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Quality Assurance in Light Incontinence Products

Investigating Super Absorbent Polymers and Pulp Across the
Phases of the Development Chain

Master Thesis Project in Product Development 2025

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Quality Assurance in Light Incontinence Products

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Abstract

The master's thesis investigates the procedure of specifying and monitoring the key materials Super Absorbent Polymers (SAP) and pulp in light incontinence products at Essity. The project focuses on four phases within the value chain from product development, design verification, process validation to running production. The aim was to evaluate existing procedures to identify potential gaps and opportunities for improvement.

The research approach was based on the DMAIC framework originating from the Six Sigma philosophy, integrating qualitative methods and data from semi-structured interviews, workshops with quantitative data from laboratory testing on prototype products. Statistical tools were also implemented to analyze variation and correlation and to perform capability studies.

The study identified that variation in SAP and pulp amount and distribution affects the product performance. Due to process-related influences, such as environmental conditions and technical factors, variation will always be present in the production system. Therefore, the importance of robust design strategies was highlighted together with the value of proper monitoring of SAP and pulp amount and distribution across the value chain.

Control measures based on gathered information were proposed to enhance process control and stability, emphasizing the importance of centering processes around target values rather than only specification limits. While the limited sample size and test scope restrict broad generalization, the results provide a solid foundation for further investigation and practical improvements when it comes to quality assurance. Additionally, the research highlights the value statistical tools can bring within the organization to sustain quality improvements.

Overall, this thesis contributes to a deeper understanding of SAP and pulp management in hygiene products and supports Essity's efforts to optimize product consistency and customer satisfaction through data-driven quality control.

Keywords: Quality Assurance, Super Absorbent Polymers (SAP), Pulp, Statistical Tools, Light Incontinence Products, Requirement Setting

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1

Introduction

This chapter provides an overview of the context of the project, outlining the background and the problem definition. It introduces the purpose and research questions for the project together with the delimitation.

1.1 Background

Essity is a company focused on hygiene and health, active in three different business categories [1]. These categories are Health and Medical, Consumer Goods, and Professional Hygiene. Essity develops, produces, markets and sells products such as incontinence protection, baby diapers, sanitary pads and toilet paper. Well-known brands are TENA, Libero, Libresse and Tork. Essity's purpose is expressed as "Breaking Barriers to Well-being", through creating increased awareness of the importance of hygiene and health and how it links to well-being [2]. Furthermore, Essity strives to improve care and break silence around areas such as menstruation and incontinence.

Incontinence is defined by the International Continence Society as "the complaint of any involuntary leakage of urine" [3]. Moreover, incontinence is one of the greatest public health disorders, primarily due to an aging population. On the other hand, it is not only the elderly who can be affected by the problem, it can affect anybody at any age. In addition, the severity of the problem can vary, from small amounts to large amounts of urine leakage.

Product quality is critical for ensuring the functionality, user experience, and sustainability of incontinence products [4]. A key factor affecting this is the performance of the absorbent core, which is primarily made up of two materials: Super Absorbent Polymers (SAP) and Pulp [5]. SAP is a material that is capable of absorbing and retaining large amounts of liquid, while pulp helps to distribute the liquid throughout the core. These materials have a direct impact on many of the product's essential functions, such as quick absorption, leakage security overall discretion during use. Since the amount and distribution of SAP and pulp are known to influence product performance, monitoring these parameters throughout the value chain may contribute to maintaining consistent quality.

1.2 Problem Formulation

In this project, the focus is placed on products meant for light incontinence, typically involving smaller volumes of leakage. When developing light incontinence products, it is important to understand how SAP and pulp, the two main materials of the absorbent core, are specified, verified and controlled throughout the value chain, from requirement setting, design verification, process validation to production. These materials are closely connected in the way they interact to fulfill the core's functional requirements. Understanding how

variations in their amounts and distribution may impact product quality is important. moreover, maintaining control over these parameters throughout the value chain is crucial to ensure consistent functionality and performance for light incontinence products.

1.3 Purpose and Research Questions

The purpose of this master thesis was to investigate four phases of the value chain and understand how two of the key materials in light incontinence products, SAP and pulp, are specified, verified and controlled along this chain with regards to amounts and distribution. By investigating existing quality assurance procedures, the thesis aimed to identify potential gaps and opportunities for improving product consistency.

Furthermore, the project investigated the impact of key design parameters on product functions, with the aim of understanding how to develop reliable and robust specifications. The study also explored how statistical analysis could support more robust target setting and process control along the value chain.

The purpose form the basis for the following research questions that the project aimed to answer:

- What impact do the amount and distribution of SAP and pulp have on the product functions and overall quality?
- What are the main challenges associated with controlling SAP and pulp throughout the value chain?
- How do variation and centering requirements influence process control and product performance?
- In what ways could the integration of statistical tools and methods influence and support development and quality control processes?

1.4 Delimitations

The project had several delimitations that should be considered when interpreting the results. The collection of customer needs and the process of translating these into requirements and specifications was not included in this project. However, existing customer needs were evaluated to understand how they relate to the current requirements, with focus placed on how these requirements are maintained and controlled in the current processes. Emphasis was given to examining whether the amounts and variations of SAP and pulp ensured the required product performance and compliance with established initial specifications. Improving production systems and machines was not within the scope of the project. Instead, the focus was mainly on understanding and evaluating variations that arise from the production process.

The project specifically focused on material parameters related to SAP and pulp. Other components of incontinence products, such as the topsheet, backsheet, and adhesives, were excluded from the analysis. Therefore, any potential variations or interactions involving these elements fell outside the scope of this work.

Due to time constraints, only a limited number of laboratory tests were performed. Moreover, testing was conducted on conceptual or simplified prototypes rather than on fully developed products available on the market. As a result, the findings may not fully reflect real-use conditions but can instead be regarded as indicative.

Additionally, the work was conducted over five months during the spring of 2025, and completed by mid-June. The research was carried out at Essity, under supervision from both Essity and Chalmers University of Technology. The study was also subject to confidentiality constraints, specific data and exact numerical values are not disclosed.

2

Theoretical Framework

This chapter presents the theoretical foundation of the project, addressing key aspects of incontinence as a condition and the structure and functions of incontinence products. Additionally, it includes relevant quality assurance theories to support the evaluation of a products overall quality.

2.1 Urine Incontinence

Urine incontinence is defined as the loss of bladder control that results in unintentional urine leakage [3]. Considering that the population trends to becoming older, issues with urinary incontinence will continue to grow. However, while incontinence may be associated with aging, it is a condition that can affect anybody across all stages of life.

The problems can range from occasionally leaking urine when sneezing or coughing to having an urge to urinate that is so sudden that the person doesn't make it to the toilet in time [6]. There is also a large proportion of elderly people in nursing homes who are unable to go to the toilet at all. Urinary incontinence can be divided into different categories and types depending on the nature of the problem. Some of these are stress incontinence, urge incontinence, overflow incontinence, functional incontinence, and mixed incontinence. Below, these types are described and examples of individuals with these problems are presented.

- Stress incontinence. Urine leakage due to pressure on the bladder. This can occur when an individual sneezes, coughs, laughs, or lifts something heavy. This type of incontinence can affect young women active in sports, women after childbirth, or men with prostate issues.
- Urge incontinence. A sudden and intense urge to urinate that leads to leakage. A person with this type often needs to urinate frequently, including during the night.
- Overflow incontinence. Urine leakage through continuous dripping due to a bladder that never fully empties.
- Functional incontinence. A physical or mental condition that prevents an individual from reaching the toilet in time.
- Mixed incontinence. A person experiencing multiple types of incontinence, often related to both stress and urge incontinence.

Generally, urinary incontinence is a condition that affects quality of life. There are several ways to get help with these problems, with both medical treatments but also with other solutions such as protections [3]. There are products such as liners, pads, pants and heavy incontinence products that can be used in daily life according to needs. The problem is often considered taboo, which means that the proportion of the population with the

problem is underestimated. Among adult women in the United States, over 60% reported some form of incontinence, with stress incontinence being the most common. For men, the percentage was around 30%.

2.2 Key Product Functions for Incontinence Products

Urinary incontinence, as previously explained, poses numerous challenges for individuals living with it, affecting their quality of life [3]. Therefore, incontinence products play a crucial role in supporting people's daily lives. To fulfill their purpose, these products must meet certain functions.

Leakage security and absorption of liquid is the most crucial function of an incontinence product [7]. This process can be divided into several sub-functions, such as *Inlet time*, to capture the liquid fast and absorption capacity, to keep the liquid inside the product. When these functions are met, the product is considered leakage secure, ensuring that no liquid will soil the user's clothes or the surroundings.

The dryness of a product is important for ensuring comfort and skin health [7]. Dryness means that liquid is stored and retained inside the product, creating a dry surface against the user's skin. One key function is *Rewet*, which ensures that liquid remains safely in the structure even when pressure is applied, such as during body movements or when the user sits down on the product.

Discretion is a key concern for users, as many wish to avoid revealing that they are wearing an incontinence product [8]. This leads consumers to prefer thinner, less bulky products that are less noticeable under clothing.

2.3 Key Materials in Incontinence Products

Products designed for incontinence typically consist of several layers, a top sheet (the layer in contact with the skin), an acquisition and distribution layer (ADL), an absorbent core and a back sheet (which acts as a barrier layer) [9]. Usually, an incontinence product is composed of the following materials: fluff pulp, SAP, nonwoven material, adhesives and elastics [10]. The absorbent core consists of the two materials SAP and pulp, and plays a vital role in ensuring that the liquid is absorbed, distributed and retained within the product. These materials are further explained in the following sections.

2.3.1 Super Absorbent Polymers

One of the main benefits of SAP is its capability to absorb and retain saline solution, up to 100 times their own weight [11]. The material is a cross-linked polymer, typically made from sodium polyacrylate. In its dry state, the material exists as small granules with tightly coiled polymer chains. Upon contact with liquid, they chains uncoil, expanding the molecular network, allowing liquid to be stored within the structure [12]. This reaction turns the material into a gel, effectively locking the liquid in place, providing security

against leakage. Figure 2.1 shows the gel-like state that SAP transforms into after absorbing liquid [13].



Figure 2.1: An example of the material SAP after it has absorbed liquid [13]

SAP is a material that offers several important benefits and is widely used in hygiene products such as diapers, feminine pads and incontinence products [12]. Not only does it absorb and draw the liquid away from the surface but it can also retain the fluid under pressure, such as when sitting down [5]. This helps to ensure comfort for the use but also to prevent skin irritation and infection caused by long exposure to moisture [12]. The SAP-to-pulp ratio in the absorbent core is an important factor for product performance. Pulp typically makes up the majority of the mixture in the core, however, as incontinence products trend toward becoming thinner, the proportion of SAP is gradually increasing, helping to maintain high absorption performance in a more compact form [5].

2.3.2 Fluff Pulp

The other major component in the absorbent core is pulp, also known as fluff pulp, which is made from cellulose fibers made from wood or other fibrous materials [14]. Pulp has the ability to quickly absorb liquid, enabling fast fluid intake before the SAP captures and locks the liquid in. It is highly hydrophilic, meaning it attracts and absorbs liquid, and helps distribute it throughout the core via wicking and capillary forces along the fiber network. Additionally, pulp contributes to the structural stability of the core, helping the core to stay in place and prevent cracking or shifting during use [5].

Pulp is composed of a network of cellulose fibers with airspace between them, giving the material a low density [15]. This structure contributes to a soft cushioning feel as well as adding *Thickness* to the product [16]. However, this means that the material is highly sensitive to moisture. When exposed to humidity, it can begin to swell, affecting its absorption capacity [17]. Therefore, maintaining appropriate levels of moisture both during manufacturing and storage is important to preserve the pulps absorbent performance.

2.4 Quality Assurance Theories

Quality assurance as concept refers to a systematic approach to reduce defects and to address faults across the whole value chain before they occur to improve overall product quality [18]. This theoretical framework integrates quality assurance theories to establish a foundation for analyzing and improving product development systems.

2.4.1 Deming's Philosophy of Quality Improvement

Dr. W. Edward Deming is known for his theories related to quality thinking and especially his systematic point of view [19]. He emphasizes the importance of optimizing the entire system instead of isolated parts, since individual components interact within a larger system. A critical element in achieving alignment across all parts of a system is the use of operational definitions. Deming emphasizes that these definitions, such as “acceptable” or “on time” need to be clear and well understood. Without this, data collected from different facilities or parts of the system may be incomparable or misleading, leading to inconsistent outcomes.

Another key aspect for improving a system is understanding the causes of variation, some are common, meaning they are inherent in the system and some are special, meaning they are unusual or unexpected [19]. Common causes of variation are usually stable and predictable and can be due to inadequate testing, faulty design, wrong specifications, misunderstandings and uninformed workers. A possible misstep is treating a special cause of variation as a common one. For instance, replacing machinery or a staff member due to a special cause may introduce new disruption to the system, further decreasing the quality outcome. To improve the process Deming also emphasizes the need for precise definitions of specifications. The definitions needs to increase communication between involved parties and have the same meaning for all.

Deming also identified barriers that can prevent effective quality improvement[19]. One challenge is the misunderstanding or lack of use of statistics. Managers may try to improve a process without knowing what they don't know, trying to interpret data without understanding the context. He argues that statistical expertise is essential and that decisions must be guided through data and structured experimentation. There are also human factors to consider, such as the resilience from managers to let go of control over the process, as well as the reluctance among workers to adapt to a new system.

2.4.2 Robust Design

Robust design focuses on designing systems, processes and products that are insensitive to variation [20]. The idea is to build in quality thinking into the design stage, rather than relying on correction after production. Robust design is structured into three main stages, system design, parameter design and tolerance design. System design serves as the foundation and includes customers requirements and evaluates the products intended functions, considering possible trade-offs. Parameter design focuses on identifying controllable factors that can be adjusted in order to improve quality. It's about determining parameter settings that can make the product insensitive to noise factors, such as environmental factors, machine error or production variation [21]. The next step is tolerance design and

focuses on specifying how much variation is accepted in production without compromising product quality [20]. Too tight tolerance intervals can drive up costs, while loose tolerance intervals may cause decreased quality.

In robust design, causes of variation can be due to factors including equipment differences, material variation and environmental conditions [20]. These are factors that might be hard to control during manufacturing. In contrast, controllable factors are variables that can be adjusted during design or production, such as material type or machine settings. A key concept in robust design stems from Taguchi’s method which is structured experimentation. This involves a planned series of experiments to analyze how different combinations of design parameters and noise factors influence the product’s performance. By seeing what parameters have the biggest impact on quality and determining what levels result in the most stable performance, engineers can adjust the design to achieve a more reliable product.

2.4.3 Shewhart Control Charts

Control chart is a common tool applied in statistical process control, developed by Walter A . Shewhart in the 1920s [22]. It is used to monitor production data over time and therefore the stability of a process. As presented in Figure 2.2, a control charts typically consists of a time-order plot with a center line and an upper (UCL) and lower (LCL) control limit, typically falling within ± 3 standard deviations from the process mean. The theory is based on differentiating between common causes of variation and special causes of variation. Common causes of variation are expected by the system and are the variation of the data points that still falls within the established control limits. Points falling outside the control limits indicate more special causes of variation, which should be investigated. A special cause of variation could indicate a process change, which is possibly because of assignable causes, meaning that corrective actions may be taken.

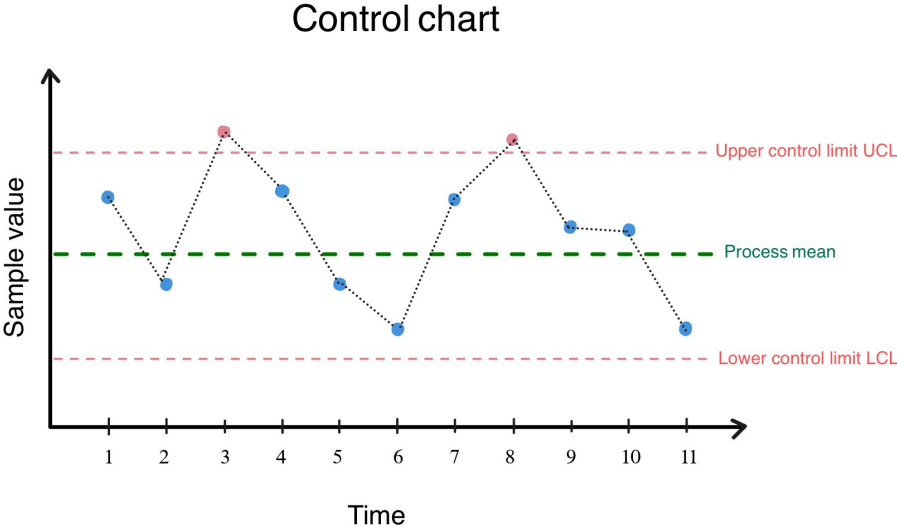


Figure 2.2: Visualization of Control Chart (Own Illustration)

2.4.4 Process Capability

Process capability is a statistical measure that is used to assess how well a process meets specified limits by evaluating its variability [23]. It is used to help organizations determine if a process can consistently produce acceptable outputs within its upper and lower specification limits, (USL) and (LSL) [24]. Two commonly used metrics to evaluate this are Process Performance (Pp) and Process Performance Index (Ppk). The Pp measures the potential capability for the process by comparing the width of the specification limits to the spread of the process. It does however not take into account whether the process mean is centered between these limits [23].

The Ppk value, on the other hand, does consider the location of the process mean relative to the specification limits, as can be seen in Equation 1[23]. Meaning that the Ppk value considers both how well the process is centered and the variation requirements when evaluating the process capability. If the process mean shifts towards one of the specification limits, the Ppk value will decrease, meaning that there is a decrease in process capability [24].

$$Ppk = \min \left(\frac{\bar{x} - LSL}{3S}, \frac{USL - \bar{x}}{3S} \right) \quad (1)$$

\bar{x} = Mean

S = Standard deviation

In practice, Ppk, together with control charts are used to monitor, control and improve processes [24]. Control charts evaluate the process stability (predictability) and Ppk evaluates the process capability, i.e, the ability of the process to produce within set specification limits. These indices help track process performance and potential areas for improvement. For the Ppk value to be valid, it is important to ensure that the data are representative of the process [25].

