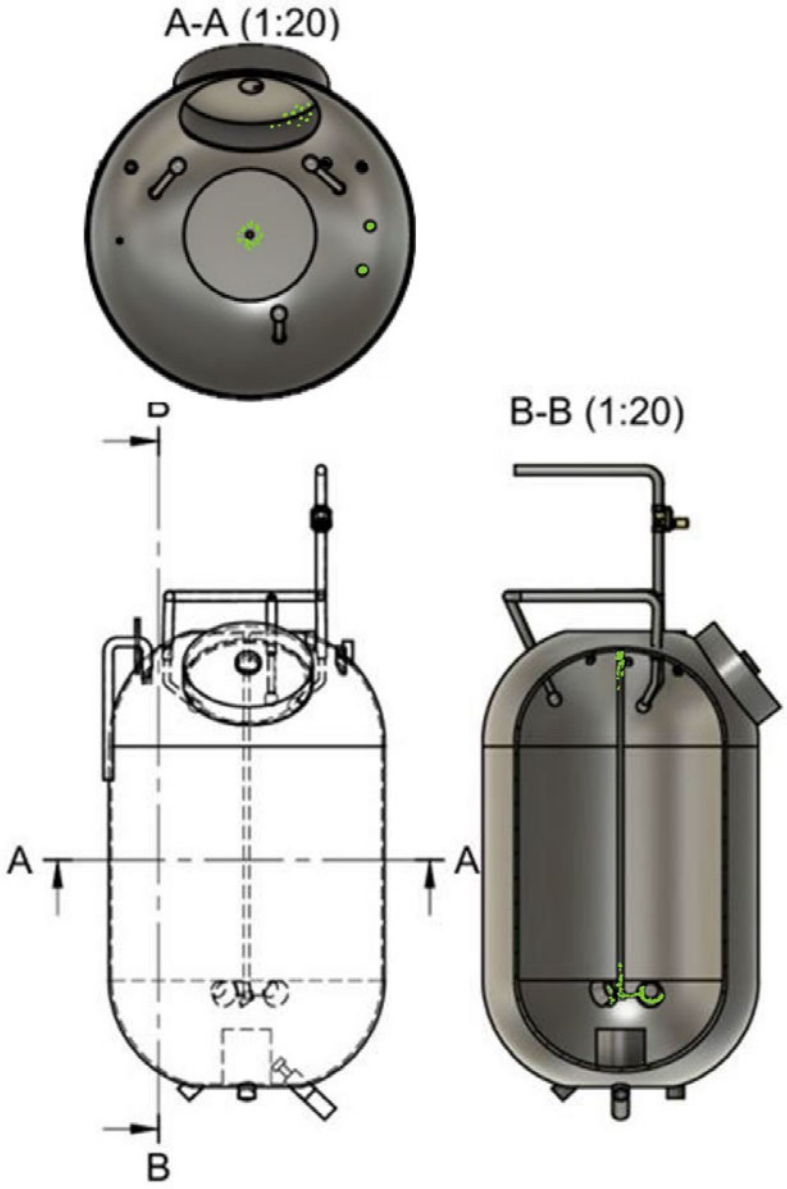


Figure 14: Illustration of the riboflavin detected in the tank after a spray shadow test conducted with 9 bar and Position 2 of the spray balls

In Figure 15, the spray shadows of test 6 are illustrated and marked in green.

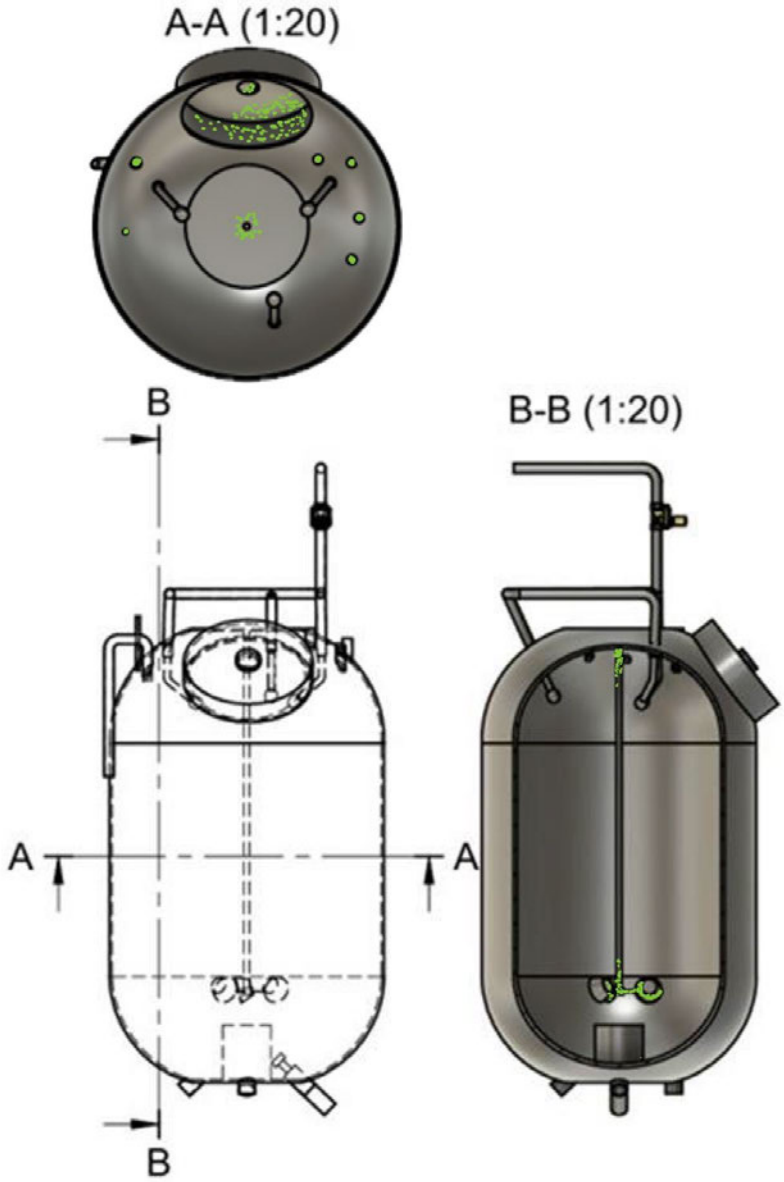


Figure 15: Illustration of the riboflavin detected in the tank after a spray shadow test conducted with 9 bar and Position 3 of the spray balls

In Figure 16, the spray shadows of test 7 are illustrated and marked in green.

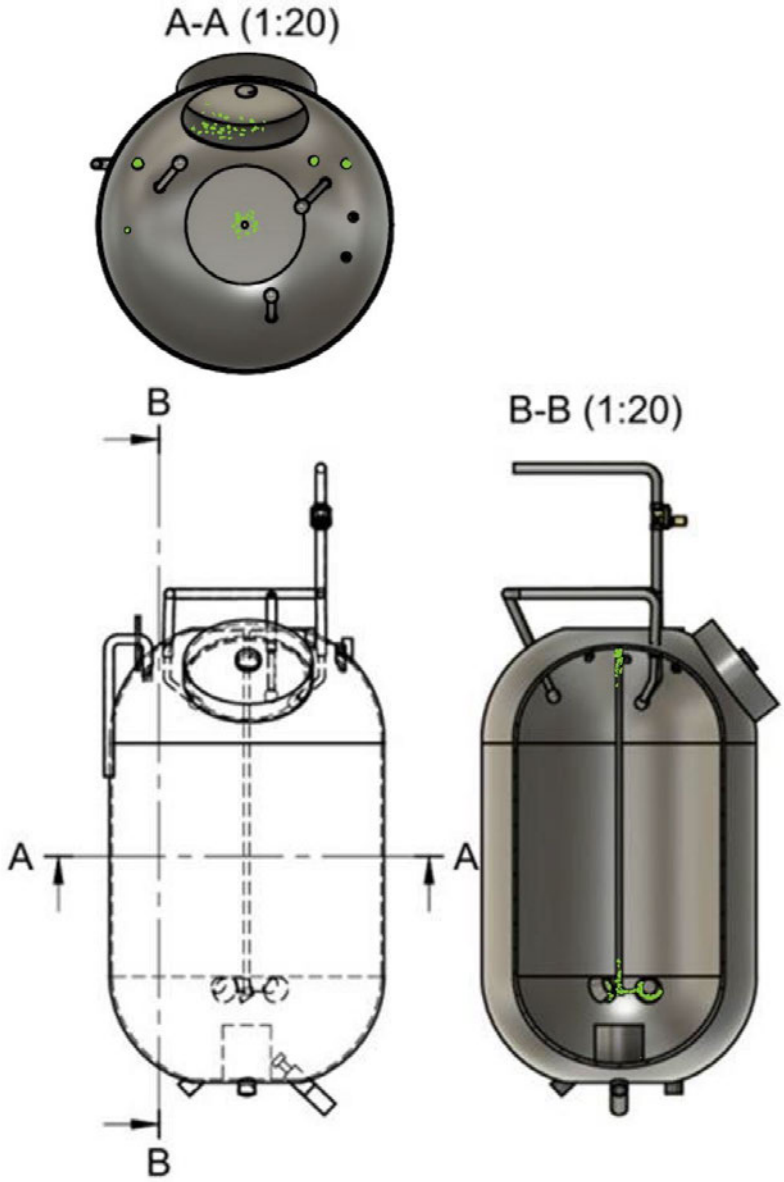


Figure 16: Illustration of the riboflavin detected in the tank after a spray shadow test conducted with 9 bar and Position 4 of the spray balls

Figures 11, 14, 15, and 16 illustrate the spray shadow patterns identified during the riboflavin tests at different spray ball positions, all conducted at 9 bar pump pressure.

At Position 2, the riboflavin residues on the tank lid were almost entirely removed compared to Position 1, with only minor traces remaining. Four of the top inlets that were previously affected were now fully reached and no longer in the spray shadow. However, the stirrer showed no improvement, and the shadow pattern remained unchanged.

At Position 3, the spray shadow on the lid got significantly bigger, with larger areas retaining riboflavin. All inlets at the top remained within the shadow zone. The stirrer again showed no change.

At Position 4, the spray shadow on the lid shifted to the opposite side compared to previous tests. Two of the upper inlets were now fully cleaned. The stirrer still showed persistent spray shadows.

Approximately 500 mL of water containing riboflavin was visible in the outlet area at the tank bottom after each test (Figure 13).

5.3 Microbial and ATP Examination

Although previous results indicated that a pump pressure of 9 bar is required for effective spray ball performance (addressed further in the discussion chapter), the microbiological and ATP analyses were conducted after cleaning cycles at 7 bar. This adjustment is necessary due to current technical limitations in the CIP system, which does not allow running a full cleaning cycle at higher pump pressures than 7 bar. Specifically, the pump is not able to extract the water from the tank quickly enough during the circulation between the CIP unit and the tank to maintain higher flow rates.

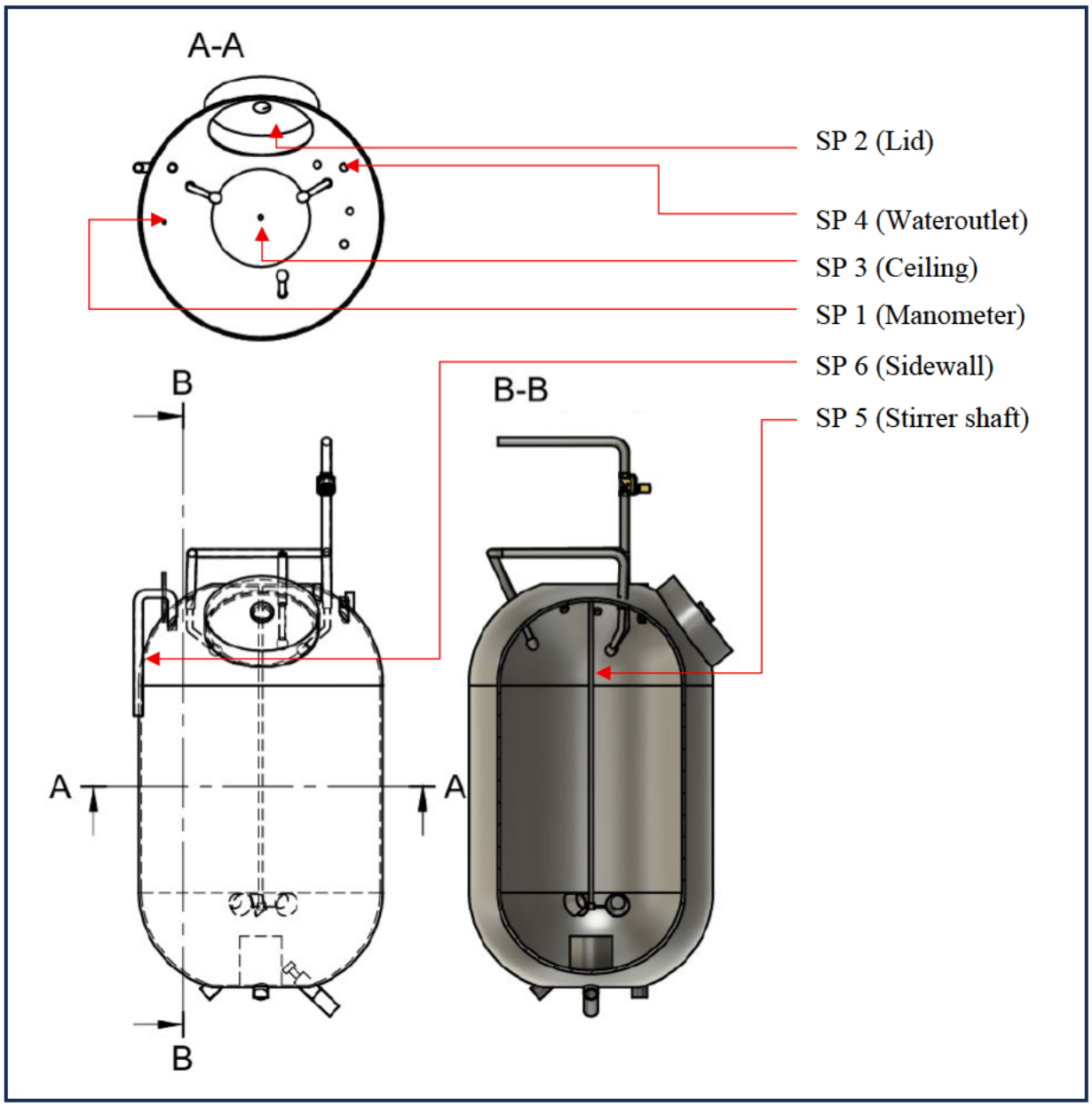


Figure 17: Technical drawing of the 1000 L tank showing the sampling points (SP 1–SP 6) used for surface microbiological and ATP investigations. The sampling points are located at critical positions, including the manometer connection, lid, ceiling area around the stirrer shaft, water outlet, stirrer shaft, and sidewall as a reference.