3

Methodology

In this chapter, the methodology applied in this project is presented. It provides an overview of the research approach together with a description of how Six Sigma methodologies were applied during the project. Finally, the specific methods used for data collection, laboratory testing and data analysis are outlined.

3.1 Research Approach

This section outlines the research design used to carry out the project. It describes the steps followed during the process of the project. The structure of the report is presented to guide the reader through the different stages of the study.

3.1.1 System Perspective on the Value Chain

The project was conducted from a value-chain perspective, to include all relevant stages of the chain, from product development to production. The main purpose was to examine the characteristics of SAP and pulp such as their amounts, distribution and how they are controlled, and to capture it in a holistic view. This included understanding the product development stage where amounts and material details are specified based on customer needs. It involved gaining an understanding of how the specifications are tested and verified and how the specifications are later transferred into the production facilities. The project investigates potential noise factors and gaps at all phases of the chain and their impact on the expected outcome. This comprehensive approach allows for a broader understanding of inter-dependencies and cause and effect relationships, helping to identify possible bottlenecks and gaps. By optimizing several steps of the value chain, rather than isolated segments, the project aims to find opportunities for improvement to enhance overall quality throughout the chain.

3.1.2 Application of the DMAIC Framework

The DMAIC framework, which stands for Define, Measure, Analyze, Improve, Control, has served as a foundational framework for the projects structure [26]. Originating from the philosophy Six Sigma, DMAIC provides a systematic approach to identifying inefficiencies and implementing solutions for achieving better quality and customer satisfaction. The method is divided into five stages, however, throughout the project, these stages have been revisited and revised for an iterative and comprehensive understanding.

- 1. Define** The initial step involved creating a problem statement that clearly defined the objective of the project and the processes that need improvement. Several meetings were held with relevant people that had knowledge that related to the scope of the project in order to gather input on the specific area that was to be investigated. An

workshop was conducted together with semi-structured interviews. Process mapping was also done to better understand the company's way of working.

- 2. Measure** To get a comprehensive understanding of the process and the specific areas to be investigated, data were collected from various sources. This data was used to analyze cause and effect relationships and to identify key metrics of interest. Laboratory tests were applied to identify key indicators and methods used to assess product quality.
- 3. Analyze** In this stage, the data collected during the measurement phase was analyzed to uncover variation and to identify underlying gaps in current control measures. Correlation and capability studies were conducted to identify patterns or dependencies in parameters or methods. Additionally, the findings from semi-structured interviews were analyzed providing further insights.
- 4. Improve** Based on the insights gathered from the previous steps, possible improvement for more optimal and robust parameter settings and tolerance design has been suggested. The findings from the earlier stages have been used to gain a broader understanding of the causes of variation and errors, enabling the creation of recommended control measures.
- 5. Control** An essential step in this framework is the control phase, which ensures accountability for sustaining the process improvement identified. During this phase, the findings and results were communicated to relevant stakeholders and product owners to ensure that opportunities for improvement are understood and implemented. Preliminary suggestions for practical control measures were also presented, along with their benefits.

3.1.3 Process and Project Layout

In this section, the process of the entire project is explained in relation to the structure of the report. The initial stages of the project focused on defining the problem and gaining a broad understanding of the company and its operations. The methodology chapter outlines the actions taken and the data collection method used throughout the process. Data were gathered mainly from lab testing but also through workshops, literature reviews and semi-structured interviews. This is summarized and presented in the result chapter. The result and findings were analyzed using statistical evaluations and qualitative insights from interviews. The analyze chapter also included proposed improvements and practical control measures with the goal of enhancing quality assurance efforts. Final conclusions and further recommendations are presented in the concluding chapter. An overview of the practical process connected to the structure of the report is presented in Figure 3.1.

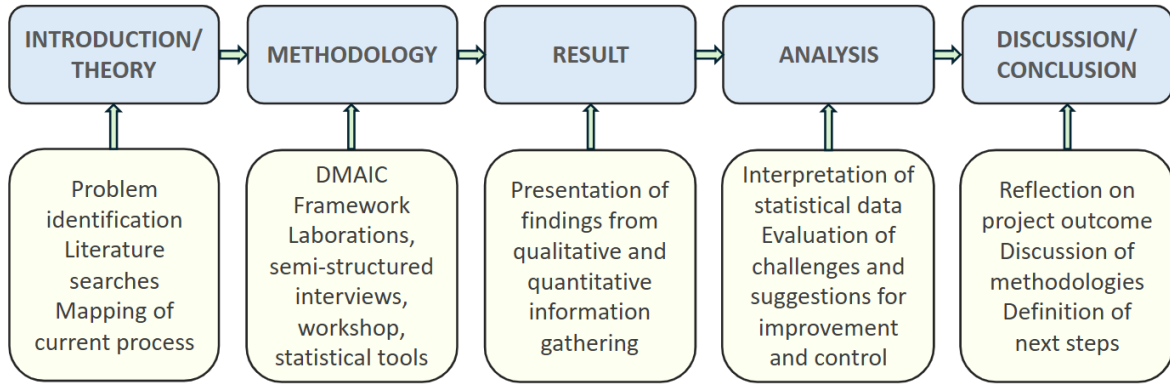


Figure 3.1: An overview of the report structure in relation to the projects process (Own Illustration)

3.2 Research Methods

In this section, the applied methods during the project will be presented. The three overarching phases of the methodology are divided into data collection, lab testing and data analysis. The details of the methods will be outlined together with an explanation of how they were conducted and implemented.

3.2.1 Data Collection

In order to ensure a broad and deep understanding of the project's problem definition, a structured data collection was carried out in the first stage. The data collection took place in several steps with the aim of gathering both qualitative and quantitative data. During this stage, interviews and workshops were held, and both internal and external searches were conducted. The methods used are presented below.

3.2.1.1 Interviews

As part of the data collection, semi-structured interviews were conducted with selected employees at the company. People from different parts of the organization were interviewed to create a broad picture, including product developers, lab engineers and those working closer to production. Interviews were used as a method in several parts of the project to capture existing processes, experiences, and challenges. Semi-structured interviews are a method based on predetermined open questions, but where it is room to discuss certain topics freely [27]. This form of interview was chosen to enable dialogue on interesting topics and to adapt the questions according to the direction the interviews took. Additionally, semi-structured interviews are a good option when a mix of qualitative and quantitative data is desired [27].

The interviews held in the beginning of the project were mainly with product developers and focused on understanding the products function and how they relate to the process of setting requirements. Interviews were also held with quality engineers at the company to understand the role of statistical tools within the company and to gain knowledge in quality practices. An interview was held with a production engineer at a prototype facility

to gain better understanding of the production process. The interviews were documented through notes, and the material was analyzed thematically to identify recurring patterns regarding needs and challenges. The questions were tailored for each interview to address the unique experience of the interviewee and to focus on the most relevant areas in relation to their role. The duration of the interviews was approximately one hour for each.

3.2.1.2 Workshop

Another method used during the data collection was a workshop, also known as the Affinity Interrelationship Method (AIM). An AIM workshop is a method for understanding and solving complex problems by breaking down the problem into several smaller parts [27]. It is a step-by-step process that ensures that qualitative data is collected. The workshop is based on a predetermined open question, where all members answer this question on their own post-it notes before the answers are grouped and further explained in several steps. The question that the AIM workshop revolved around was:

”What potential challenges may prevent the company from taking control over SAP and pulp amounts and distribution within their products?”

The purpose of the question was to get participants to not only assess current issues but also reflect on the underlying reasons with the difficulty of addressing them. This helped to understand the company’s perspectives on their own processes and quality operations. The question was formulated in an open-ended manner to encourage participants to give detailed responses. The objective of the AIM workshop was to discover a shared understanding of the root cause of a complex issue.

The workshop lasted for one hour and involved seven members of the light incontinence team at Essity, including product developers and quality engineers. Each participant was provided with a notepad and pencil to actively participate in the exercise. For 15 minutes, the participants wrote answers to the questions on notepads and then posted them on the wall for everyone to see. Following this, the responses were explained and then categorized and titled based on common themes. When the AIM workshop was completed, a follow-up session was conducted to compile everything that was discussed and revealed during the workshop.

3.2.1.3 Internal and External Searches

As a complement to the other data collection methods, a more targeted information search was conducted both internally within the company and externally in relevant databases and sources. The aim was to gather information regarding existing methods and documentation that could serve as a basis for further analysis and to ensure that the project was based on established information and expanded the knowledge base. External and internal searches are established methods for identifying relevant and existing information within a specific subject [27]. By combining internal and external sources, a wide range of perspectives is enabled.

The internal search focused on the company’s documentation, including process documents and previously conducted projects. The external search targeted scientific literature, with searches conducted via databases such as Google Scholar and Scopus. The external search formed the basis for the theoretical framework and statistical evaluation. The information

searches were conducted iteratively throughout the whole project. Search words used were: quality assurance, incontinence, super absorbent polymers, robust design, together with similar words related to the project.

3.2.2 Laboratory Testing

Lab testing is another method that has been used continuously throughout the project. The lab method used has been linked with the parameters SAP and pulp, as well as relevant methods connected to these materials. These tests have been used a way to verify amounts and distribution and product performance, in order to link lab results to specifications. Both design parameters and technical functions have been analyzed to identify potential opportunities.

Two product concepts were created with the purpose of testing their performance, referred to as product concept A and B in the results and analysis chapters. The two product concepts were prototype products designed to resemble incontinence products. They vary in both *Thickness*, Weight and SAP and pulp amount, enabling a broader perspective when evaluating the concepts. The concepts were manufactured on a prototype machine that closely replicates regular production. The goal of this analysis has been to evaluate how various quality requirements such as target, specification limits and equivalence limits can be applied and controlled. To facilitate a comparison, a simplified specification has been created from which the concept will be evaluated. The values have been set based on dialogue with product developers to find reasonable values. No exact values will be provided, instead, everything will be described as a percentage of the target.

A test plan was developed for the concepts, defining test parameters, test methods, and the number of variants to be tested in each method. The tests were carried out in a lab environment using established test methods within the company. Before the methods were carried out, training in the methods was conducted to ensure they were performed properly and consistently. All tests were documented, and photos were taken to capture interesting findings. The methods used were related to material amounts, material distribution, and functional tests.

The two different sampling strategies used were random sampling and stratified sampling with a focus on extreme values. For product concept A, a total of 240 samples were received. To capture the entire population's spread of high and low SAP amounts, stratified sampling was chosen as the method. Stratified sampling involves selecting variants from subgroups based on relevant parameters, ensuring that extreme values and thus critical cases are included in the testing[28]. This involves dividing the population, in this case based on Weight. Thereafter, products were randomly picked from each group. This sampling strategy ensured that extreme values such as low and high weights, but also intermediate weights were included in the testing. Through this, a good conclusion about the current state and variations could be drawn.

For product concept B, random sampling was used, where products were randomly chosen from the bag. Random sampling means that a population is represented by a random selection of test variants [28]. By distributing the selection randomly, it is ensured that the result is not affected by conscious preferences and systematic errors. However, there is a risk that some extreme values are missed.

The number of concepts tested for each method was considered for both concepts. For both concepts, a sample size of 24 was used as the standard for most lab methods, however, when time constraints limited testing, a reduced sample size of 10 was applied instead. Exceptions were when measuring Product Weight where 240 samples were tested for concept A and 100 for concept B. Additionally, the measurement for *Thickness* had a smaller sample size for both concepts due to time constraints.

The laboratory procedures will be described in detail in the result section, alongside the execution and the outcomes, to better connect the results in relation to how the tests were performed.

3.2.3 Data Analysis

The collected data from interviews, workshops, internal/external searches and lab tests were analyzed using a combination of qualitative and quantitative methods. The purpose of the analysis was to transform the collected data into structured insights.

3.2.3.1 Qualitative Analysis

Qualitative data, such as collected data from semi-structured interviews, results from the AIM workshop, and information from internal and external searches, were analyzed using qualitative methods. Initially, thematic analysis was used, where recurring themes were discovered and listed. These themes were further broken down into various cause-and-effect analyses, where Quality Function Deployment (QFD), Process mapping, P-diagrams, Fishbone diagrams and Design Failure Mode and Effects Analysis (DFMEA) were used as tools.

QFD was used as a tool to identify relationships between customer needs, technical functions, and design parameters[29]. QFD is a method where, for instance, customer needs are listed on one axis and technical requirements on the other. The relationship between individual parameters is assessed and weighted, making it possible to prioritize which technical functions have the greatest impact on customer satisfaction. The grading was based on a numbering system of 1, 3, or 9, where 9 indicates the strongest impact. The grading criteria are further detailed in the results, reflecting the knowledge gained throughout the process and the insights from interviews and workshops.

Furthermore, process mapping and P-diagrams were used as tools to identify and visualize the process and potential causes of variation [26]. Process mapping was used to describe the development flow, where an overall picture described the different phases of the value chain. A process mapping is a good tool to identify the flow of events in a process as well as inputs and outputs in each step of the process. Based on this comprehensive process map, separate P-diagrams were established for each individual phase of development. These diagrams are used to systematically identify factors affecting each step, including controllable parameters, uncontrollable parameters, failure modes, and desired outcomes.

Fishbone diagrams were used to structure and visualize cause-and-effect relationships between identified problems and their possible causes[26]. Fishbone diagrams are a method in which everything starts from the main problem, and the causes of the problem are divided into categories such as people, machine, material, method, environment, and measurement. Each category of causes is then broken down into underlying causes.

Another method that was used during the qualitative analysis was a DFMEA. A DFMEA is a risk analysis method used to identify and analyze potential failure modes in a products design by evaluating potential failures in individual components or materials, their causes, and consequences [30]. Each potential failure was graded based on severity, occurrence and detectability. Severity describes the impact on product quality and customer satisfaction should the failure mode occur, rated from 1 (not severe) up to 10 (very severe). Occurrence explains the likelihood of the failure mode happening, with 1 being unlikely and 10 being very likely. Detection indicates the probability that the current control system will identify the failure before it reaches the next process step, with a lower value indicating a higher chance of detecting the issue. Together these form the Risk Priority Number (RPN), where a higher value indicates the need for investigations and improvement.

3.2.3.2 Quantitative Analysis

Quantitative data from lab testing and existing data were processed using Excel and statistical tools. The software Minitab was used as a statistical tool to analyze the collected data. The purpose of the quantitative analysis was to identify patterns, variations, correlations and significant differences between the different product concepts. Depending on the data type and objective of the analysis, various tools in Minitab were used. The following section outlines the main statistical tools used in this project.

Gage Repeatability and Reproducibility (Gage R&R) was a method used to perform a Measurement System Analysis (MSA) on specific methods, such as *Thickness* measurement and Weight measurement. Gage R&R is used to assess the reliability of a measuring instrument [26]. The analysis shows the proportion of total variation due to measurement uncertainty and whether this uncertainty comes from random causes (Repeatability) or special causes (Reproducibility). When conducting a Gage R&R study, it is essential to compare the results against established acceptance criteria. Table 3.1 below outlines these criteria, their threshold values, and their interpretation [26].

	Contribution(%)	Total Variation(%)
Marginally Acceptable	< 9%	< 30%
Good	< 4%	< 20%
Excellent	< 1%	< 10%

Table 3.1: GR&R Acceptance Criteria

Histograms were used to visualize the distribution of measured values. The graph in the histogram can show the mean and variation of a data set [26]. Vertical lines can be used to indicate target values, set specification limits for maximum and minimum values, and equivalence limits if these exist. The histograms provided a good overview of the data distribution and facilitated the assessment of normality, spread, and deviations from specifications.

Analysis of Variance (ANOVA analysis) was another tool used. ANOVA analysis is a method used to examine differences in mean values between groups and to determine whether a specific factor has a significant impact on the mean value of a response or not [26]. ANOVA enables an objective comparison and reduces the risk of visual misinterpretations.

Regression analysis was also used to examine relationships between. Regression analysis provides a predictive model that helps identify and understand significant factors influencing the results [26]. To complement this analysis, factorial plots were employed to visualize interactions and main effects, making it easier to interpret complex relationships in the data.

Furthermore, capability analysis was used to assess of the lab results performed in relation to the defined specification limits. As part of this analysis, Ppk was a statistical measure applied to evaluate how well the process performs in relation to its specification limits[26]. This helped to support a more data-driven understanding of the process behavior in relation to quality expectations.

4

Result

This chapter presents the results of the thesis, structured according to the various phases of the value chain highlighted in this study. It begins with an overview of the current state, describing each phase, from product development and design verification to process validation and ongoing production, and their current practices. The chapter then follows the sequence of these phases, detailing the activities done within each part in relation to the project. A cause-and-effect analysis is presented to provide insights into the product development phase. Next the design verification process is explained, including the results from laboratory tests conducted on test concepts. The process validation phase is then presented, focusing on the relevant validation measures involved together with a root-cause analysis. Finally, the ongoing production phase is described, highlighting the current process and the quality practices employed.

4.1 Current Situation

This section provides a comprehensive overview of the current situation, detailing the existing procedure from product development, design verification, process validation and running production. This serves as a foundation for identifying potential areas for improvement. The information presented in this chapter is based on insights from semi-structured interviews, workshop and internal research. Several mentioned similar challenges and insights, contributing to a broad understanding of the current situation. An overview of the value chain, from a high-level perspective is illustrated in Figure 4.1. This project will primarily focus on the product development, design verification, process validation and running production, as highlighted by the yellow boxes. Meaning, the process of translating customer needs into a *Requirement specification* will not be a central focus in this report and is seen as input to the phases analyzed in this study.

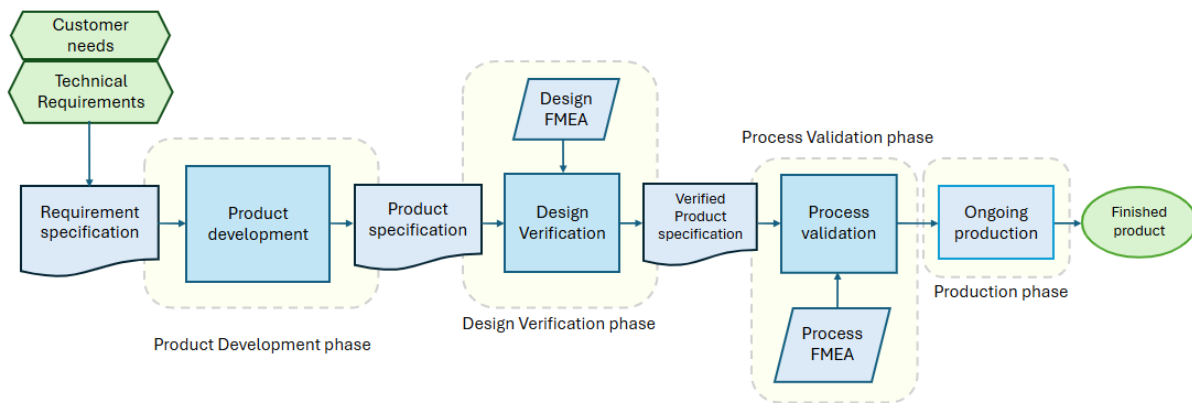


Figure 4.1: Schematic overview of the value chain (Own Illustration)

4.1.1 The Product Development Phase

In the product development phase, the *Requirement specification* serves as a foundation and input when starting to develop the design and *Product specification*. During the design stage, initial target values, centering and variation requirements for design parameters, like SAP and pulp levels are determined.

A common theme in the interviews was the emphasis on setting clear and specific requirements in the *Requirement specification*. These requirements form the basis for the *Requirement specification* which is handed over to production. This helps to not only ensure that customer needs are properly addressed, but also that these are accurately communicated to production for correct implementation. Anything not clearly specified in the *Requirement specifications*, *Product specifications*, and other documents will not be adhered to and implemented by the production. Therefore, using proper specifications as a tool to improve control and quality was something the interviewees highlighted.

The design solution developed is assessed to identify potential failures throughout the development process. The interviewees highlighted that the process is complex, making it crucial to analyze and consider all steps. They emphasized the importance of clear and precise communication at all parts of the development process, in order to reach high quality. Additionally, the interviewees explained that it is important to clarify and establish clear areas of responsibility early on. This is particularly important for ensuring that areas such as following up on the correct SAP and pulp levels are properly managed, preventing any omissions. Responsibilities are distributed across several teams working together. The Innovation team is responsible for generating concept ideas. These concepts are then developed into producible products by the product developers in the R&D department. The Technology team ensures that the necessary machinery is in place to produce the developed products, after which the Manufacturing team takes over for full-scale production. This means that understanding the cross-functional perspective can help R&D and the developers to make better-informed decisions by considering both upstream and downstream interfaces.

In Figure 4.2, the primary process steps are outlined by the blue boxes in the middle, together with the input and output marked by the dark blue boxes. The green boxes represent the control measures that are applied to manage these steps. The pink boxes highlight noise factors, influences that may introduce variation or uncertainty into the process. The orange box represents a potential failure mode that demonstrates what could go wrong if the process steps are not properly monitored.

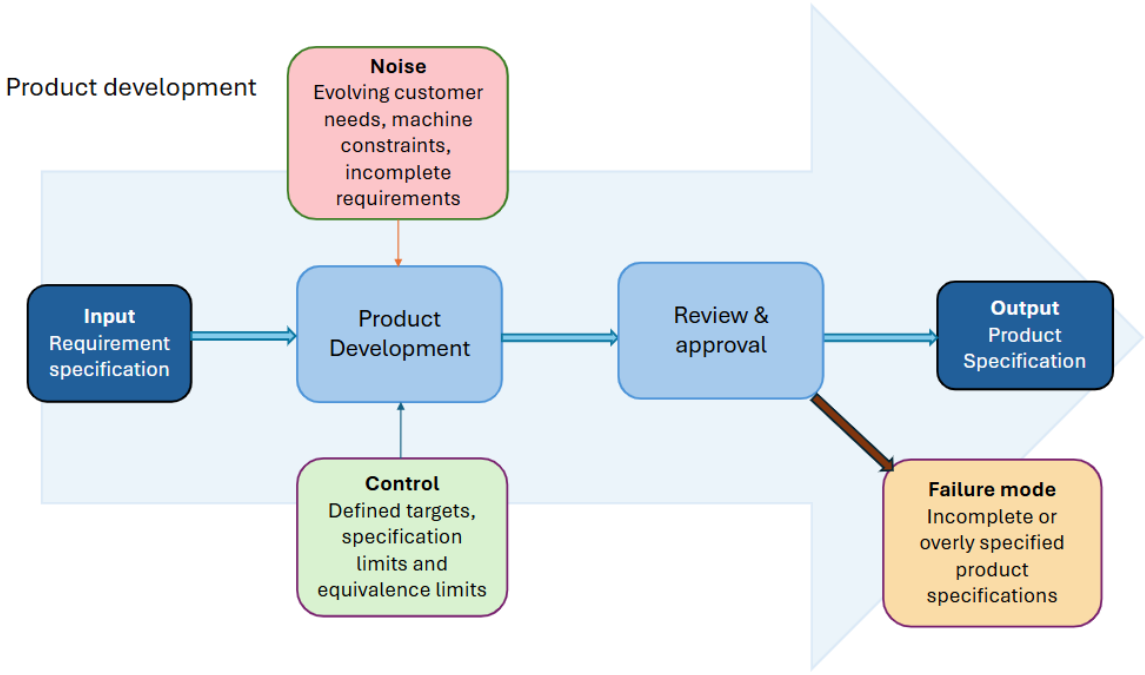


Figure 4.2: Process map of the product development phase (Own Illustration)

4.1.2 The Design Verification Phase

The *Requirement specification* is received as a design input in this phase. During this stage, a DFMEA is conducted to identify potential failure modes and areas of concern with the design. Based on this, a design verification plan is developed and implemented. The activities outlined in the plan depend on the specific areas intended for verification, such as changed design parameters, impacted technical requirements and claims made about the product. When the design solution is verified against the technical requirements, the output from this stage is a verified *Product specification*.

During the workshop, the risk of focusing more on functional parameters and less on design parameters was highlighted. For instance, when evaluating absorption properties it is important to also ensure that the correct amount of SAP and pulp are specified as well. The product is currently viewed and tested as a whole, potentially making it difficult to know what exactly is causing variations in the product. The process map for the design verification phase is presented in Figure 4.3.

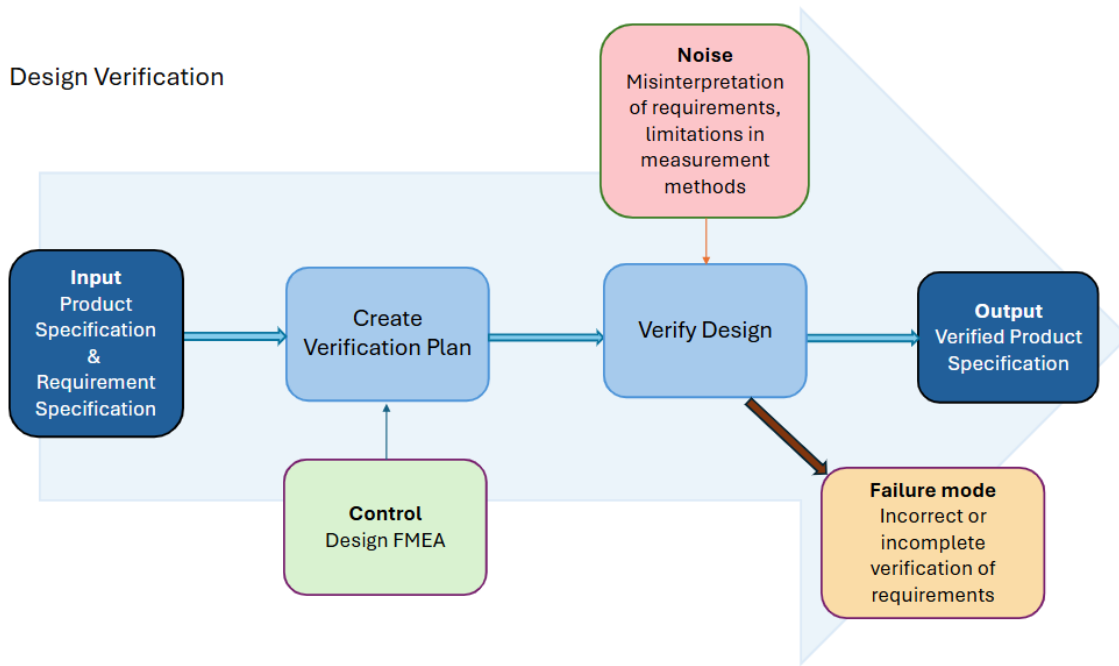


Figure 4.3: Process map of the design verification phase (Own Illustration)

4.1.3 The Process Validation Phase

An important part of the development chain is the transition from product design to running production, where process validation is a key intermediary step for this. The objective of this stage is to evaluate whether the production system can produce according to the verified *Product specification*. The process step for this phase is outlined in the process map in Figure 4.4. The extent of the validation activities depends on the risks and potential failure modes associated with producing the product. The process validation stage includes creating a clear validation plan, outlining what will be tested and how. Secondly, all equipment and systems are validated to ensure that they are installed correctly and meet the standards. Before executing the process validation plan, all objectives related to quality are set. The plan is then executed and evaluated to see if the process can meet quality and performance standards. In this phase, a validation method (referred to as SAP Validation Method 1) is implemented to calibrate the machines and ensuring that correct amount of SAP is applied to the product.

Interviewees have indicated that if variations in SAP amount are present, it is believed to be reflected on variation in the overall product weight. They also expressed that there may be certain challenges in controlling and ensuring the accuracy of SAP and pulp amounts and distribution.

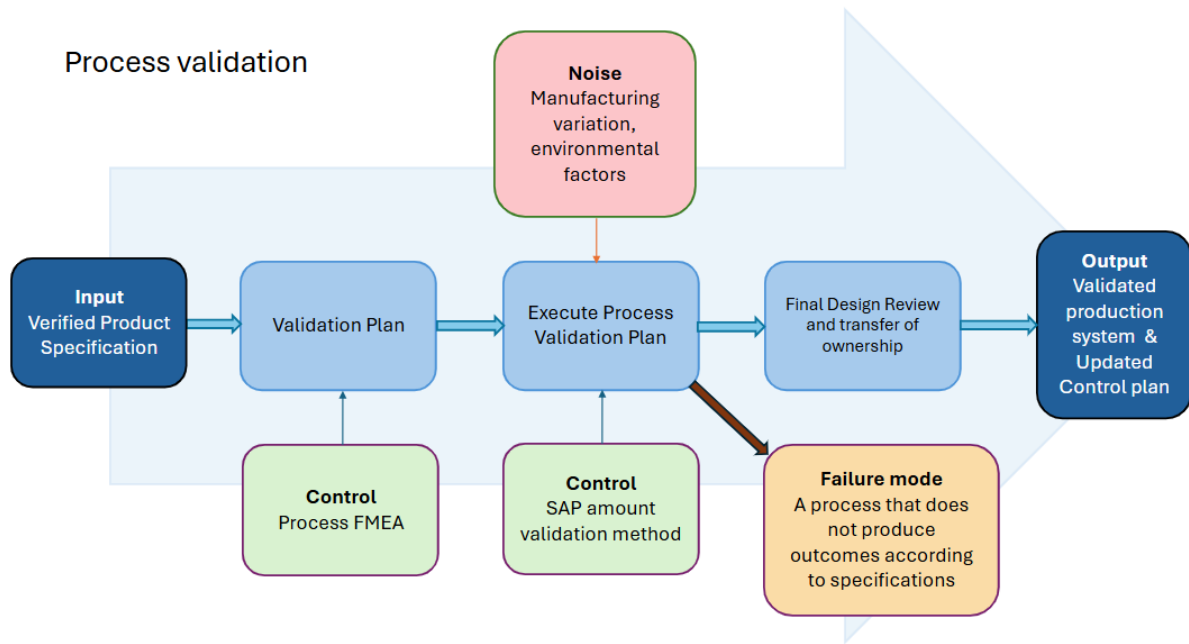


Figure 4.4: Process map of the process validation phase (Own Illustration)

4.1.4 Running Production

Once the design verification and process validation phases are successfully completed, the product is ready for production. A Device Master Record (DMR) is handed over to production, that includes a comprehensive compilation of all documentation and specifications required to manufacture a product. Included in the DMR are Standard Operating Procedures (SOP) that outlines the specific procedures and tasks that must be performed.

During production, products are periodically tested to ensure they meet the *Product specifications*. The product developers receive reports monthly for measured parameters during running production. The interviewees explained the importance of having a proper control plan in place with relevant sample size and frequency for testing. The interviewee also highlighted potential risks, particularly related to technical challenges during running production. SAP and pulp are mixed simultaneously in a mill using turbulent airflow and later sprayed onto the product. A full explanation of the manufacturing process is presented in Chapter 4.5.1. The interviewees explained that there is always an ongoing effort to develop and build better machines. However, variations will always be present, making it essential to identifying the underlying causes for manufacturing variation and, in parallel, seek robust design solutions that are less sensitive to manufacturing noise. During the workshop, the cost of continuous monitoring of SAP and pulp amounts and distribution was discussed, as well as the importance of an aligned view of how to interpret *Product specifications*. The process map for running production is presented in Figure 4.5

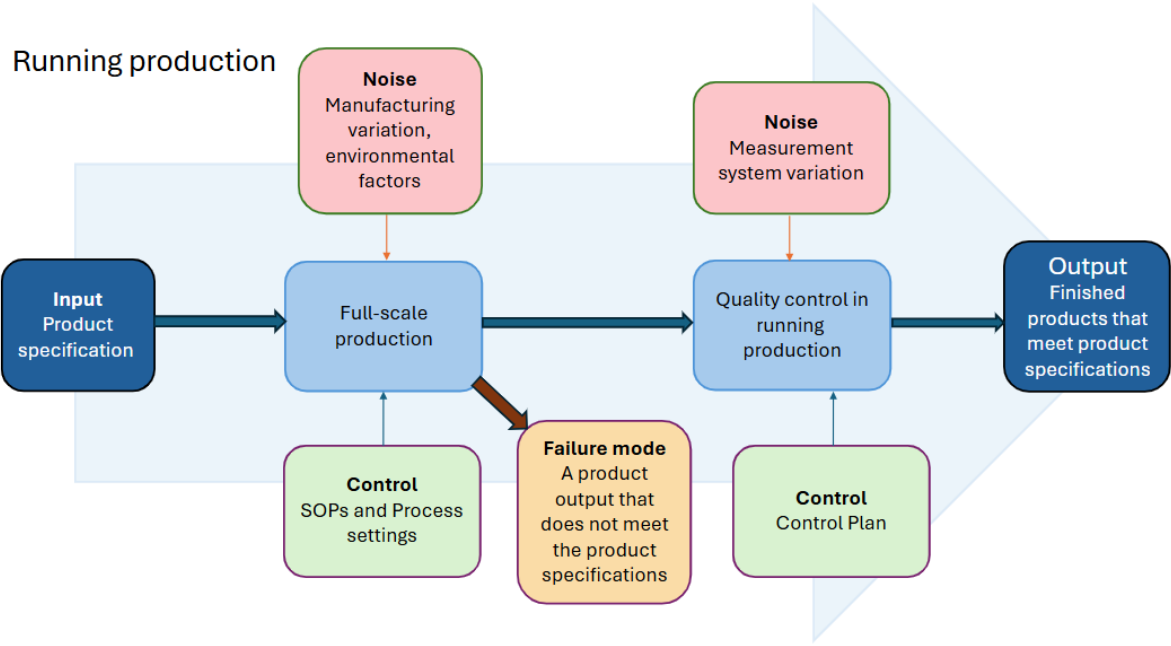


Figure 4.5: Process map of running production (Own Illustration)

4.2 The Product Development Process

This chapter presents a systematic review of the parameters used in this project to support product development. It begins with a fundamental description of some of the most relevant customer needs related to SAP and pulp. Followed by a derivation of product functions and finally the design parameters, which constitute the actual factors for the design output. To clarify the relationships between needs, technical requirements, and design parameters, a QFD is presented. Finally, lab results are analyzed to explain and demonstrate the actual impact of the design parameters on product functions. It is of interest to concretely see the consequences of variation in SAP and pulp amounts and distribution. Furthermore, measurement systems used within the company to evaluate design parameters and technical requirements, as well as the precision of the measurement systems, are presented.

4.2.1 Identification of Key Parameters for Incontinence Products

During the development of a product, the functionality and design are always based on the user's needs. It is from the user's needs that the technical requirements on product functions are determined. The technical requirements are then used as design input to determine a design, where the design parameters become the design output.

For an incontinence product, there is a wide range of needs, however, for this project, three overarching needs related to SAP and pulp have been selected for further examination. The needs included were based on both interviews and the theoretical framework. The technical requirements are in the next step a translation of the customer's and user's perceived needs into measurable and verifiable properties. Based on the technical requirements, the design parameters are determined. These parameters are the design choices of the product developer. It relates to construction and often involves material choices and amounts. In Figure 4.6 below, the dimensions are listed.