The ATP and microbiological measurements were performed at five critical points inside the tank, identified by the spray shadow test, as well as at one reference point with confirmed effective spray coverage (Figure 17). The tests were primarily conducted in the upper section of the tank, as the lower tank section was difficult to access for swabbing. The sampling was performed after each of five cleaning cycles, with normal production carried out between cycles. It is important to note that these measurements were conducted with the spray balls orientation optimized in the previous spray shadow tests, which were designed to improve fluid distribution and cleaning coverage compared to the original setup. The microbiological analysis showed no detectable microbial colonies on any of the agar plates from all sampled points, as shown in

Table 12. Additionally, the ATP measurement at all locations detected values below 10 RLU, which is widely accepted as the cleanliness threshold for stainless steel food contact surfaces. These results demonstrate consistently low levels of organic and microbial contamination in the upper areas of the tank, including locations previously considered critical due to spray shadowing.

Table 12: ATP and microbiological surface test results at critical and reference sampling points after each of five cleaning cycles

Cleaning cycle	**Sample point**	**ATP result [RLU]**	**Microbiological result [cfu/mL]**
1	1	0	<1
	2	6	<1
	3	0	<1
	4	1	<1
	5	2	<1
	6 (Reference)	0	<1
2	1	0	<1
	2	1	<1
	3	0	<1
	4	0	<1
	5	0	<1
	6 (Reference)	0	<1
3	1	0	<1
	2	2	<1
	3	0	<1
	4	2	<1
	5	0	<1
	6 (Reference)	1	<1

Cleaning cycle	Sample point	ATP result [RLU]	Microbiological result [cfu/mL]
4	1	3	<1
	2	4	<1
	3	0	<1
	4	0	<1
	5	1	<1
	6 (Reference)	0	<1
5	1	0	<1
	2	0	<1
	3	0	<1
	4	0	<1
	5	0	<1
	6 (Reference)	0	<1

5.4 Surface Roughness

To assess the surface conditions of the stainless steel tank relevant for CIP verification, roughness measurements were carried out at five different locations inside the tank. The sampling points were selected to cover various geometric and functional areas of the tank, including the sidewalls, bottom, and internal fittings (Figure 18). Tables 13–17 present the arithmetic mean surface roughness (Ra) values for each location, as well as the overall mean values. Each replica was measured five times to ensure reliability and reproducibility. Table 18 shows the results of the areal surface roughness (Sa) measurements for all replicas.

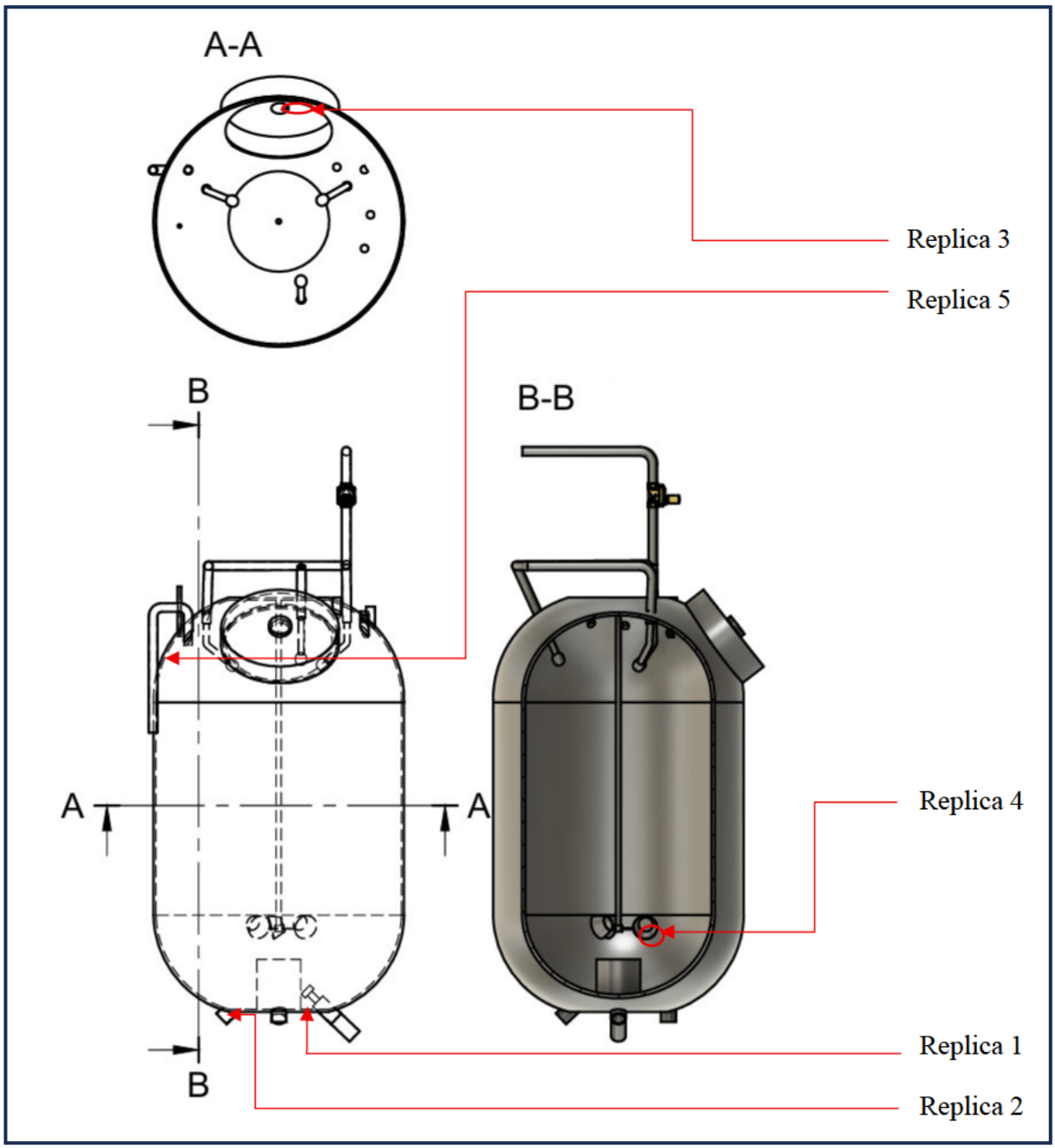


Figure 18: Technical illustration of the 1000 L tank showing the sampling locations used for surface roughness analysis. The drawing is intended solely for illustrative purposes in the context of this thesis and is not for technical or production use.

Table 13: Individual line profile measurements (Ra and Rz) for Replica 1.

Replica of the bottom 1 (Replica 1)		
Measurement number	**Ra (µm)**	**Rz (µm)**
1	0,515	2,904
2	0,507	3,089
3	0,498	2,817
4	0,537	2,767
5	0,489	2,801
Mean	**0,509**	**2,876**

Table 14: Individual line profile measurements (Ra and Rz) for Replica 2.

Replica of the unused outlet (Replica 2)		
Measurement number	**Ra (µm)**	**Rz (µm)**
1	0,32	1,517
2	0,191	0,907
3	0,25	1,251
4	0,383	1,633
5	0,264	1,258
Mean	**0,282**	**1,313**

Table 15: Individual line profile measurements (Ra and Rz) for Replica 3.

Replica of the lid (Replica 3)		
Measurement number	**Ra (µm)**	**Rz (µm)**
1	0,496	1,523
2	0,35	1,093
3	0,313	1,262
4	0,313	1,114
5	0,303	1,196
Mean	**0,355**	**1,238**

Table 16: Individual line profile measurements (Ra and Rz) for Replica 4.

Replica of the stirrer (Replica 4)		
Measurement number	**Ra (µm)**	**Rz (µm)**
1	0,258	1,058
2	0,256	1,105
3	0,247	1,186
4	0,298	1,316
5	0,366	1,285
Mean	**0,285**	**1,19**

Table 17: Individual line profile measurements (Ra and Rz) for Replica 5.

Replica of the sidewall (Replica 5)		
Measurement number	**Ra (µm)**	**Rz (µm)**
1	0,449	2,064
2	0,374	1,979
3	0,331	1,779
4	0,318	1,614
5	0,336	1,825
Mean	**0,362**	**1,852**

The line profile measurements (Ra and Rz) indicate that Replica 1 (Bottom 1) had the highest mean Ra value (0,509 µm) and the highest Rz value (2,876 µm). In contrast, Replica 2 (unused outlet) and Replica 4 (Stirrer) showed the lowest Ra values (0,282 µm and 0,285 µm). These findings are consistent with the areal surface roughness (Sa) results (Table 18), where Replica 3 (Lid) showed the highest mean Sa value (0,402 µm) and Replica 4 again showed the lowest (0,302 µm). The first measurement of Replica 4 for the Sa value (marked orange in Table 18) was not included in the calculation of the mean value due to air bubbles on the replica at this point, which caused a higher value than the other measurements. Importantly, all measured roughness values for Ra, Rz, and Sa remained below the hygienically relevant limit of 0,8 µm.

Table 18: Areal surface Roughness (Sa) measurements in µm for five replicas from different locations inside the tank. The value marked orange was not included in the calculation of the mean value for Replica 4 due to air bubbles at this point.

	Replica 1	Replica 2	Replica 3	Replica 4	Replica 5
	Areal surface roughness Sa (µm)				
Measurement 1	0,461	0,336	0,325	0,751	0,330
Measurement 2	0,331	0,339	0,474	0,274	0,298
Measurement 3	0,225	0,306	0,408	0,330	0,317
Mean	**0,339**	**0,327**	**0,402**	**0,302**	**0,315**

The 3D topography visualizations (Figures 19-23) confirmed the quantitative measurements by highlighting structural surface features in detail. Replica 1 exhibited distinct grooves and directional scratches across the scanned area, reflecting higher Sa and Rz values and suggesting

mechanical wear at the tank bottom. Replica 3 showed a clear brushed structure with local elevation differences. In contrast, Replica 4 and Replica 2 appeared visually smoother and more uniform in their topography, supporting their low roughness metrics. Replica 5 (tank wall) displayed a regular texture, consistent with mechanical polishing, and a moderate Sa value of 0,330 µm.

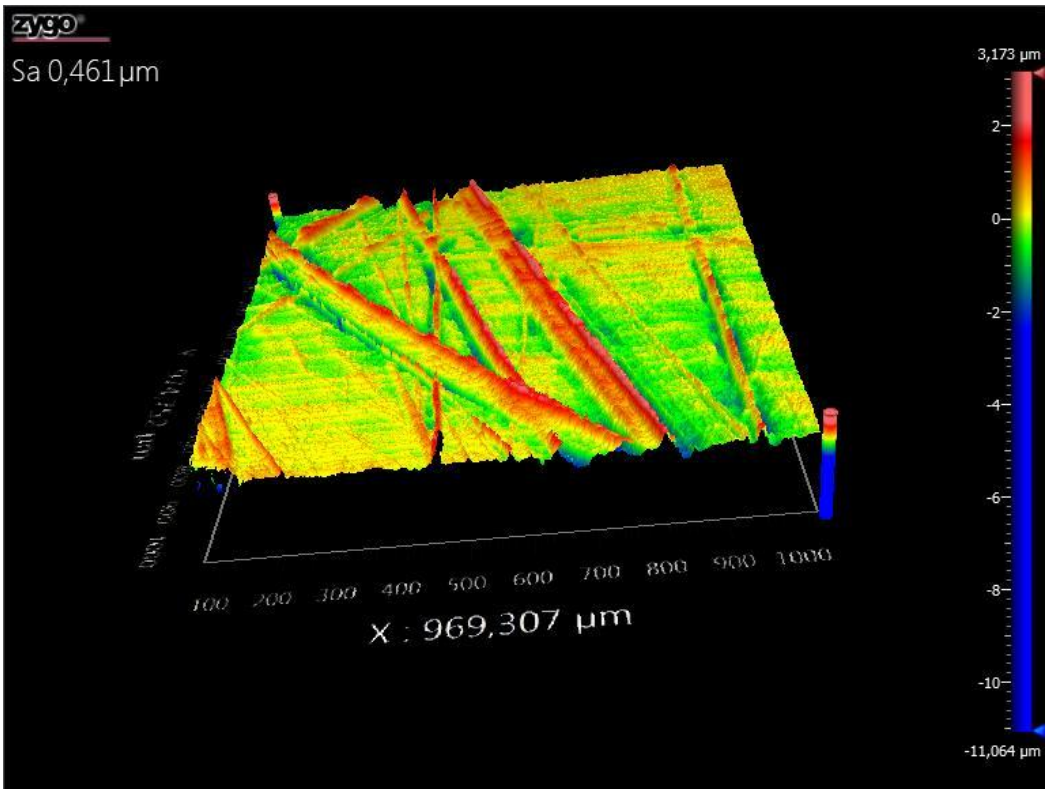


Figure 19: 3D surface topography of Replica 1 (tank bottom) obtained using optical non-contact profilometry. The areal surface roughness (Sa) was measured at 0,461 µm.

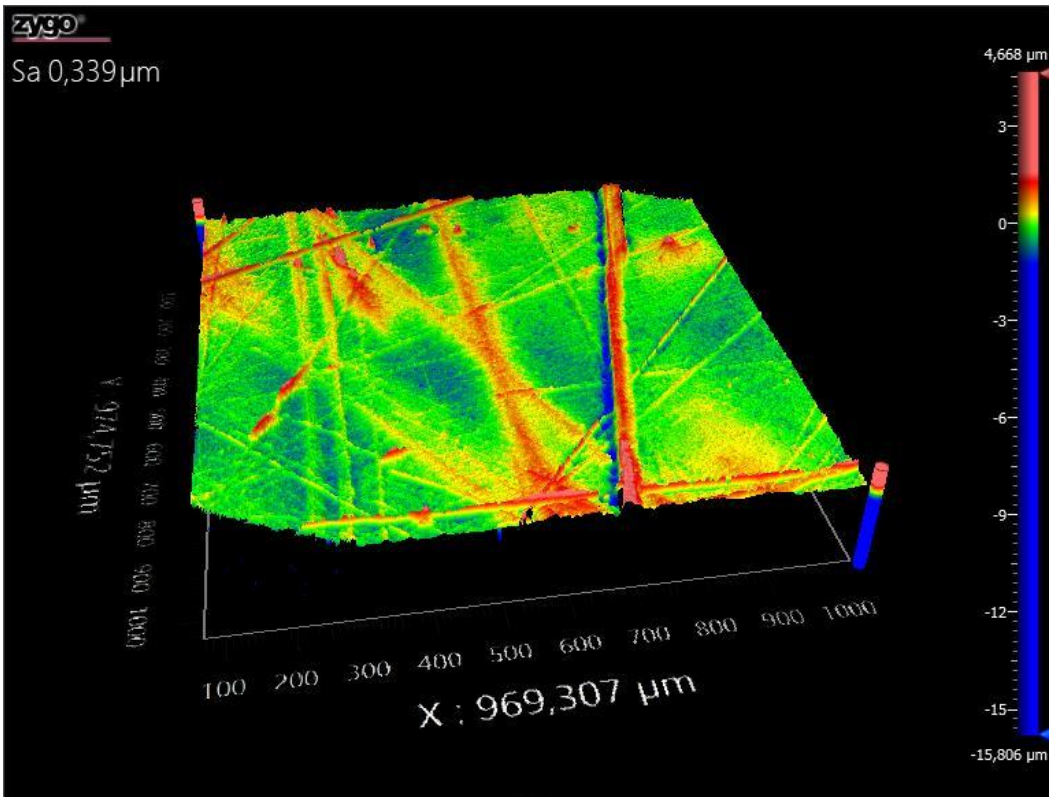


Figure 20: 3D surface topography of Replica 2 (unused outlet area) obtained via optical non-contact profilometry. The areal surface roughness (Sa) was measured at 0,339 µm.