Customer needs		
N1	Leakage security	To feel secure in everyday situations without fear of discomfort due to urine leakage.
N2	Dryness	To feel clean, dry and comfortable during the use, without irritation or moisture against skin.
N3	Discreetness	To feel discreet and unnoticeable when wearing a product in everyday situations.
Technical requirements (design input)		
T1	Inlet time	How quickly the liquid is absorbed into the product
T2	Rewet	How much liquid returns to the surface when pressure is applied
T3	Absorption capacity	The amount of liquid that the product can absorb
T4	Thickness	The physical thickness of the product
Design parameters (design output)		
D1	SAP amount	The amount of Super Absorbent Polymers in the product
D2	Pulp amount	The amount of Pulp in the product
D3	SAP distribution	The distribution of SAP in the product
D4	Product weight	The total product weight
D5	Thickness	The physical thickness of the product

Figure 4.6: Key parameters for incontinence products

4.2.2 Quality function deployment

In order to understand the relationships that exist between the three dimensions described in the previous chapter, two QFDs were developed based on information gathered through interviews and the theoretical framework. One describes the relationships between the customer needs as a function of technical requirements. Furthermore, the technical requirements are broken down as a function of product design parameters. The functions can be described as follows, N stands for needs, T for technical requirements and D for design parameters.

$$N_x = f(T_x) \quad (2)$$

$$T_x = f(D_x) \quad (3)$$

In the QFD diagrams below, the strength of the correlation between different elements is rated. In this case, the numbers 1, 3, and 9 are used to indicate the strength of the correlation, where 1 indicates a low, 3 represents a medium, and 9 means a strong correlation. There is also a case where the box is left empty, indicating that no correlation between the parameters can be drawn. The relationship ratings are presented in Figure 4.7 below.

Relationship:			
9	3	1	
Strong	Moderate	Weak	None

Figure 4.7: Importance rating for the QFD

The QFD diagram explaining the relationships in Equation 2, how the technical requirements contribute to customer needs, is presented in Figure 4.8 below. The importance rating describes from 1-5 which user need is the most important, where 1 is the least important and 5 is the most important. The rating is based on the previously presented theory as well as knowledge that has been gained during the project. Of the three presented needs, *Leakage security* is the most important need to fulfill, followed by *Dryness* and then *Discreetness*. On the other hand, it should be kept in mind that the rating can vary for different products and purposes.

As can be seen in Figure 4.8, *Leakage security* is strongly related to *Inlet time* and *Absorption capacity*. A fast *Inlet time* ensures that the liquid is removed from the surface quickly which reduces the risk of leakage. A high *Absorption capacity* is essential for capturing and retaining liquid which prevents leakage. *Dryness* is mostly correlated with *Rewet*, since low *Rewet* keeps the surface dry. *Discreetness* is mostly correlated with *Thickness*, since a thicker product may be more visible through clothing. The Table shows that *Absorption capacity* has the highest technical importance score. However, all the technical requirements serve a critical role in the product and are often interrelated, highlighting the need to consider them collectively.

Customer Needs vs. Technical Requirements					
Importance rating	Customer Needs ↓	Technical Requirements →			
		T1. Inlet	T2. Rewet	T3. Absorption Capacity	T4. Thickness
5	N1. Leakage security	9	3	9	3
4	N2. Dryness	3	9	3	3
3	N3. Discreetness	1	1	3	9
Technical importance score		60	54	66	54
Importance %		26%	23%	28%	23%
Priorities rank		2	3	1	3

Figure 4.8: QFD 1 - Customer needs and Technical requirements

A second QFD diagram, which presents the relationships in Equation 3, how the design parameters contribute to the technical requirements, is presented in Figure 4.9 below. In this diagram, the technical requirements are also rated based on importance, where *Inlet time* and *Absorption capacity* are considered the most important, which also emerged from the previously conducted QFD. Figure 4.8 presents that SAP amount is a prominent driver of *Rewet* and *Absorption capacity* since it is the main material that can retain large volumes of liquid. The Pulp amount poses a correlation between *Thickness* since the pulp is the main material that adds *Thickness* to the product, therefore, product *Thickness* will also be further investigated as the amount and distribution control of the pulp is to some extent encompassed by *Thickness*. The Distribution of SAP is correlated with *Absorption capacity* and *Rewet* and helps to ensure that the liquid is captured. The

diagram also shows a strong correlation between *Thickness* and *Inlet time*, as a thicker product allows the liquid to pass through and spread within the product more quickly. SAP amount, Product Weight and *Thickness* receive the highest importance scores due to their correlation with different technical requirements.

Technical Requirements vs. Design Parameters						
		Design Parameters →				
Importance rating	Technical Requirements ↓	D1. SAP amount	D2. Pulp Amount	D3. SAP distribution	D4. Product Weight	D5. Thickness
5	T1. Inlet time	3	3	1	3	9
4	T2. Rewet	9	1	3	3	3
5	T3. Absorption Capacity	9	3	3	9	1
4	T4. Thickness	1	3	1	3	9
Technical importance score		100	46	36	84	98
Importance %		27%	13%	10%	23%	27%
Priorities rank		1	4	5	3	2

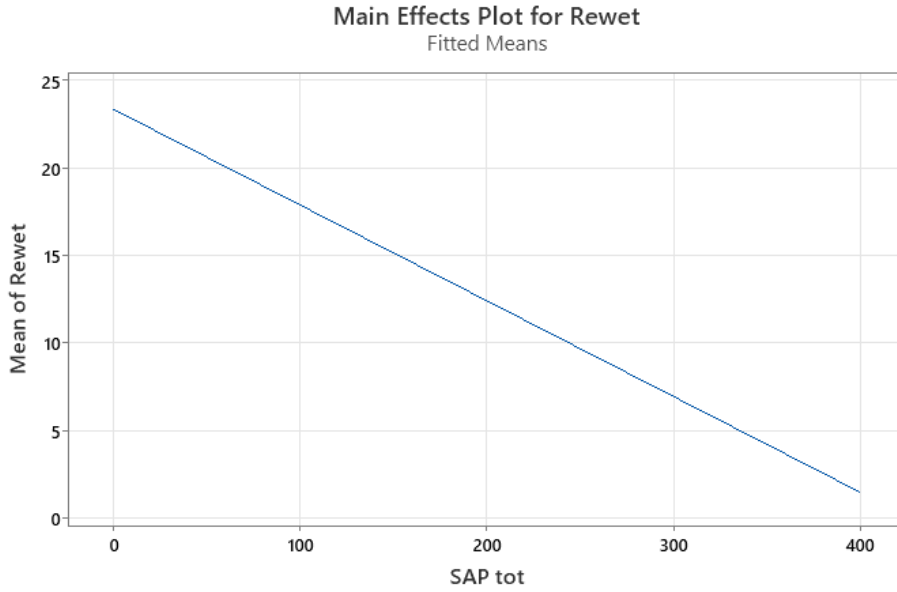
Figure 4.9: QFD 2 - Technical requirements and Design parameters

4.2.3 Correlations Between Design Parameters and Technical Requirements

In this chapter, the impact of SAP amount and *Thickness* on the product functions *Inlet time* and *Rewet*, will be presented in more detail. Both main effects and potential interaction will be analyzed to identify their impact on the product’s functionality. The two design parameters, SAP amount and *Thickness*, were chosen for further analysis as they had a high technical importance score in the QFD diagram, but also because they are interesting to study from a specification perspective. The decision to examine only these was based on the strong correlation shown between the selected design parameters and technical requirements in the QFD diagram but also because of existing data available. When studying *Inlet time*, two different times are measured. The first one involves applying liquid to a concept and measuring how long it takes for the liquid to disappear from the surface of the product. Then, the product is dosed a second to determine the *Inlet time* for a second dose.

4.2.3.1 SAP Amount Correlations

In this section, the correlation between SAP amount and the two technical functions, *Rewet* and *Inlet time*, will be presented. In Figure 4.10, the relationship between SAP amount and *Rewet* is shown, the higher the amount of SAP in a concept, the lower *Rewet*. With an SAP amount of 400 grams per square meter, the *Rewet* is as low as 2g, while for a concept without SAP, the *Rewet* is up to 25g.



All displayed terms are in the model.

Figure 4.10: Correlation between SAP amount and *Rewet*

The relationship between SAP amount and the *Inlet times* can be seen in Figure 4.11, where the correlation shows that the higher the SAP amount, the faster the *Inlet time*. It is especially true for *Inlet time 2*, seen on the right side. Where an even steeper curve can be observed for the significance of SAP amount, indicating that the SAP amount plays an even greater role for the second *Inlet time*.

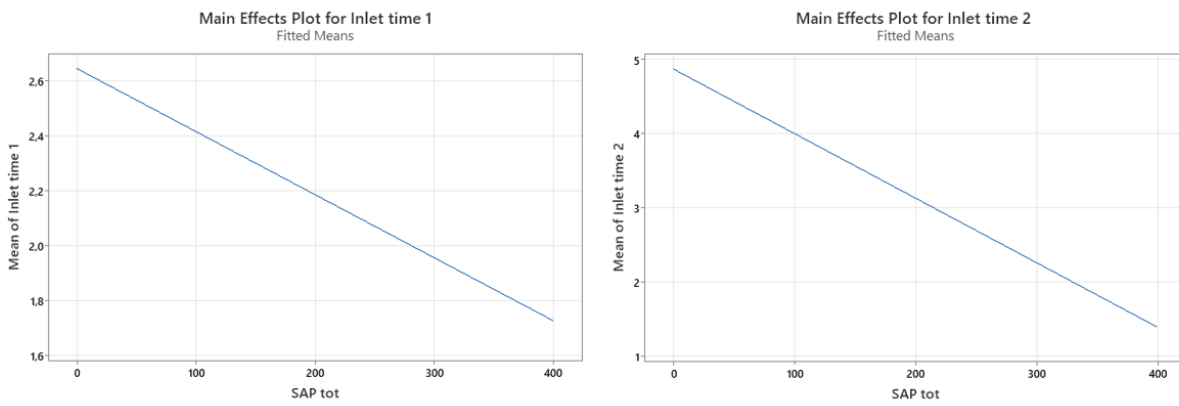


Figure 4.11: Correlation between SAP amount and *Inlet time*

4.2.3.2 Thickness Correlations

For *Thickness*, the relationships with *Rewet* and *Inlet time* are presented below. In Figure 4.12, the relationship between *Thickness* and *Rewet* is shown. It can be seen that the thinner the product, the lower the *Rewet*.

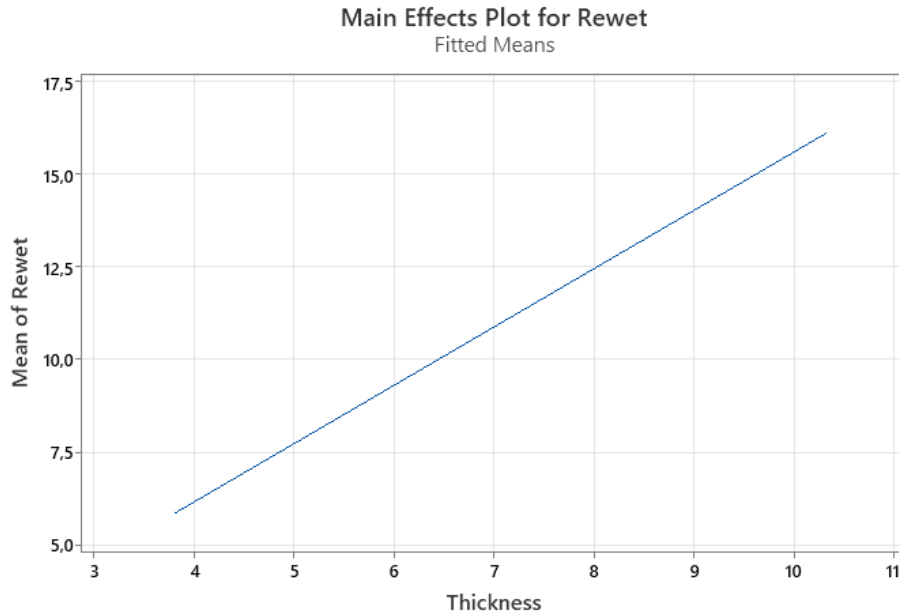


Figure 4.12: Correlation between *Thickness* and *Rewet*

Figure 4.13 describes the relationship with the *Inlet times*, showing that the thicker the product, the faster the *Inlet time*. The same relationships applies for the two different *Inlet times*. *Inlet time* and *Rewet* are therefore in conflict, one function improves with a thin product while the other improves with a thick product. To optimize these functions, careful consideration is required to find a balanced solution.

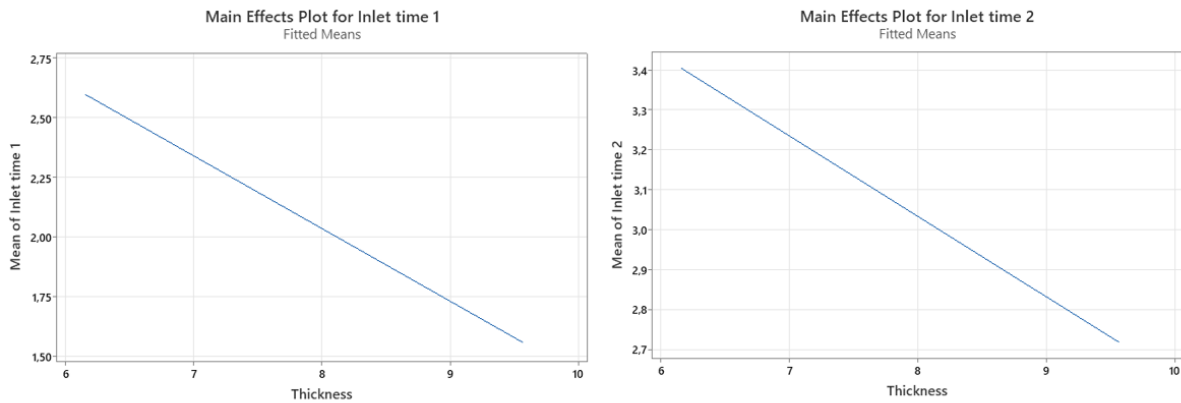


Figure 4.13: Correlation between *Thickness* and *Inlet time*

4.2.3.3 Interaction Effects Between SAP Amount and Thickness

In addition to the main effects of SAP amount and *Thickness* on *Rewet* and *Inlet time*, interaction effects can also be observed. The interaction effect of SAP amount and *Thickness* on *Rewet* can be seen in Figure 4.14 below. In the lower left quadrant, the results show that the higher the amount of SAP in a concept, the less impact *Thickness*

has. With a lower amount of SAP, *Thickness* plays a larger and more decisive role in *Rewet*. The red curve in that quadrant represents a *Thickness* of 10.33mm, while the blue curve represents 3.82mm. The upper quadrant describes the same relationship, showing that for a concept with no SAP at all, *Thickness* plays a significant role. When there are high amounts of SAP in a concept, *Thickness* has less impact. In this figure, the blue line represents no SAP, and the red line represents 400 grams per square meter of SAP.

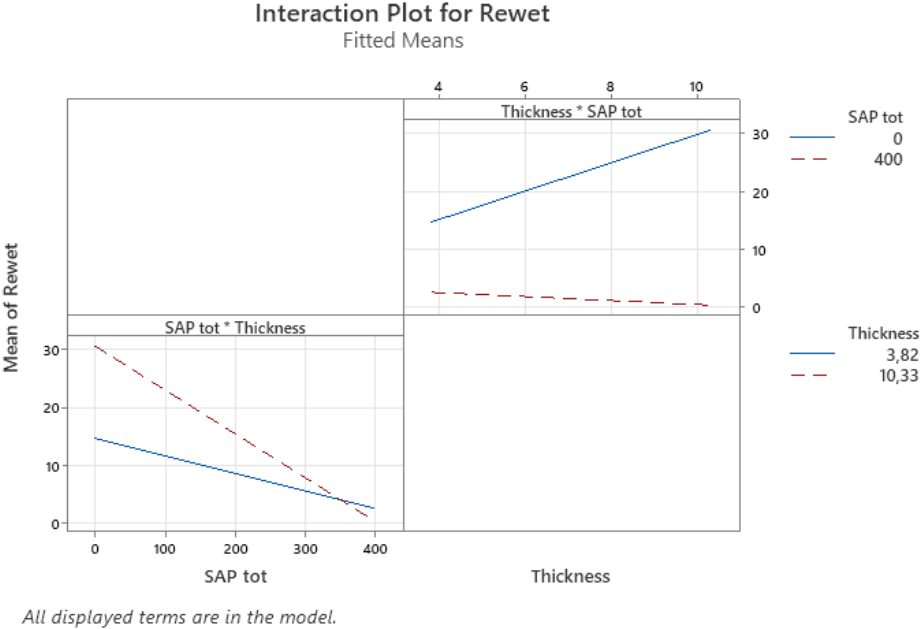


Figure 4.14: Interaction effects for *Rewet*

The interaction effects for *Inlet time 1* can be seen in Figure 4.15. It is evident that when the SAP amount is low, *Thickness* does not play a role in improving the *Inlet time*. *Thickness* has the most impact when the SAP amount is simultaneously high, then a thicker concept performs better. For a thin concept, the SAP amount does not significantly affect a faster *Inlet time*.