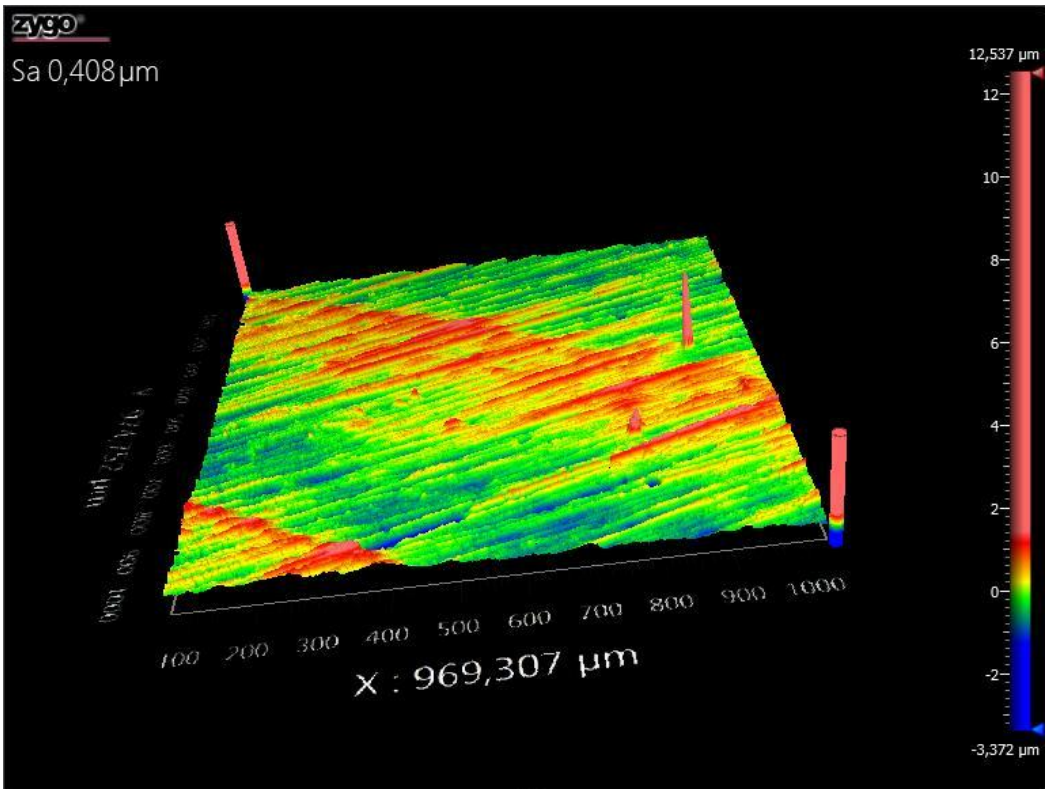


Figure 21: 3D surface topography of Replica 3 (tank lid) measured using optical non-contact profilometry. The areal surface roughness (Sa) was determined to be 0,408 µm.

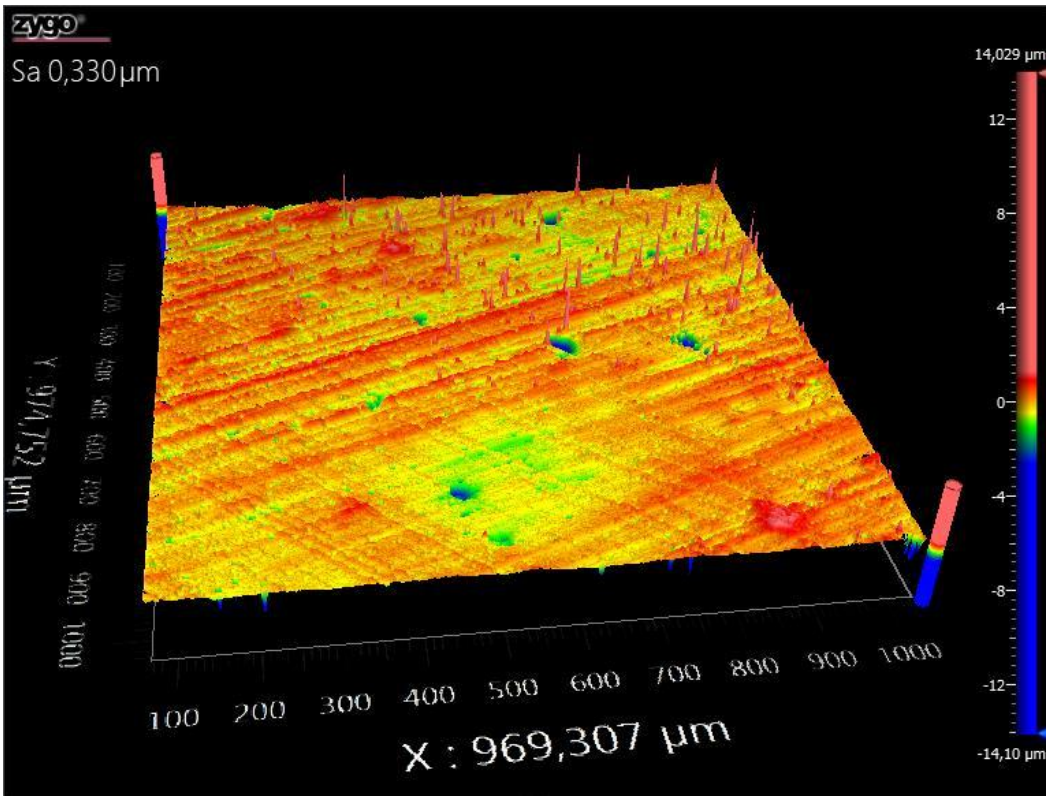


Figure 22: 3D surface topography of Replica 4 (stirrer) obtained through optical non-contact profilometry. The areal surface roughness (Sa) was measured at 0,330 µm.