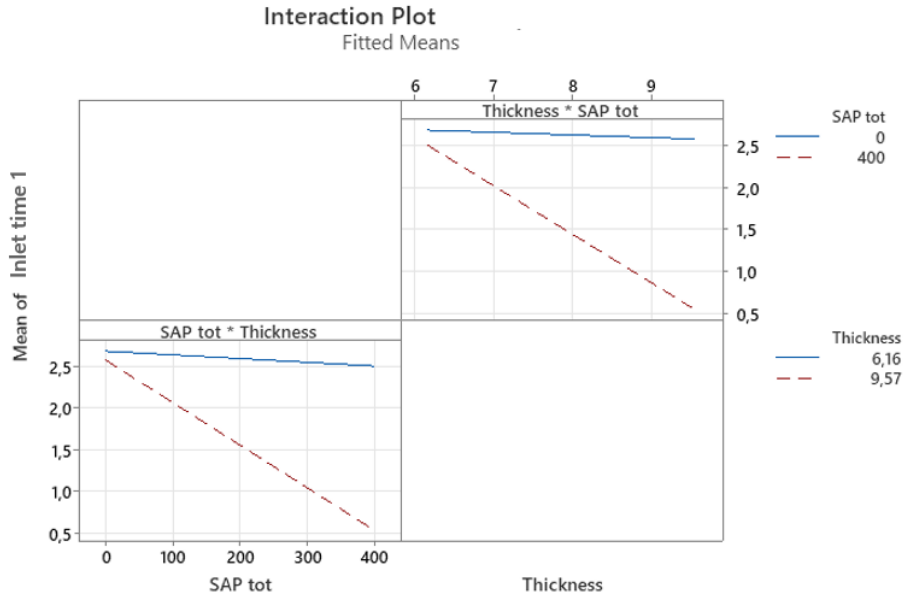


Figure 4.15: Interaction effects for Inlet 1

The interaction effects for Inlet 2 are presented in Figure 4.16. For a concept with low SAP amount the effect of *Thickness* is low, and the *Inlet time* remains on a low level even with increased *Thickness*. In contrast for a concept with high SAP amount, the effect of *Thickness* is high with a fast inlet for a higher *Thickness*. Somewhere in between, with medium SAP amount, *Thickness* does not play a role.

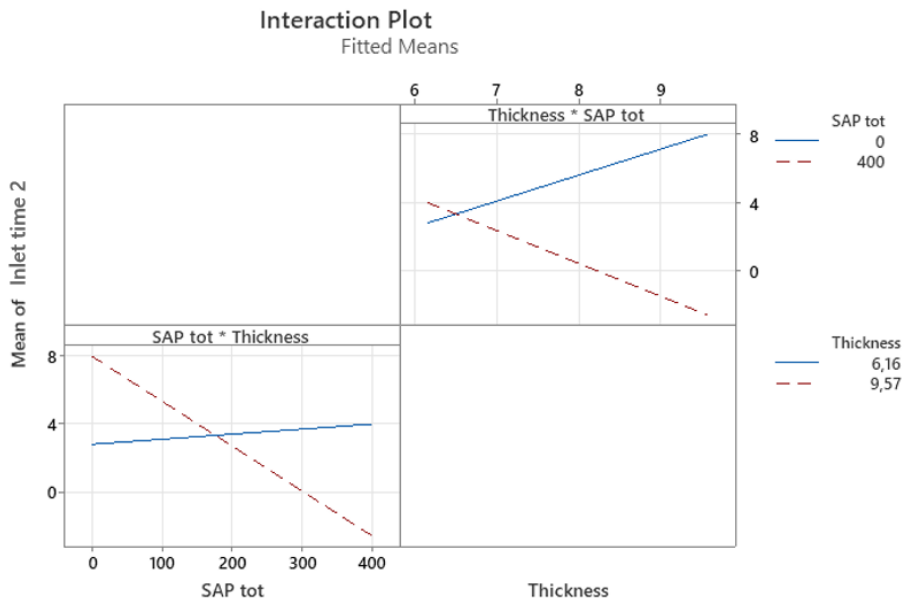


Figure 4.16: Interaction effects for Inlet 2

4.2.4 Precision of Measurement Systems

In this chapter, methods related to the previously presented design parameters and technical requirements will be presented, as well as an evaluation of their precision. Methods are used during laboratory execution to evaluate and measure the performance of a product. During product development, design verification, and process validation, laboratory testing is used to make various decisions. The most basic methods to ensure the correct amount of material is present in the products and in the right place are *Weight* and *Thickness*. In addition to these, there are more complex and specific methods, where individual material amounts can be determined, such as SAP amount methods. Furthermore, there are methods related to determining the material distribution and methods linked to test product functions. Due to the fact that this project will be based on several laboratory tests, it was considered relevant to evaluate some of the most used methods.

4.2.4.1 Weight and Thickness

Weight and *Thickness*, as previously described, are two of the most basic methods, which are easy to perform and providing a quick overview. The methods are related to two parameters that, from a product perspective, can affect many of the desirable functions of an incontinence product, such as *Inlet time* and *Rewet*.

Weight is measured using a calibrated scale placed on a stable, level surface. The product is positioned in the center of the scale and once stabilized the *Weight* is recorded. *Thickness* is measured using a *Thickness* gauge that is placed on a stable surface. The product is positioned between a measuring foot and the surface ensuring the product is centered and flat.

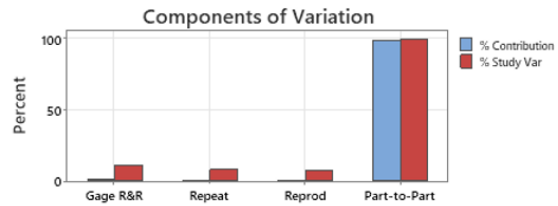
An MSA was conducted on *Thickness* and *Weight* to determine its precision. 5 samples to each methods were used. The results from the MSA are presented below.

The *Weight* measurement system proved to be precise based on the Gage R&R analysis conducted. See Figure 4.17 for a summary of contribution and study variation for the *Weight* measurement. According to the established acceptance criteria (see Table 3.1 in Chapter 3.2.3.2), the reproducibility and repeatability have a contribution value of less than 1%. In this case, the reproducibility consists of variation between operators. Together, they have a value of 1.2% for the total contribution of variation. With a result under 1%, the acceptance criteria indicate that it is excellent, and under 4% is considered a good result. Additionally, the study variation is within the acceptable range, with a percentage between excellent (under 10%) and good (less than 20%). This demonstrates that the measurement system is precise. It is also noted that the greatest source of variation is part-to-part, meaning that the measurement system variation is small in relation to the different parts. In Figure 4.17, the relationships for the different parameters can be read through the graphs, where it can be seen that the operators follow the same pattern but also how the variation for the different components looks.

Gage R&R

Variance Components

Source	VarComp	%Contribution (of VarComp)
Total Gage R&R	0,0001144	1,22
Repeatability	0,0000617	0,66
Reproducibility	0,0000528	0,56
Operators	0,0000528	0,56
Part-To-Part	0,0092753	98,78
Total Variation	0,0093897	100,00



Gage Evaluation

Source	StdDev (SD)	Study Var (6 × SD)	%Study Var (%SV)
Total Gage R&R	0,0106979	0,064187	11,04
Repeatability	0,0078528	0,047117	8,10
Reproducibility	0,0072648	0,043589	7,50
Operators	0,0072648	0,043589	7,50
Part-To-Part	0,0963082	0,577849	99,39
Total Variation	0,0969006	0,581403	100,00

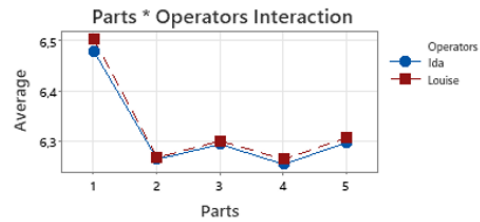


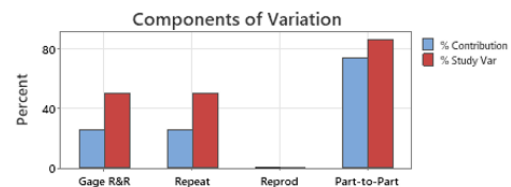
Figure 4.17: Measurement System Analysis for Weight

The *Thickness* measurement, however, showed a different result. The Gage R&R analysis indicated that reproducibility was excellent, but repeatability had a contribution of variation of 25.5%, which is above the threshold for marginally acceptable. The same relationship applied to study variation for the different parameters, which can be seen in Figure 4.18. Through the presented graphs, it can be seen that the operators follow the same pattern. Additionally, it can be observed that there are differences in the various measurements for the same product and how it ranges.

Gage R&R

Variance Components

Source	VarComp	%Contribution (of VarComp)
Total Gage R&R	0,00128	25,50
Repeatability	0,00128	25,50
Reproducibility	0,00000	0,00
Operators	0,00000	0,00
Part-To-Part	0,00374	74,50
Total Variation	0,00502	100,00



Gage Evaluation

Source	StdDev (SD)	Study Var (6 × SD)	%Study Var (%SV)
Total Gage R&R	0,0357771	0,214663	50,50
Repeatability	0,0357771	0,214663	50,50
Reproducibility	0,0000000	0,000000	0,00
Operators	0,0000000	0,000000	0,00
Part-To-Part	0,0611555	0,366933	86,31
Total Variation	0,0708520	0,425112	100,00

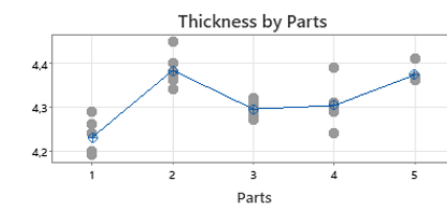
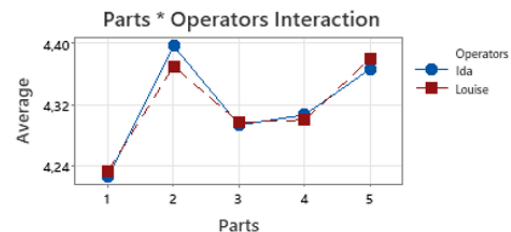


Figure 4.18: Measurement System Analysis for *Thickness*

Due to this result, with a high percentage of repeatability, it was deemed relevant to further investigate and determine the underlying cause. Initially, a hypothesis was formed that the products might be compressed during testing, becoming thinner and thinner, which would result in a decreasing *Thickness*. This would mean the testing was destructive in that way. Therefore, a time series plot was created to study the testing over time, as shown in the Figure 4.19 below. The graphs indicate that the *Thickness* generally increases over time and with the number of measurements, which contradicts the initial hypothesis. In fact, the opposite is true, the products become thicker and thicker.

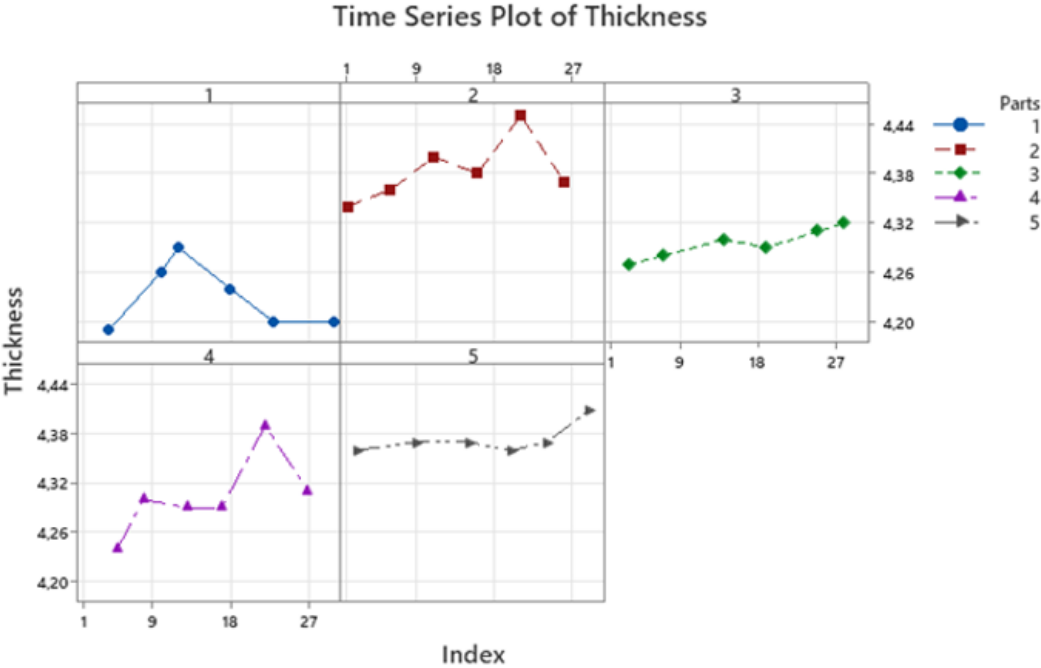


Figure 4.19: Time series plots for *Thickness*

4.2.4.2 SAP Amount Methods

To determine the amount of SAP present in different products, established internal methods provided by the company were used. There is always uncertainty regarding the measured values and how well they reflect reality. In this project, three internal methods were evaluated and applied, referred to as SAP Method 1, SAP Method 2, and SAP Method 3.

- SAP Method 1 is relatively simple and requires minimal preparation, allowing for spontaneous execution. Additionally, this method is quick to perform.
- SAP Method 2 is more complicated and requires several steps to be prepared before testing. Consequently, the time required to execute this method is somewhat longer compared to Method 1.
- SAP Method 3 is even more complex, and it is believed that this increases accuracy. Despite its complexity, it usually does not take longer to perform than Method 2. However, preparation can make it feel more time consuming.

The three methods were compared to see the difference in average values. Additionally, the intended SAP amount in the concepts was compared with the methods measured

value, to conclude which method was the most correct. The results are presented in Figure 4.20 below. It can be seen that the SAP Method 3 has the highest SAP amount mean and it is closest to the intended SAP amount in the product concept. It can also be seen that the SAP amount method 2 and 3 has some overlapping values. However, an ANOVA analysis shows that there is a significant difference between the methods. Therefore, only SAP Method 3 will be further used to evaluate the SAP amount in the concepts.

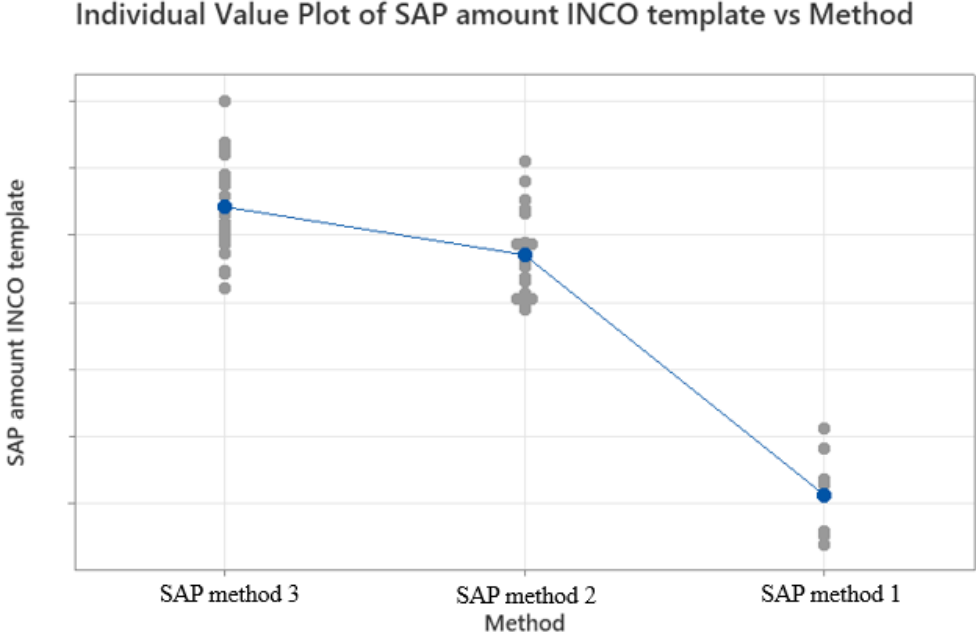


Figure 4.20: Individual value plot for SAP amount methods

4.2.4.3 Material Distribution Methods

In this project, two distinct methods were used to analyze the material distribution in product concepts. This section presents both approaches, referred to as Distribution Method 1 and Distribution Method 2, and provides a comparison between them.

- Distribution Method 1 uses visual imaging to provide a good estimate of material distribution. Additionally, this method provides a Coefficient of Variance (CV) value, which is a statistical measure that can be used to draw conclusions about the uniformity of material distribution in the concept. A lower CV suggests a more uniform distribution, while a higher CV indicates higher variation. The methods also provides an estimated surface weight of the studied concepts.
- Distribution Method 2 is another method for studying material distribution. This method is somewhat simpler and can be used to study different parts of a product or concept by punching out and analyze these.

The two distribution methods were also evaluated in regard to their accuracy. Distribution Method 1 was used to analyze both entire products and a smaller area on a product. It was known that the smaller area studied contained more material per square meter than the entire product. The basis weight obtained can only be seen as an approximate estimate as it is known that this is not particularly accurate. However, the basis weight for the

entire product and the small, analyzed area with more material than the whole product was the same, which indicates that distribution method 1 cannot identify these differences in material amount. This can be seen in Table 4.1 below.

Variant	Basis Weight (gsm)
Whole Product	632
Smaller Area (7x7cm)	629

Table 4.1: Evaluation of Distribution method 1

The purpose of this analysis was to see if Distribution Method 1 could be used similarly to Distribution method 2, to study the CV and basis weight of different areas. By doing so, conclusions could be drawn about how much material that is present in these areas, as a complement to the visual image of the distribution. The result showed that Distribution method 1 is a good method for visual study, as it provides a quick overview of how the material is spread across the product. It also generates a CV value that quantifies the material distribution. However, the basis weight cannot be applied to study material amounts in specific points based on analyzed data.

4.2.5 Target and Tolerance Design in Specifications

Based on interviews and meetings with quality engineers at the company, together with internal searches, the process for setting target values and tolerance limits has been outlined. Specifications serve as a crucial link between the voice of the customer and the tangible characteristics of the product. The process involves translating customer needs into technical requirements and design parameters. As previously presented in the QFD, these parameters are closely interconnected. Two key types of specifications used by the company are Technical Requirements and *Product specifications*. The Technical Requirements define the essential functions and performance levels that the product must achieve. These requirements guide the product developers in designing solutions that fulfill the set criteria. Following the product development process, the *Requirement specification* is created, detailing specific material amounts, *Thicknesses*, and other attributes necessary to meet the technical requirements. The insights presented in this chapter are based on interviews with product developers and a review of existing specification documents.