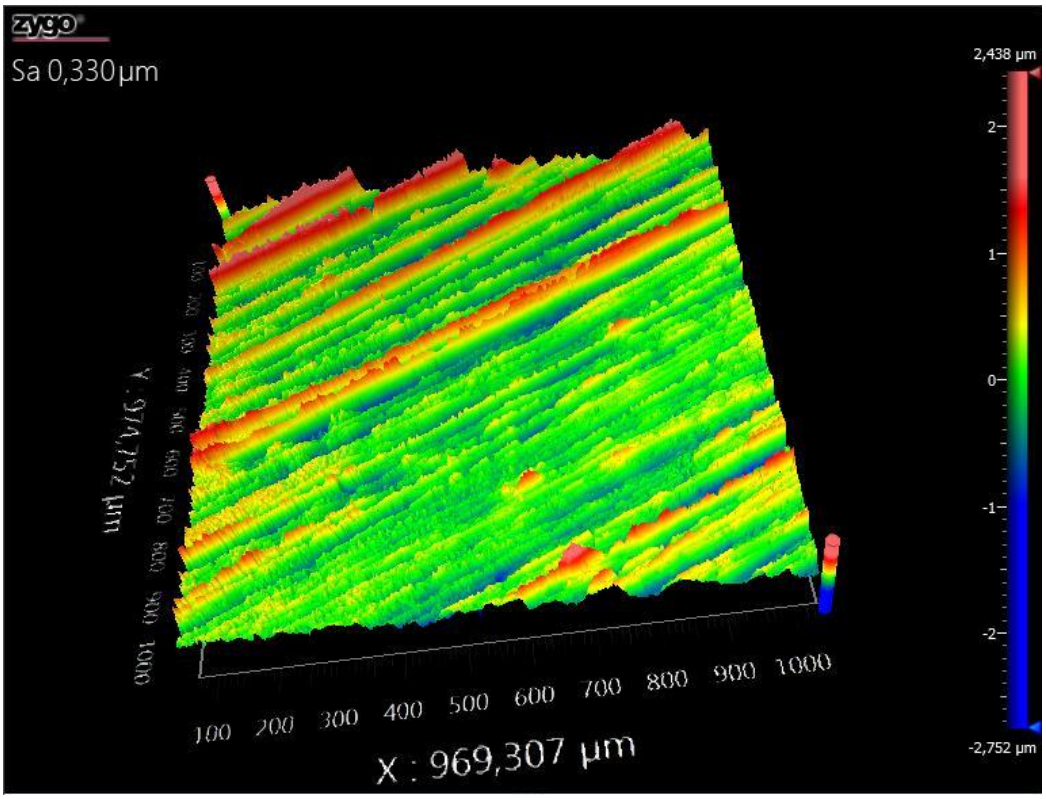


Figure 23: 3D surface topography of Replica 5 (inner tank wall) recorded using optical non-contact profilometry. The areal surface roughness (Sa) was measured at 0,330 µm.

6 Discussion

In the following section, the results from the individual test procedures are discussed in detail. Each finding is critically evaluated regarding its relevance for the cleaning verification process. Based on this, a final risk assessment is carried out to determine the overall effectiveness and reliability of the cleaning procedure under the tested conditions.

6.1 Determination of an effective Pump Pressure based on the Flow Rate

In the following, the results of the volumetric flow measurement and their implications for the effectiveness and reliability of the CIP cleaning process are discussed. Each aspect is examined individually, followed by an overall assessment regarding cleaning performance and transferability to real CIP conditions.

The measurements at MP1, MP2, and MP3 allowed for a calculated estimation of the volumetric flow to each spray ball. The results showed an uneven distribution, with spray ball 1 receiving constantly less flow than spray balls 2 and 3. This could be attributed to the pipe geometry and flow resistance upstream of spray ball 1. The imbalance may influence cleaning uniformity and should be further monitored and compared to the results from the spray shadow test.

To verify the transferability of the tests, measurements under actual CIP conditions were conducted. The results showed only minor deviations in flow rates when using hot water or a chemical disinfecting solution. The deviations remained within ±3 %, indicating that the room-temperature water tests are a reliable basis for determining the needed pump pressure and the spray ball performance.

According to the manufacturer´s specifications, a minimum volumetric flow rate of approximately 60 l/min per spray ball is required to ensure effective cleaning performance for a tank of the given size (Figures 5 and 6). As shown in the flow distribution results, this target value was achieved for all three spray balls at a feed pump pressure of 8 bar. However, additional flow measurements taken during actual CIP operations revealed small but consistent deviations from these reference values, with slightly lower flow rates observed during chemical cleaning steps and slightly higher values during hot water rinses. To account for these operational variations and ensure a robust cleaning performance under all realistic CIP scenarios, a feed pressure of 9 bar is recommended. This pressure setting provides a sufficient safety margin while remaining within equipment specifications and without causing excessive mechanical or hydraulic load to the pump.

While the subtraction method (MP1-MP2, etc.) provides an approximate flow estimation to each spray ball, it relies on the assumption of no losses or bypasses between the measurement points. During a later inspection of the system, it was discovered that a valve located directly downstream of MP1 raised concerns that it might have unintentionally restricted the flow and potentially caused a pressure drop. However, throughout the measurements, the flow signals at all measuring points remained stable and consistent through all measurements. Additionally, the flowmeter was installed by standard guidelines, maintaining the recommended straight inlet and outlet pipe lengths (10D and 5D, respectively). This ensured a stable flow profile and reliable measurement conditions, minimizing the influence of upstream or downstream disturbance, such as valves or bends. Further measurements using an alternative valve are planned to verify the results and to cross-check potential measurement deviations caused by flow disturbances or valve positioning. Determination of Spray Shadows with different Spray Ball Directions

The following sections present and evaluate the results of the riboflavin spray shadow tests, focusing on the influence of volumetric flow discrepancies, pump pressure levels, and spray ball orientations on the overall cleaning performance within the production tank.

6.1.1 Note on Flow Rate Measurements during the Riboflavin Tests

During the riboflavin spray shadow test, the volumetric flow rate to the spray balls was monitored in real time to ensure that the same volumetric flow rate was applied as in the initial volumetric flow test. However, a significant discrepancy was observed: the measured flow rates during the spray shadow test were systematically lower by approximately 30 liters per minute across all measurements, despite unchanged pump pressure, system configuration, pipe dimensions, and spray ball setup. This consistent deviation suggests the presence of a systematic measurement error rather than a process-related fluctuation. One potential cause identified was the correction factor for flow disturbances (disturbance factor), which had to be entered into the measurement software due to the proximity of an upstream pipe irregularity, such as an elbow or a reducer. In transit-time ultrasonic flow measurement systems, such as the one used in this study, disturbances in the flow profile can affect the signal path and the velocity averaging, particularly when sensor placement is close to fittings. To compensate for such irregularities, the software allows the entry of a disturbance factor that adjusts the calculated flow rate based on empirical data or manufacturer guidelines.

It is likely that the disturbance factor used during the spray shadow test was inaccurately estimated or did not correspond precisely to the actual geometry of the pipe section. As a result,

the calculated flow rates may have been systematically underestimated. Since all other parameters remained constant and because the deviation was consistent across all test conditions, this explanation appears plausible. Although this measurement error limits the comparability of flow rate values between the initial volumetric test and the spray shadow test, it does not affect the qualitative interpretation of the riboflavin test results themselves. The hydraulic cleaning conditions, which means pump pressure and system configuration remained unchanged, ensure that the visualized spray coverage during the test still reflects the actual cleaning performance under the tested conditions.

6.1.2 Influence of Pump Pressure on the Spray Coverage

The riboflavin spray shadow tests conducted in this study revealed a clear correlation between pump pressure and spray coverage within the stainless steel production tank.

The first series of tests (Tests 1–4) aimed to identify the minimum pump pressure required to achieve sufficient cleaning. A marked improvement in cleaning performance was observed as the pressure increased from 5,5 to 10 bar. At 5,5 bar, which represented the previously used pressure for cleaning, extensive spray shadows were found on several critical components, including the stirrer, the homogenizer, the inner lid surface, and around the spray ball fittings. These findings confirmed that the existing cleaning pressure was insufficient to ensure complete hygienic coverage across the tank interior.

Increasing the pressure to 8 bar significantly reduced the riboflavin residues, particularly around the homogenizer and the spray ball mounts. However, residual contamination remained on the stirrer shaft and the cups, the tank lid, and inside all inlets at the top of the tank.

At 9 bar, further improvement was observed. The tank lid showed fewer residues, and coverage around the homogenizer and spray balls improved notably. Nevertheless, the stirrer still exhibited riboflavin residues at the top and bottom, and all inlets remained partially affected.

At 10 bar, additional improvements were observed, though relatively minor. Two inlets that previously showed contamination were now fully cleaned, and no further staining was observed on the stirrer shaft and the outside of the cups. These findings suggest that increasing the pump pressure to 9 bar provides a substantial improvement, while the additional benefit at 10 bar is marginal. This indicates a potential plateau in cleaning efficiency beyond 9 bar, especially for areas that are not physically shielded from the spray. By selecting 9 bar instead of the pump's maximum capacity of 10 bar, the system also benefits from reduced mechanical load on the pump, which may help decrease wear and extend equipment lifespan.