Setting the specification involves finding optimal target values for each parameter. However, in reality, due to variation in manufacturing and systems, it is almost impossible to hit these targets with perfect precision. Therefore, robust design principles are valuable to try to make the design insensitive to incoming variation. Two commonly used tools are variation and centering requirements, which will be presented in more detail below to understand the significance of using these requirements. In Figure 4.21 below, a schematic picture of the difference between the two can be seen.

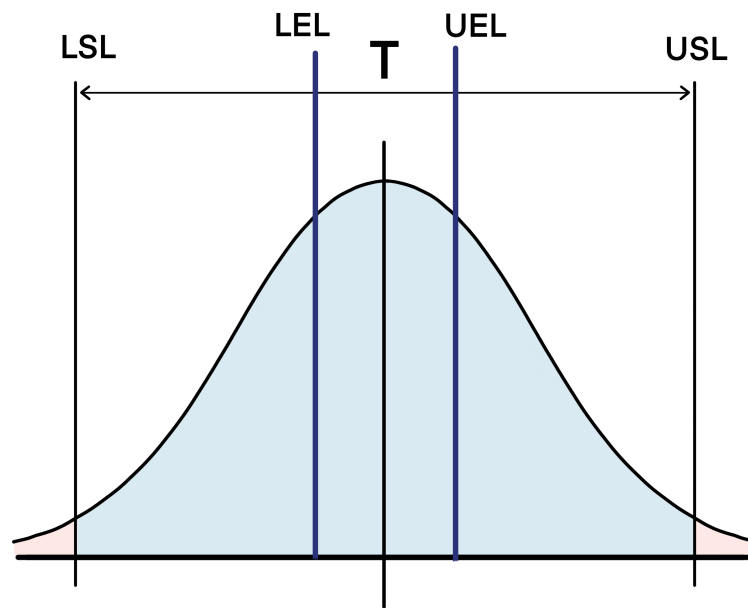


Figure 4.21: Schematic figure of variation and centering requirements (Own Illustration)

4.2.5.1 Variation Requirements

Variation requirements are defined by upper and lower specification limits, referred to as USL and LSL. Specification limits define when a product is considered to be defective. For instance, if a product has a target weight of 15 grams, an acceptable specification range may be 15 ± 2 grams. Products falling outside of this range are classified as defectives, as they may not meet performance or quality expectations. Variation requirements are used in both *Requirement specifications* and *Product specifications* and have been used for a long time. It is important to analyze both process variation and Ppk demand in order to set a producible specification.

Ppk defines the proportion of products allowed to fall outside the specification limits. Essity follows industry standards and has a requirement for $Ppk \geq 1.33$ for design parameters and $Ppk \geq 1.0$ for technical requirements. A Ppk value of 1.33 indicates that 99.9937% of all values will fall within the specified limits, while a Ppk of 1.0 means that 99.73% of all values will fall within the limits.

4.2.5.2 Centering Requirements

Centering requirements are defined by equivalence limits, which can be seen in Figure 4.21 above where LEL and UEL describe the lower and upper equivalence limits. Centering requirements are used to center a parameter around the mean value. This means defining the acceptable range within which the mean value of a given parameter may differ from the target. Unlike variation requirements, which control the variation of individual values, centering requirements focus on the mean of the population. Centering requirements are used in the Requirements Specification but are currently being implemented in the *Product specification*. The reason centering has not previously been applied in the *Requirement specification* is that the same product may be manufactured on different machines with varying conditions, making it difficult to define appropriate levels.

4.2.6 Design FMEA

A DFMEA was conducted in order to systematically identify design related causes to failure modes of critical functions such as *Inlet time*, *Rewet* and *Thickness*, and assessing their impact. This risk assessment helps to gain a holistic understanding of SAP and pulp, from design input to final product output and to identify potential mitigating actions. Figure 4.22 , presents the key parameters assessed in the DFMEA including severity, occurrence and detection and their rating. These three factors are multiplied to obtain a risk priority number, which is used to prioritize actions.

Function	Potential Failure Mode	Potential Failure Effects	Severity	Potential Causes	Occurrence	Current Controls	Detection	RPN	Potential Mitigating Actions
Inlet time	Slow fluid inlet	Leakage, reduced dryness	6	Uneven or insufficient SAP and pulp amount and/or distribution	7	Specification and design guidelines	7	294	Lab testing of inlet time, review of SAP and pulp amount
Rewet	High rewet	Leakage, reduced dryness	6	Insufficient SAP amount	7	Specification and design guidelines	7	294	Lab testing of rewet function and SAP amounts
Absorption Capacity	Low absorption	Leakage, reduced dryness	6	Insufficient SAP and pulp amount in design	6	Specification and design guidelines	2	72	Absorbency lab tests, SAP level testing
Thickness	Too thick/thin or uneven thickness	Not discreetness, high rewet/slow inlet time	7	Too high or low levels of pulp and/or SAP amount, Compression issues	8	Specification and design guidelines	2	112	Measure thickness. Test design against various humidity conditions

Figure 4.22: DFMEA (Design Failure Mode and Effects Analysis)

The highest RPN value are seen for *Inlet time* and *Rewet*, both of which share a common potential cause of failure, insufficient SAP amount. This highlights the need to gain better insight into these parameters and the importance of setting clear specifications based on variation. Although *Absorption capacity* has a lower RPN of 72, due to potential failures being easily detected by performing absorbency lab tests, it is still a critical function that needs to be considered. The potential cause of failure related to *Thickness* showed a RPN of 112 but has the highest severity and occurrence scores. This underscores the need for further understanding of environmental influences like moisture and compression during production when setting *Product specifications*. These potential failure modes highlight critical areas where increased control and understanding may be needed to ensure product consistency throughout the value chain.

4.3 The Design Verification Process

In the design verification process, product concepts are tested to evaluate whether the proposed design solution will meet the Technical Requirements. When testing product performance, it is equally important to check the compliance to *Product specification*. In this stage, two different test concepts, named A and B, that were produced in a prototype facility at Essity were analyzed. This section presents the results and findings from all the laboratory tests that have been conducted on the two product concepts. The purpose has been to understand the importance of design verification and identify any existing gaps.

4.3.1 Overview of the Evaluated Parameters

The selection of parameters for the laboratory testing was based on the relevant design parameters and technical requirements presented. An overview of the evaluated parameters together with their purpose is presented in Figure 4.23 .

Parameter	Purpose	Product concept
Product weight	Assess the total material content, including SAP and pulp and whether it's a good representation of all the combined material.	A and B
SAP amount	Isolating the SAP amount helps evaluate its contribution to the total weight.	A and B
Thickness	Assessing product thickness in relation to weight, SAP amount and distribution and its impact on product functions.	A and B
Material Distribution	Evaluate the evenness of SAP and pulp in the concepts.	A and B
Rewet	Test the technical function related to SAP and pulp as well as thickness and distribution.	A

Figure 4.23: An overview of the evaluated parameters

4.3.2 Evaluation of Variation and Centering Requirements for Product Concept A

This chapter presents the results from testing and evaluating product concept A. In Figure 4.24 below, the limits against which the concept will be compared can be read. For concept A, centering requirements were set for SAP and pulp amounts. For the Product Weight, variation requirements are used. *Thickness* has previously been shown to be a critical parameter related to both SAP and pulp, and is therefore specified with variation requirements and centering requirements. The same applies to the technical requirement *Rewet*, which is strongly linked to *Thickness*.

Product concept A					
	Centring requirements Equivalence Limits			Variation requirements Specification Limits	
	Target	UEL	LEL	USL	LSL
Design parameters					
SAP amount	T	+3%	-3%	-	-
Pulp amount	T	+3%	-3%	-	-
Product weight	T	-	-	+12%	-12%
Distribution	Even				
Thickness	T	+2,4%	-2,4%	+24%	-24%
Technical requirements					
Rewet	T	+13%	-13%	+67%	-

Figure 4.24: Specification for Concept A

In the following chapter, the results from testing Product Concept A using the previously described methods are presented. In addition to these methods, a standardized *Rewet* measurement method used internally by the company was also included.

4.3.2.1 Product Weight for Product Concept A

Product Weight was one of the first tests conducted as it is a good way to get a quick overview. The total Product Weight can be used as a measure to understand if the correct amount of material is present in the product. However, it is difficult to distinguish specific material types. In Figure 4.25 below, an overview of the 240 samples that were weighed is shown.

As shown in Figure 4.24, the Weight parameter is defined by both a target value and a variation requirement. The measured mean is very close to the target, although slightly skewed toward the higher side. From a visual inspection of the distribution graph, the majority of the values appear to fall within the specified variation limits. The process capability was evaluated, resulting in a Ppk value of 1.18. However, due to the limited sample size, there is a degree of uncertainty associated with the estimate. A lower bound of the Ppk was calculated at 1.08 with 95% confidence. Since the required Ppk for this parameter is 1.33, neither the estimated value nor its lower confidence bound meets the Ppk demand. Furthermore, no centering requirement is currently defined for this parameter, which allows the process mean to drift within the variation limits.

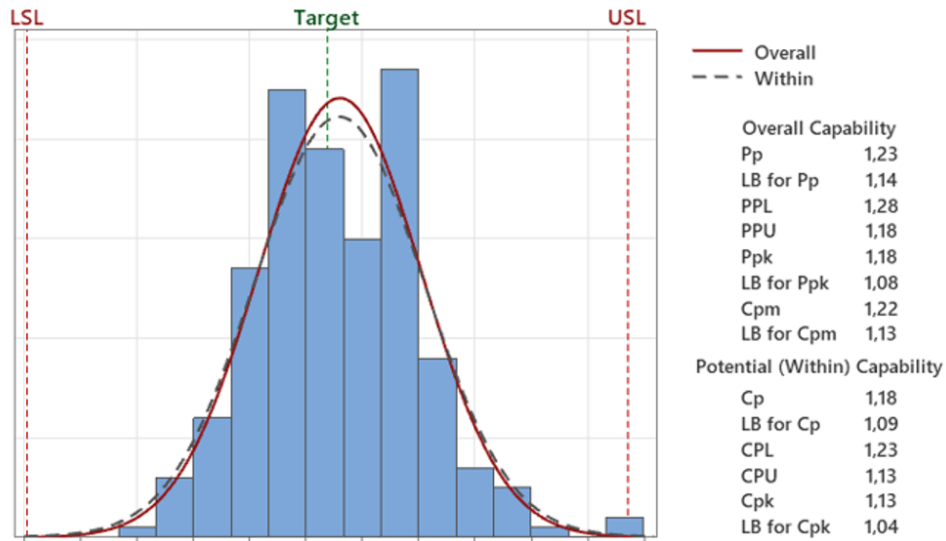


Figure 4.25: A process capability report of the Product Weight for Product Concept A

4.3.2.2 SAP Amount for Product Concept A

Of the 240 samples that were weighed, 24 of them, both high and low weight products, were used to determine the amount of SAP and compare it with the specification. The subset was chosen to ensure a representative sample size while also balancing the time required to perform the method. In Figure 4.26 below, the results are presented through a histogram. The SAP amount is specified with target and equivalence limits. The average SAP amount was slightly shifted towards the lower end but remains within the lower equivalence limit. The equivalence limits thus enable control over the average shift relative to the target. It can also be noted that there was a large spread between the measured maximum and minimum values. Since there are no variation requirements for SAP amount, there is no requirement limiting the variation of individual values.

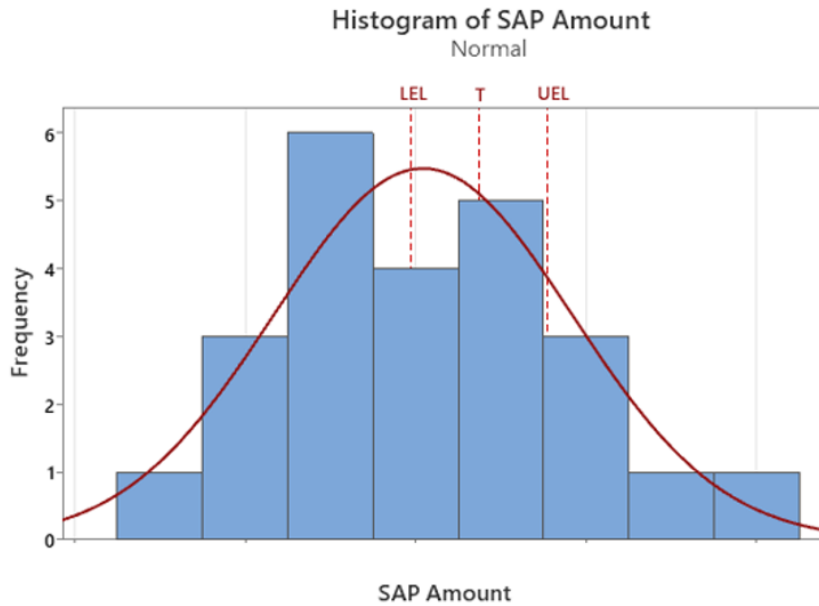


Figure 4.26: A histogram of the SAP Amount for Product Concept A

Visually, it can be observed that the SAP amount falls within the set centering requirements. To study this further and with the small sample size in mind, an equivalence test was conducted. The equivalence test is presented in Figure 4.27 below. In the equivalence test, it can be seen that equivalence cannot be claimed and the lower bound for 90% confidence interval goes below the LEL.

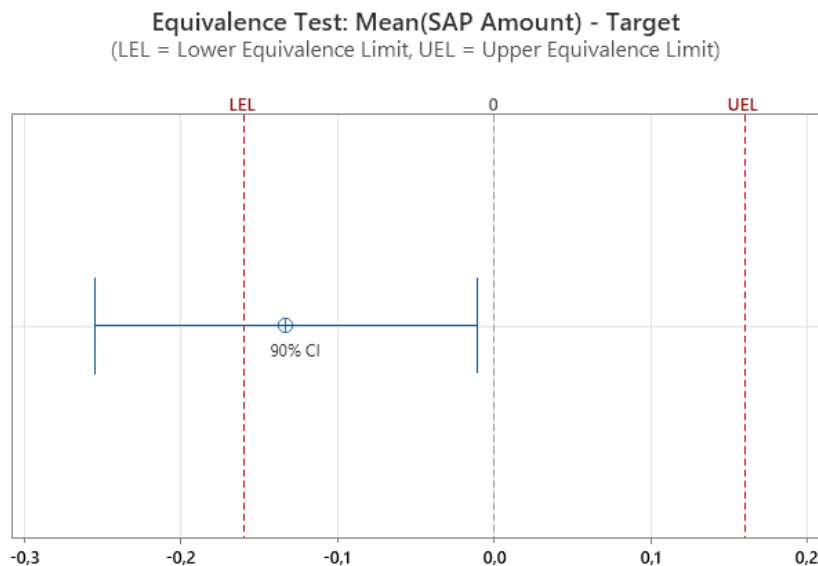


Figure 4.27: Equivalence test of the SAP amount for Product Concept A

Since the SAP amount in this case lacks variation requirements in the set specification list, it was deemed relevant to analyze what appropriate limits could be based on the gathered data. Using variation limits in the form of upper and lower specification limits can restrict SAP variation in the products. The tolerance intervals were obtained through the measured standard deviation and the mean set to the target, as the tolerance limits

should be symmetrical around the target. In Figure 4.2 the interval is presented with a set requirement on Ppk of 1.33 and a sample size of 24 measured values. With a sample size of 24 and a tolerance factor of 5.4, the corresponding tolerance limits were $\pm 35\%$.

There are a significance impact of sample size and therefore, the same analysis was conducted for an increased sample size. With the increased sample size (N=100), the calculated tolerances become somewhat narrower. The suggested tolerance limit was $\pm 30\%$, with a tolerance factor of 4.56. A tolerance factor of 4.56 corresponds to a two-sided tolerance interval that extends ± 4.56 standard deviations from the sample mean, capturing 99,9937% of the population. However, while the analysis was repeated using a larger sample size (N = 100), the standard deviation used in calculating the tolerance interval was still based on the smaller sample size. As a result, the estimated tolerance interval may not fully reflect the true variability of a larger sample size. For a more accurate and representative interval, the standard deviation should ideally be recalculated based on the increased sample size, as it provides a more robust estimate of population variability.

In Table 4.2 below, a quick overview of the tolerance intervals corresponding to different sample sizes and tolerance factors can be seen.

SAP amount		
Sample size	Tolerance factor	Tolerance interval
24	5.4	$\pm 35\%$
100	4.56	$\pm 30\%$

Table 4.2: Tolerance intervals for SAP Amount - Concept A

Furthermore, a correlation analysis was performed to examine the relationship between Product Weight and SAP amount. The objective was to assess whether variations in total Product Weight could be explained by differences in SAP content, that is, whether a heavier product contains more SAP, and a lighter product contains less. As illustrated in Figure 4.28, the correlation line is nearly flat, indicating no significant relationship between the two variables. This suggests that an increase in Product Weight does not correspond to an increase in SAP amount, and vice versa.

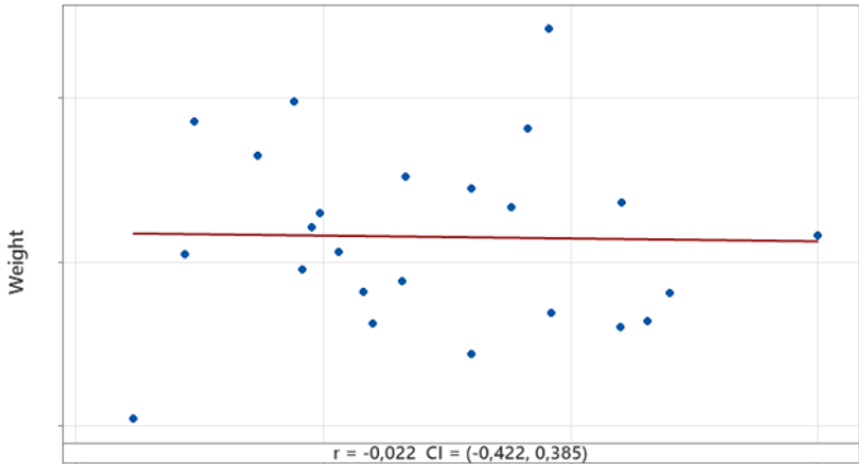


Figure 4.28: Correlation between SAP amount and Product Weight for Product Concept A

4.3.2.3 Thickness for Product Concept A

Thickness is specified with target, specification and equivalence limits. A *Thickness* measurement was conducted on 10 products. The results are presented in Figure 4.29 below. This result shows that the average value does not fall within the acceptable equivalence limits. Additionally, the majority of the products exceed the upper specification limit.