6.1.3 Influence of different Spray Ball Orientations on the Spray Coverage

The second part of the investigation (Tests 5–7) focused on the effect of spray ball orientation at a fixed pump pressure of 9 bar. These tests were performed to evaluate whether adjusting the spray angle could eliminate remaining spray shadows identified in earlier tests.

The spray shadow test with Position 2 produced the most favorable result. The tank lid was nearly free of riboflavin residues, and four of the previously affected top inlets were now fully covered. However, the stirrer remained unaffected, showing the same residual pattern as before, changing the orientation.

In contrast, Position 3 resulted in significantly poorer coverage. Riboflavin residues on the lid increased, and none of the inlets were sufficiently cleaned. As with Position 2, the stirrer showed no improvement, further underlining its role as a persistent cleaning challenge.

In Position 4, the spray shadow on the lid shifted to the opposite side compared to previous configurations. Two of the top inlets were successfully cleaned, while others remained shadowed. Again, the stirrer showed no meaningful improvement.

Across all three tests, approximately 500 mL of riboflavin-stained water remained in the outlet area of the tank. This was consistently observed in unused outlet sections that are closed off with stoppers and therefore not connected to the drain. As a result, water cannot flow out of these areas, which may lead to liquid retention. Although these outlets are not used during production, they are part of the internal tank geometry. This creates a hygienic risk, as stagnant water in these areas reduces the mechanical cleaning action during CIP and may hinder the removal of potential residues or biofilm formation. To address this issue, it is recommended to replace the existing flat stoppers with a modified plug design that extends slightly into the outlet opening, filling the recessed section and thereby eliminating the cavity where liquid would otherwise collect. By aligning the stopper's inner contour with the tank's bottom profile, the formation of a retention zone can be prevented without altering the outlet itself. This simple adjustment would help ensure better cleaning fluid flow over the area and reduce the risk of residue accumulation.

In summary, the results show that spray ball orientation has a significant impact on localized cleaning performance, particularly at complex geometric areas like the top inlets and the tank lid. The stirrer consistently remained a problematic area, regardless of orientation, indicating possible shielding effects or limitations of the spray ball system. To further investigate these findings, the surface roughness of several tank areas, which include the stirrer, the lid, the tank

bottom, and the side wall, was measured using replica impression sampling. Since the stirrer showed persistent spray shadows and may pose a hygienic risk due to limited mechanical cleaning action, it is recommended to conduct an additional riboflavin test with 9 bar and position 2 as part of a complete CIP cycle to validate the cleaning effectiveness under fully realistic conditions.

6.2 Microbial and ATP Examination

The absence of microbial growth and ATP values below 10 RLU at all sampling points and after each production and cleaning indicates that the CIP process effectively removes contamination, even in areas identified as critical by the spray shadow test. These results were obtained using the optimized spray ball orientation that had been implemented before testing, which may have contributed to improved coverage in previously critical areas. This occurs despite the cleaning cycles being conducted at a pump pressure of 7 bar, which is below the previously determined optimal pressure of 9 bar needed for ideal spray ball operation. The findings suggest that, despite the lower pressure and limitation in flow distribution, the CIP procedure with 7 bar pump pressure achieves a hygienic standard across the tank surface. This may be attributed to the multiple cleaning steps performed during the daily CIP procedure. The spray shadow tests performed involved only a brief 30-second flush, which provides a limited snapshot of the fluid distribution and coverage. The duration was constrained by the volume capacity of the CIP tank, which does not allow for a longer flush into the production tank. In contrast, the actual CIP cleaning cycles lasted up to 20 minutes, allowing the cleaning fluid to circulate thoroughly throughout the tank over an extended period. This longer duration, combined with the continuous rotation of the spray balls, likely resulted in improved coverage and more effective cleaning, especially in areas initially identified as critical during the short spray shadow test. The tanks are used exclusively for producing a single product type, specifically liposomal dietary supplements. Although the formulation varies daily with the ingredients such as magnesium or curcumin, these differences did not appear to affect cleaning efficiency as indicated by similar ATP values and microbiological results across all the product variants. However, it should be noted that at one sampling point, a very narrow pipe section to the pressure gauge with a large dead end, a visible red product residue remained after cleaning. This suggests that in such geometrically unfavorable areas, some product can persist despite the generally effective cleaning performance. This residue is likely due to the reduced mechanical cleaning force resulting from the use of 7 bar pump pressure during the CIP process, instead of the 9 bar determined as optimal in previous tests.

A logical next step would be to repeat the spray shadow test using a full CIP cycle at 9 bar, incorporating the currently implemented spray ball orientation. This would allow a more realistic evaluation of the actual cleaning coverage under representative process conditions.

6.3 Surface Roughness

The results from the Ra and Rz measurements of the surface roughness suggest a relatively rougher surface for Replica 1, taken from the bottom of the tank. In contrast, the surface of the stirrer (Replica 4) and the other sample from the unused outlet (Replica 2) were the smoothest surfaces among all samples. When comparing it to the areal surface roughness (Sa) results, the Replica 3 had the roughest and the Replica 4 again had the smoothest surface. It is reasonable that Replica 4 (the stirrer) exhibits the smoothest surface roughness, as it was only installed six months ago and appears to be manufactured to modern hygienic standards. In contrast, the older tank components may have been produced according to different surface requirements or may have experienced surface degradation due to prolonged use. Since no manufacturing documentation is available for the tank, the exact original surface quality cannot be verified.

From a hygienic design perspective, EHEDG recommends that product-contact surfaces should ideally have a surface roughness (Ra) of $\leq 0{,}8$ µm to ensure sufficient cleanability, especially when cleaning is performed without mechanical assistance. All measured surfaces in this study complied with the EHEDG guideline limit of 0,8 µm. Although Ra values met the requirements, the Rz values provided further insights into potential hygienic risks. Unlike Ra, which reflects the average roughness, Rz describes the maximum peak-to-valley height within a sampling length. Elevated Rz values, as observed in Replica 1, may indicate the presence of deep surface grooves or machining marks, which can act as microbial retention sites. These grooves may retain product residues and moisture, increasing the risk of biofilm formation, especially in areas where mechanical cleaning force is limited.

Despite the acceptable Ra and Sa values in Replica 1 (Sa consistently below 0,5 µm), the comparatively high Rz value suggests the existence of local surface irregularities. This highlights the importance of considering Rz in addition to Ra and Sa when evaluating cleanability and hygienic risks.

Although the EHEDG guideline primarily refers to Ra values and does not explicitly specify limits for Sa, it is reasonable to infer that a low Sa value correlates with improved cleanability. This is because Sa represents an average roughness over a surface area, effectively encompassing many Ra measurements. Therefore, the low Sa values observed support the assumption that

Replica 1´s surface may be more hygienically favorable and easier to clean than the Ra values alone might indicate.

Notably, Replica 3 (lid) showed a relatively high Sa value (0,402 µm), although its line roughness values (Ra = 0,355 µm) were moderate. This underlines the relevance of combining both line-based (Ra, Rz) and areal (Sa) surface roughness parameters to obtain a more comprehensive picture of the surface topography and its cleaning behavior.

In this context, the 3D topography images (Figures 19-23) provided visual confirmation of the numerical roughness data. Pronounced grooves in Replica 1 and the structured brushed pattern in Replica 3 visually support the higher Sa and Rz values observed. In contrast, the smoother and more uniform surfaces of Replicas 2 and 4 were reflected in their flatter topography. These images contribute valuable spatial understanding and underscore the link between visual features and hygienic assessment.