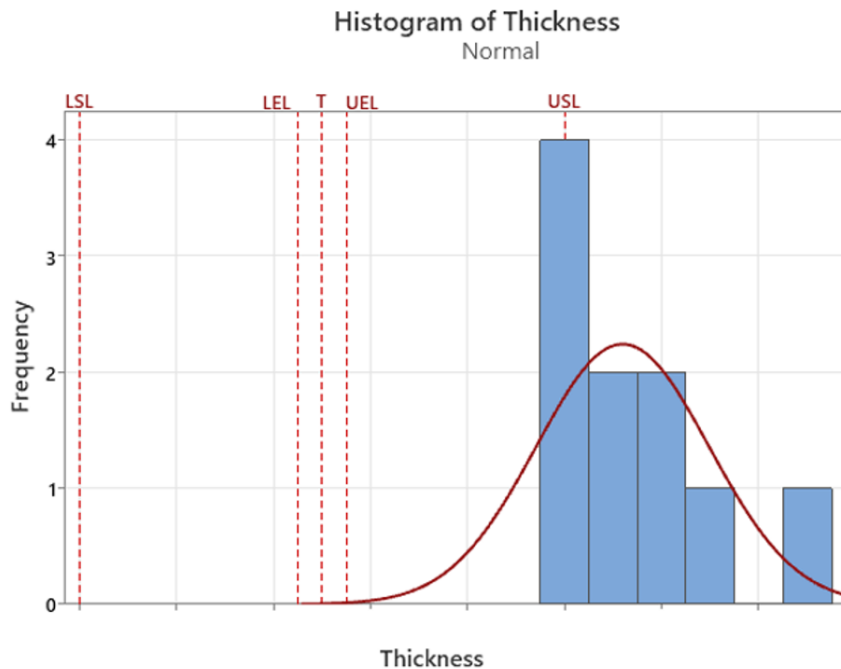


Figure 4.29: A histogram of *Thickness* for Product Concept A

Furthermore, a capability analysis is presented, which examines the set variation requirements based on the process's ability to meet these requirements. Performing an equivalence test was deemed unnecessary as the previous analysis already demonstrated that the parameter does not meet the equivalence limits.

In Figure 4.30 below, a process capability report for *Thickness* is shown, where the measured Ppk value and its lower confidence bound are reported. The Ppk value describes how capable the process is of staying within the specification limits. It can be seen that the Ppk for this process is -0.22, which is below the target value, and the lower bound for Ppk is -0.42. A negative Ppk value means that more than half of all samples are outside the specification limits. This further indicates that the *Thickness* does not meet the capability requirements.

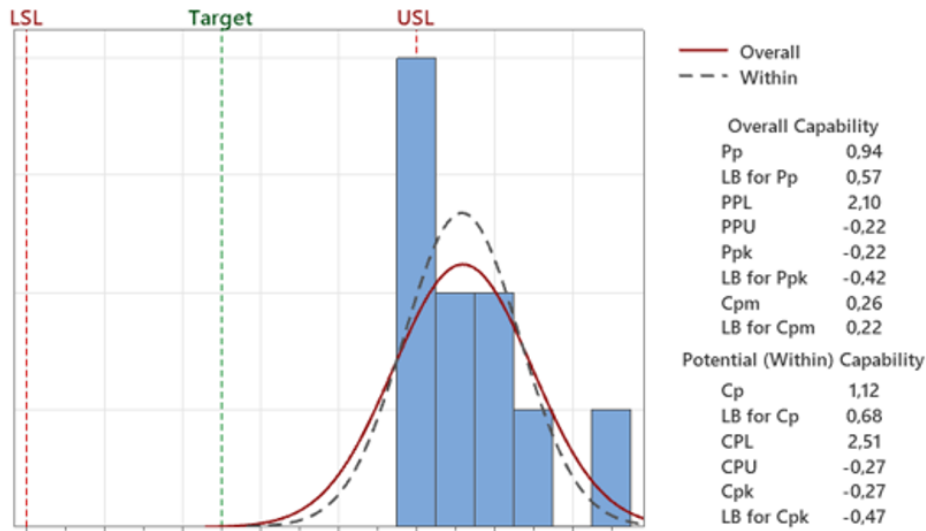


Figure 4.30: Capability analysis of *Thickness* for Concept A

Based on the previously presented Ppk values, an in-depth analysis of tolerance intervals was conducted. The purpose was to investigate how the tolerance limits would look if the Ppk was set to 1.33, which means that 99.9937 percent of all outcomes should fall within the proposed tolerance interval.

In Table 4.3 below, the suggested tolerance intervals for a sample size of 10 and 100 are presented. For a sample size of 10, the tolerance interval was estimated at $\pm 58\%$. While this may appear wide, it reflects the substantial statistical uncertainty associated with such a small sample. Both the standard deviation and the mean are less reliably estimated with only 10 observations, meaning that the true values could differ if more samples were taken. With a larger sample size of 100, the tolerance intervals became narrower. In this case, a tolerance interval of 39% with a tolerance factor of 4.56 is recommended. However, it is important to note that this calculation still uses the mean and standard deviation estimated from the original 10 samples. Thus, if the underlying data distribution changed with the larger sample, the true tolerance interval could differ from this estimate.

Thickness		
Sample size	Tolerance factor	Tolerance interval
10	6.63	$\pm 58\%$
100	4.56	$\pm 39\%$

Table 4.3: Tolerance Intervals for *Thickness* - Concept A

4.3.2.4 Material Distribution for Product Concept A

Besides having the correct amount of material in the concept, it is important that the material is evenly distributed. Above, the situation for the total SAP amount in the concept was presented. Below, the results from the distribution study conducted are presented. In Figure 4.31 below, a visual representation of the material distribution can be seen, three images have been selected to demonstrate how it can vary from concept to concept. The red areas indicate higher material quantity. The red areas can mean more SAP or pulp. With the help of these illustrations a CV value is also obtained,

which explains how even distribution the product is. A lower value means a more uniform product. The average CV value of 120 products was 20%. For this analysis, Distribution method 1 was used.

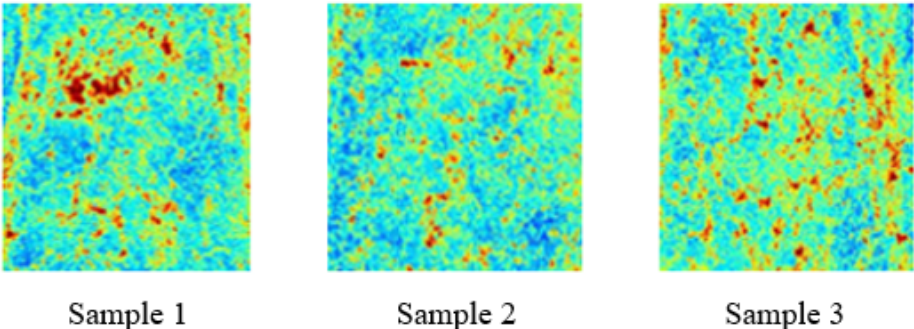


Figure 4.31: Visual imaging of three samples from Product Concept A

Furthermore, an analysis was conducted where Distribution method 2 was used. This was done to analyze a specific part of the concept and see if there was theoretically the right amount of material and SAP in this piece. A 7x7 cm piece was analyzed, the area where functional tests are performed, also referred to as the dosing point. The SAP amount and Weight on this piece were then measured. These results are compared with the theoretically calculated Weight and SAP amounts based on the knowledge that the materials should be evenly distributed throughout the product. The theoretical calculation is based on the specified material weights. In Figure 4.32 below, the measured Weight are presented. The target Weight can be seen and the average for the 24 pieces. It can be seen that the average is higher than expected at this point of the concept.

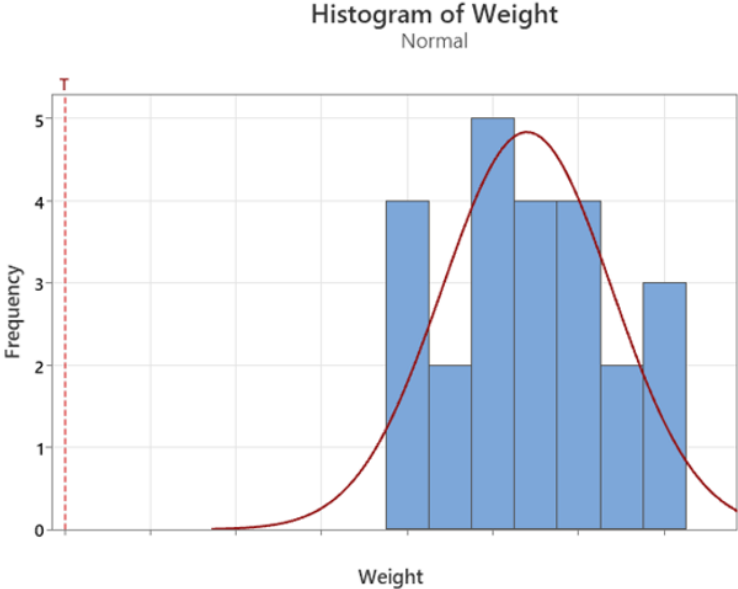


Figure 4.32: Weight of a smaller area of Concept A

The SAP amount in this piece could be determined by applying SAP amount method 3 to this smaller piece. The result showed the same relationship as the Weight. In Figure 4.33

below, the target can be seen and the average SAP amount. The piece contains too much SAP in relation to the intended and specified amount.

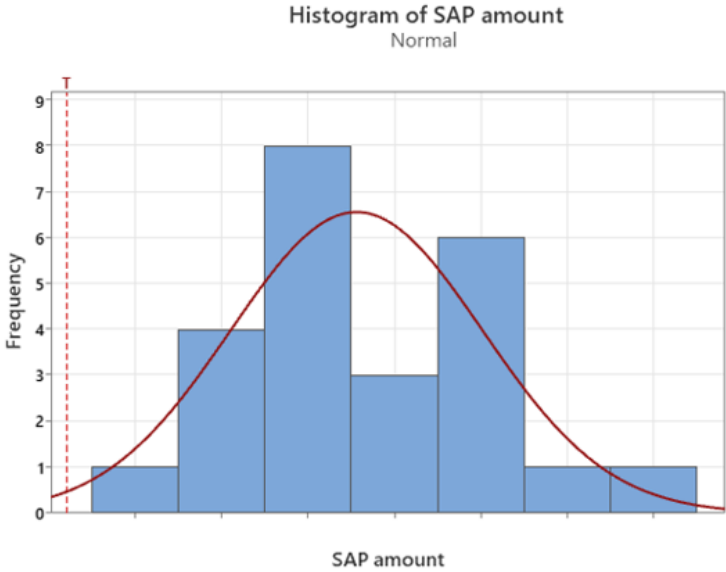


Figure 4.33: SAP amount in a smaller area of Concept A

4.3.2.5 Rewet for Product Concept A

Rewet has been analyzed through a standardized laboratory method. 10 products were tested, and the result is presented in Figure 4.34 below, where a comparison between the target, upper specification level, and equivalence limits can be seen. In the Figure, a measured average value for *Rewet* can be seen outside the equivalence limits, however, the majority of all measured individual values are within the upper specification limit and the margin to the USL is small.

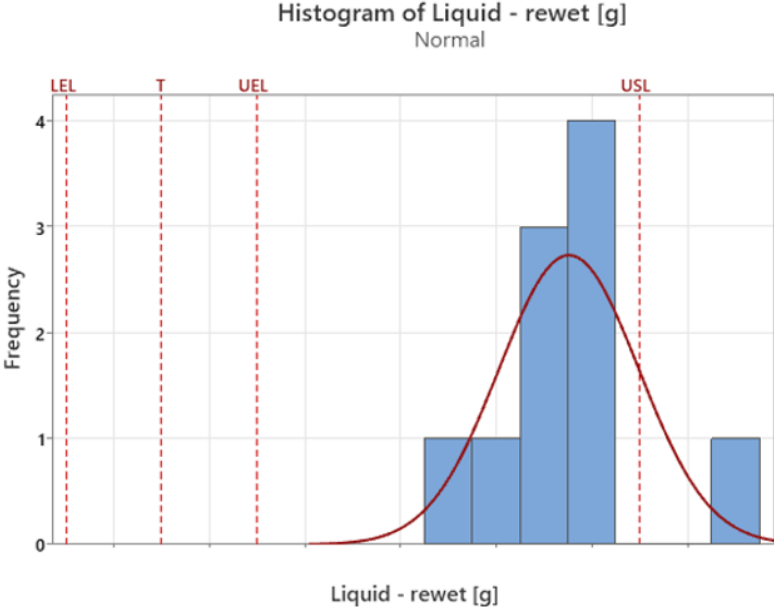


Figure 4.34: A histogram of *Rewet* for Product Concept A

For *Rewet*, the analysis of the variation requirements through a capability analysis can be seen in Figure 4.35. With the values set for the target and upper specification limit, a Ppk could be calculated, as well as a lower bound for Ppk. Since *Rewet* is a technical requirement, there is a Ppk requirement of 1, compared to design parameters. For this parameter, it can be seen that the measured Ppk is 0.34 and the lower bound is 0.12. This shows that this process is outside the specified limits and it is not capable of producing with sufficient margin to the specification limit.

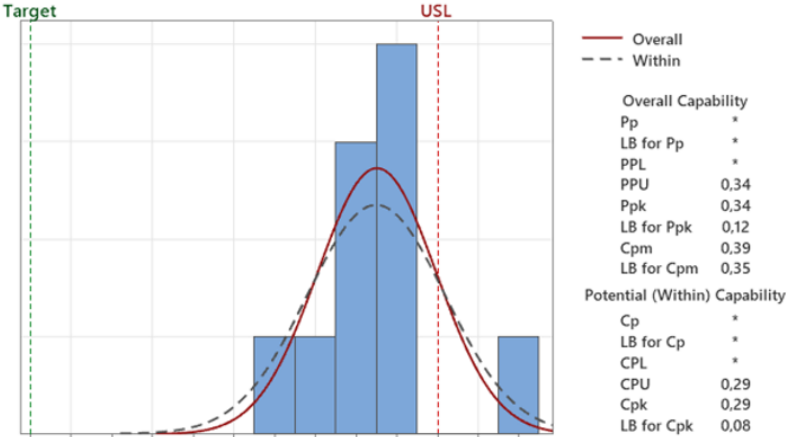


Figure 4.35: Capability analysis of *Rewet* for Concept A

To determine the tolerance limits that would result in a Ppk of 1.0, a tolerance interval analysis was conducted for *Rewet*. These proposed tolerance limits, based on a sample size of 10, are presented in Table 4.4 below. The mean value in the analysis is set to the target value, ensuring that the tolerance limits are symmetrically distributed around this value. As previously demonstrated, the sample size significantly impacts the setting of these limits. Therefore, tolerance limits were also calculated for a sample size of 100, which can also be seen in the table. For a sample size of 10, a tolerance interval of $\pm 66\%$ is recommended, whereas for a sample size of 100, $\pm 44\%$ is recommended. Since it was clearly visible that the mean value did not fall within the equivalence limits, it was deemed irrelevant, similar to *Thickness*, to conduct an equivalence test for *Rewet*.

Rewet		
Sample size	Tolerance factor	Tolerance interval
10	6.83	$\pm 66\%$
100	4.56	$\pm 44\%$

Table 4.4: Tolerance intervals for *Rewet* - Concept A

4.3.3 Evaluation of Variation and Centering Requirements for Concept B

To capture a broader understanding, a second concept was produced in the prototype facility at Essity. 100 samples were received and the sampling method used was random sampling. The goal with this concept was to evaluate how centering and variations

requirement may be applied. Tests conducted for this concept included Weight, *Thickness*, SAP amount and Distribution. No technical requirements were tested for this concept, instead the focus was placed on testing the design parameters previously described. Figure 4.36 presents the specifications established for this concept, which was developed in collaboration with product developers to find reasonable target values and limits. No centering requirements were established for this test concept.

Product concept B					
	Centering requirements Specification limits			Variation requirements Equivalence limits	
	T	UEL	LEL	USL	LSL
Design parameters					
SAP amount	T	-	-	+10%	-10%
Pulp amount	T	-	-	+10%	-
Weight	T	-	-	+10%	-10%
Distribution	Even	-	-		
Thickness	T	-	-	+16%	-16%

Figure 4.36: Specification for Concept B

4.3.3.1 Product Weight for Product Concept B

A total of 100 samples containing SAP were measured with respect to Weight, and an overview of the results is presented in Figure 4.37. The mean is close to the set target and all measured values falls within the upper and lower specification limits. A capability analysis was done to evaluate the variation requirements on this parameter. As can be seen in Figure 4.37, the Ppk value for Weight is 1.12 with a lower bound of 0.98, indicating that the process does not meet the variation requirements. However, it has a Pp value of 1.33, meaning that if the process was centered properly around the mean, it could potentially meet the capability requirements.