Overall, the replica impression technique proved effective and delivered consistent surface detail. Minor imperfections, such as small air bubbles, were observed in one area of Replica 4. As a result, the areal surface roughness (Sa) mean value for this replica was calculated based on two measurements rather than three, to ensure data integrity. Even when considering the deviation reported for the impression technique in source [11] with Ra deviations of 6,5 %, the mean roughness values remain below the critical threshold of 0,8 µm.

6.4 Risk Assessment of the Hygienic Design Based on the Experimental Findings

To assess the hygienic design of the production tank, a qualitative risk assessment was conducted based on the results from the experimental tests. Each component or area of the tank was evaluated with regard to its potential for residue retention, microbial contamination, and cleanability.

The evaluation of likelihood and severity for each component in the risk assessment Table 19 was based on the experimental findings from riboflavin testing, surface roughness measurements, and flow rate analysis. The following rationale was applied to each area:

- Stirrer: Assigned high likelihood because riboflavin residues were consistently present in all tests, regardless of spray ball orientation or pump pressure. The severity was also rated high, as the stirrer is a product-contact surface with complex geometry that is difficult to clean effectively and may harbor microbial contamination. Despite excellent

surface roughness, ATP and microbiological results, its critical position and cleaning challenges warrant further testing under full CIP conditions.

- Top inlets: These showed medium likelihood, as spray shadows were observed in some tests, depending on spray ball orientation. Severity was also rated medium, as inlets are part of the product zone but can be adequately cleaned with optimal spray ball positioning. The absence of microbial contamination suggests that current cleaning protocols with 7 bar pump pressure are effective, but adjustments as increasing the pump pressure to 9 bar, may improve consistency.
- Inner lid: The lid exhibited residual riboflavin in several tests but showed improvements with certain orientations. Thus, the likelihood was considered medium. Severity was rated medium as well, due to direct product contact and its potential to retain residues, particularly in rougher surface areas (e.g., Sa = 0,402 µm).
- Tank bottom: Although this area had slightly higher roughness values near the EHEDG limit, riboflavin tests showed no persistent residues. Therefore, the likelihood was assessed as low and the severity also low, as the area is regularly flushed and the Sa values remained below 0,8 µm.
- Tank wall: With no riboflavin detected and consistently smooth surfaces, this area was rated low in both likelihood and severity. It is well-covered by spray and has no structural obstacles. Microbiological and ATP data confirmed its hygienic safety under current CIP conditions.
- Unused outlets: Liquid retention was consistently observed in this area (approx. 500 mL after each test), giving it a high likelihood. The severity was also considered high because stagnant water in these outlets may reduce cleaning force and harbor residues or biofilms, which directly get into the next product produced. The Sa values remained under 0,8 µm.
- Overall spray coverage: Although not individually scored, the tests showed that 9 bar is required to achieve reliable spray coverage, with only minor improvements at 10 bar. While microbiological and ATP results were generally good at 7 bar, visible residues were still detectable on swabs from critical areas. Therefore, a cleaning pressure of 9 bar is recommended to ensure consistent and thorough cleaning performance.

Table 19: Overview of Identified Hygienic Design Issues and Recommendations Based on Riboflavin and Surface Analysis Tests

Area/Component	Identified Issue	Test Evidence	Hygiene Risk	Recommendation
Stirrer	Persistent spray shadow; complex geometry	Riboflavin residues in all tests	High	Full riboflavin test under actual CIP; possible design review
Top inlets	Partial spray shadows in some spray ball positions	Riboflavin test (positions 1 and 3)	Medium	Optimize spray ball orientation to Position 2
Inner lid	Residual riboflavin, reduced with spray ball position 2/4	Riboflavin test; Sa = 0,402 µm	Medium	Maintain orientation 2; monitor microbial/ATP contamination
Tank bottom	Slightly rougher surface	Sa < 0,8 µm; Ra/Rz near EHEDG limit	Low	No action needed
Area/Component	**Identified Issue**	**Test Evidence**	**Hygiene Risk**	**Recommendation**
Tank wall	Smooth surface, no residues	All tests	Low	No action needed
Unused outlets at the bottom of the tank	Stagnant water due to the stopper cavity	500 mL liquid observed post-cleaning, Sa < 0,8 µm	High	Use recessed stoppers matching the tank bottom profile
Overall spray coverage	Coverage improved at ≥ 9 bar, slight plateau at 10 bar	Flow rate + riboflavin tests	–	Maintain 9 bar as the CIP standard.

7 Conclusion and Outlook

The following section summarizes the key findings of the study, discusses their practical implications, and outlines potential directions for future research.

7.1 Summary

The results of this study confirmed that both spray ball orientation and pump pressure significantly affect the cleaning performance in stainless steel production tanks. A pump pressure of at least 9 bar is recommended to ensure sufficient mechanical cleaning force and spray

coverage, especially in geometrically challenging areas. Although microbial and ATP values remained below critical limits even at 7 bar during standard CIP, visible residues were still detectable at critical points, emphasizing the need for a higher pump pressure. Surface roughness measurements confirmed overall good hygienic conditions.

7.2 Recommendations for action

This study, conducted on-site at PlantaCorp GmbH, provides practical insights into the optimization of CIP cleaning performance and highlights critical process parameters for hygienic design verification. The findings are not only relevant for improving internal procedures at PlantaCorp GmbH but also offer a structured approach applicable to other companies facing similar cleaning challenges in the production of sensitive liquid formulations.

Based on the results, the spray ball alignment was optimized to Position 2 shown in Table 10, and a minimum required pump pressure of 9 bar was identified to ensure 360° spray coverage and to minimize spray shadows. Additionally, specific hygiene risks, such as product residue on the stirrer and liquid retention in outlet cavities, were identified. These findings led to targeted recommendations, including improved spray ball positioning, system upgrades for higher flow rates, and further verification under real CIP conditions. In this context, the CIP system must also be adapted to allow 9 bar operation during circulation, as the current return flow is insufficient to discharge liquid from the tank as quickly as it is pumped in. Moreover, the plugs of unused outlets should be adapted to the tank's inner profile to avoid dead spaces and ensure better cleanability.

7.3 Future Research Outlook

For future investigations, a riboflavin test under full CIP cycle conditions and with the spray balls in Position 2 is recommended, especially for the stirrer area. Additional flow measurements using an alternative valve in the distribution pipe to the spray balls are recommended to identify potential flow restrictions caused by the currently installed magnetic valve. If it is confirmed that the spray balls receive higher flow rates with a different valve, the required pump pressure for effective cleaning might be reconsidered and potentially adjusted downwards, which could further reduce mechanical load on the pump.

8 Use of AI

Within this thesis, artificial intelligence (AI) was utilized for two distinct purposes: (a) translating text from German to English, (b) enhancing the language, editing, and formatting of the

manuscript. All AI-generated texts were manually reviewed and revised for accuracy. It is important to emphasize that AI was not used to generate content or to develop the arguments presented in this thesis.

AI Tools Utilized (in alphabetical order):

ChatGPT by OpenAI [20]

Grammarly Word Add-in [21]

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Appendix

Appendix I: CIP Procedure to clean the 1000L Tank after production is finished

CIP-Program				
After production has been completed: Cleaning with Sibin MT (BÜFA GmbH & Co. KG), 2%-Solution and Disinfection with o33 Aktiv 5 (BÜFA GmbH & Co. KG), 1% solution				
Step	**Duration in min**	**Water in liters**	**Temperature in °C**	**Chemicals in liters**
Tap water	-	180	-	-
Sibin MT, 2%	20	180	70	3,6
Tap water (2 times)	-	180	-	-
Tap water cycle	5	180	-	-
Hot water	15	180	90	-
O 33 Aktiv 5, 1%	20	180	-	1,8