Process Capability Report for Weight 95% Confidence

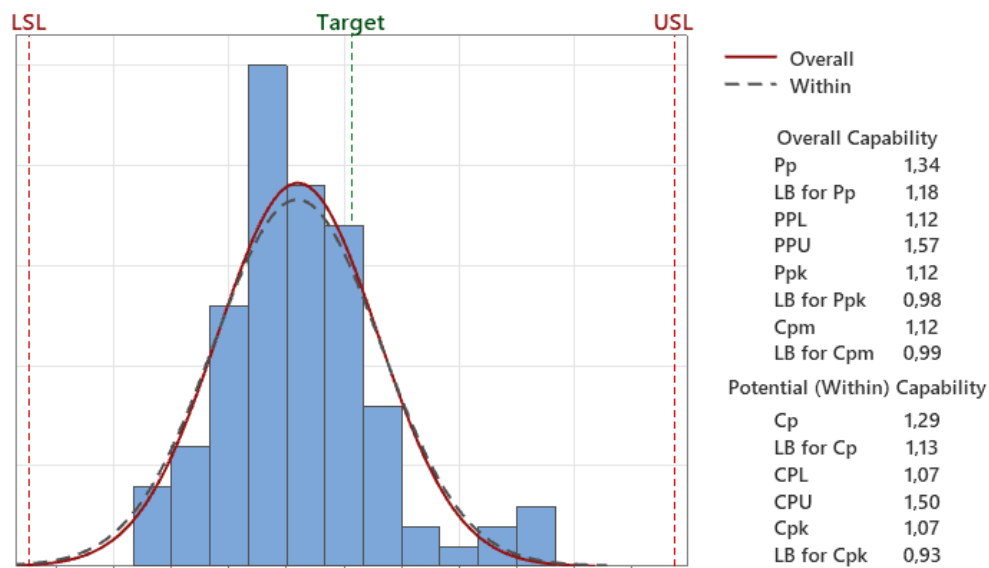


Figure 4.37: Process capability report of Weight for Product Concept B

4.3.3.2 SAP Amount for Product Concept B

To evaluate the SAP amount in the product concept, SAP amount method 3 was performed on 24 of the 100 samples. The specification limits were established to be $\pm 10\%$. An overview of the SAP amount measured from the 24 samples is presented in Figure 4.38. While the mean value seems to be relatively close to target, a significant number of samples fall outside the established specification limits, indicating that the variation requirements will not be met for this concept. Furthermore, a capability analysis where these intervals were applied is also presented in Figure 4.38. The capability analysis shows a Ppk value of 0,33 with a lower bound of 0,19 indicating that the process is not capable, based on the limited data collected.

Process Capability Report for SAP Amount 95% Confidence

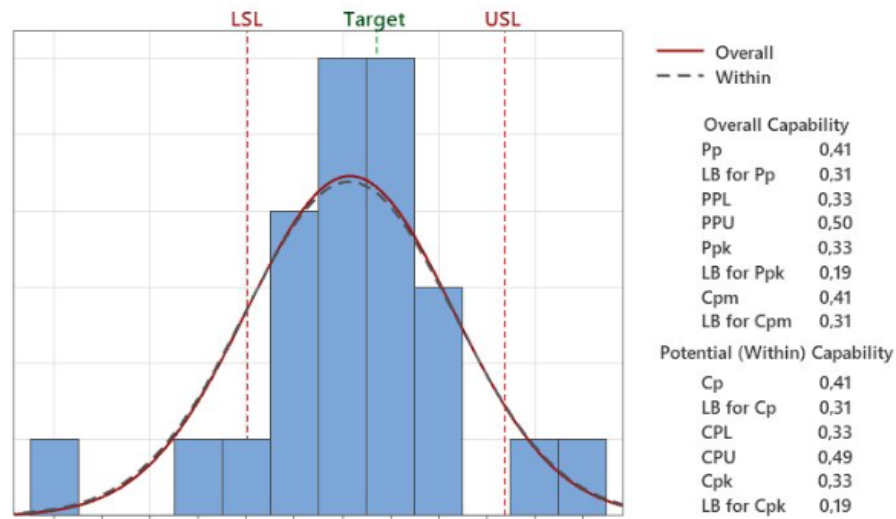


Figure 4.38: Process capability report of the SAP amount for Product Concept B

Using the standard deviation from the measured SAP amount, a tolerance interval was estimated using the software Minitab. The interval showed a tolerance span of $\pm 43\%$ with a tolerance factor of 5.4. Meaning that the tolerance interval ranges 5,4 standard deviations from the sample mean, capturing 99,9973% of the population with a 95% confidence interval. This wide interval and high tolerance factor are likely due to the small sample used. To explore the impact of sample size, this was increased in the software to 100. This led to a tolerance interval of approximately $\pm 35\%$ from target, with a tolerance factor of 4,56. Even though a larger sample size was simulated, the standard deviation used is still based on the original small sample size of 24. A summarized overview can be viewed in Table 4.5.

SAP amount		
Sample size	Tolerance factor	Tolerance interval
24	5.4	$\pm 43\%$
100	4.56	$\pm 35\%$

Table 4.5: Tolerance intervals for SAP Amount - Concept B

A correlation study was also conducted between the Product Weight and the measured SAP amount for the 24 samples, see Figure 4.39. The resulting graph indicates a positive correlation, demonstrating that an increase in Product Weight corresponds to an increase in SAP amount.

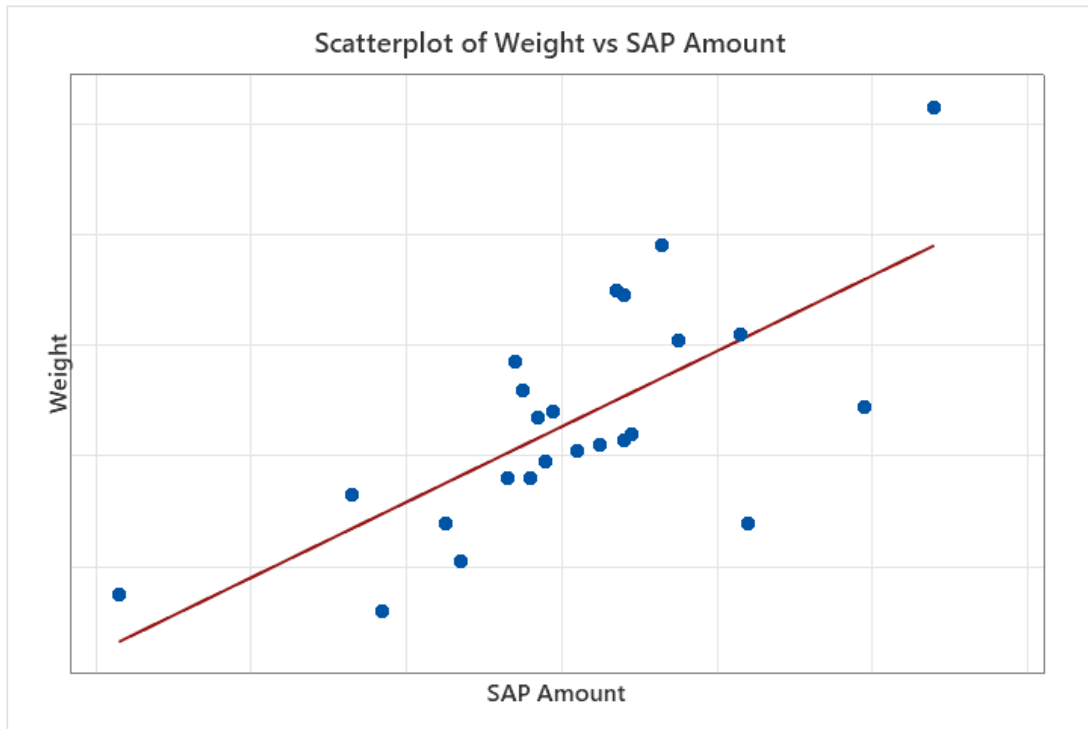


Figure 4.39: A correlation study between SAP amount and Product Weight for Product Concept B

4.3.3.3 Thickness for Product Concept B

Thickness was measured on 6 samples, which is presented in Figure 4.40. The measured *Thickness* falls within the established limits, however with a slight deviation from the target value. No capability analysis was performed for this parameter due to the small data set, as it restricts the ability to draw meaningful and reliable conclusions.

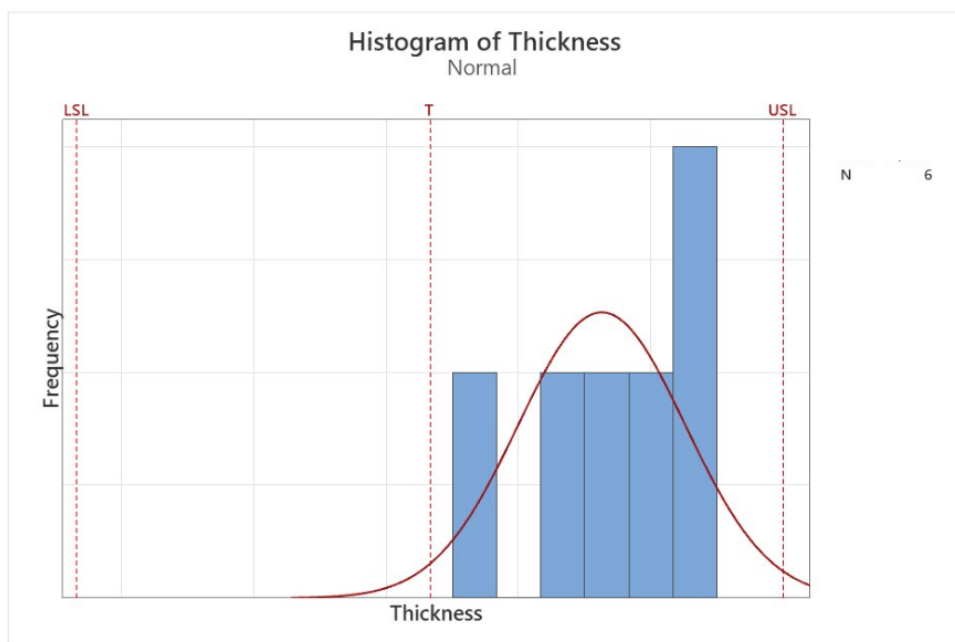


Figure 4.40: A histogram of *Thickness* for Product Concept B

4.3.3.4 Material Distribution for Product Concept B

Product concept B was also evaluated using visual imaging to assess the material distribution. Typically, the red spots indicate a denser material area, providing indications of the uniformity and distribution of the material. Three of the samples tested can be observed in Figure 4.41. No clear conclusions can be drawn between Product Weight, SAP amount, and the visual indications. The mean CV of 18.3% reflects overall distribution uniformity, but it does not capture local variation or precise material placement, limiting its usefulness for deeper analysis.

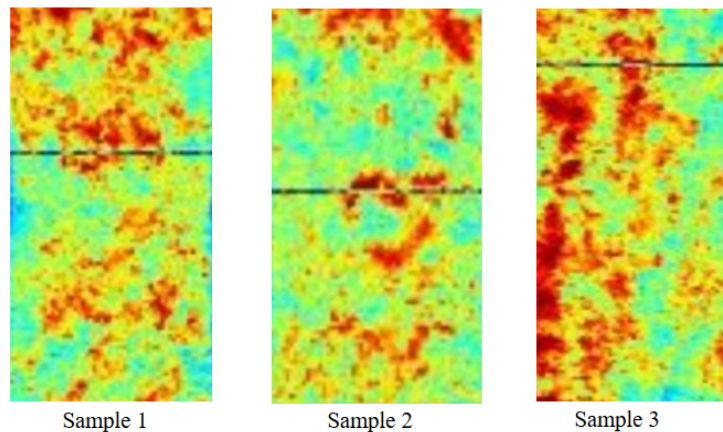


Figure 4.41: Visual imaging of three samples from Product Concept B

To further investigate the material distribution of the concept, the intended dosage point of the concept was analyzed using distribution method 2. This involved extracting a 5x5 cm area from approximately the center of the concept and weighing it. According to the established specifications, the theoretical Weight of this section could be calculated. As seen in Figure 4.42, the graph indicates a deviation from this theoretical value. However, with only six samples measured, the statistical base is not sufficient to draw definitive conclusions.

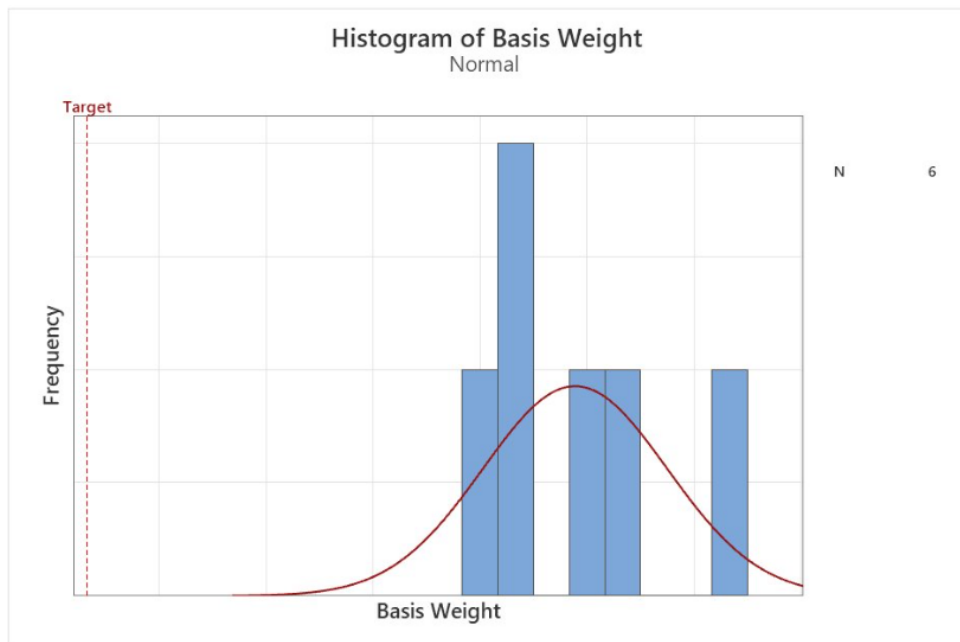


Figure 4.42: Weight of a smaller area for Product Concept B

These smaller sections were also evaluated using the SAP amount method 3 in order to find out the actual SAP amount in the critical dosage point. The theoretical SAP amount was calculated using the set specifications and was compared to the measured result. Although a deviation from the target is evident, as can be seen in Figure 4.43, the limited number of samples makes it difficult to draw precise conclusions.

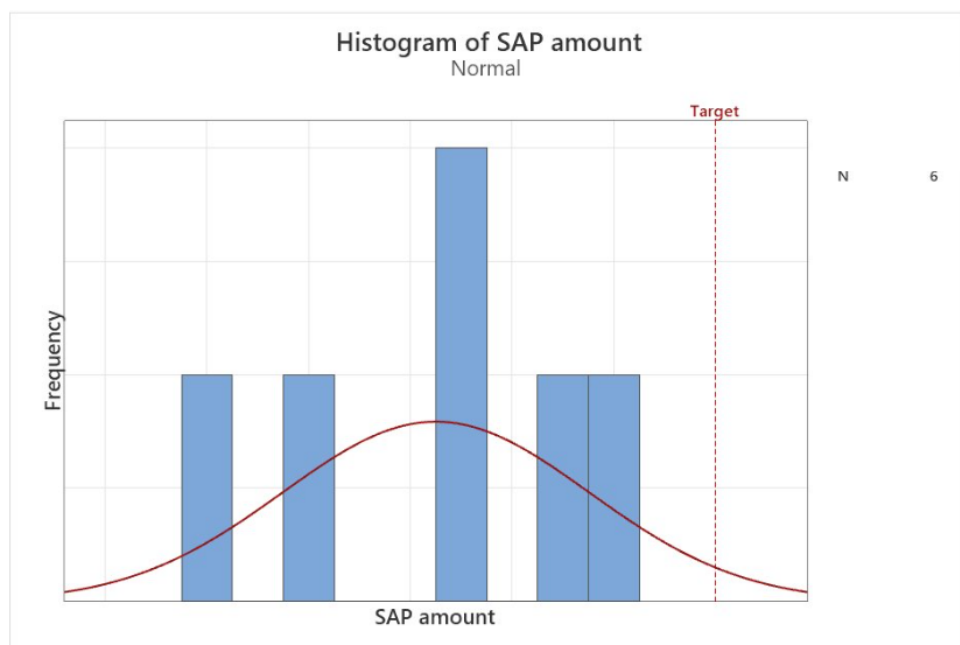


Figure 4.43: SAP Amount in a smaller area for Product Concept B

4.4 The Process Validation Process

A process validation involves several different steps. Considering that this project has primarily aimed to understand SAP and pulp, this chapter will analyze a validation method regarding the correct amount of SAP and pulp. Additionally, a section will analyze how information from the process validation of SAP and pulp is managed and documented. Lastly, a root-cause analysis for the potential failure modes in the production systems is presented using a fishbone diagram.

4.4.1 Current Measurement Method for SAP and Pulp

To ensure that an intended machine can manufacture a product based on the determined design parameters and meets the set *Product specification*, it is important to validate the machine during development. The SAP and pulp amount, as previously described, are key components where the correct amount is critical for product performance. To achieve this, it is essential that the machine is properly set up to deliver the correct material levels. Based on information gathered through interviews with production staff, one commonly used method during this phase is presented and evaluated in this chapter.

In this chapter, the method will be referred to as SAP validation method 1. The method involves temporarily pausing production to then manufacture products that are subsequently evaluated. From this method, an average value and standard deviation of the SAP amount in the products can be estimated.

The average SAP amount information is later used to validate whether the machine produces products with the correct amount of pulp and SAP, and if the data falls within set limits. Besides being used in process validation, SAP validation method 1 is sometimes used during ongoing production to study the correct amount of material. However, this method requires that ongoing production be stopped for a period, which is costly both from a time perspective and a cost perspective. With this in mind, the method during running production requires planning and is not something that can always be carried out.

SAP amount Method 3 has previously been shown to be the most accurate from a laboratory perspective. In addition, Validation Method 1 is considered a precise method for determining the total mass and SAP amount in a product. It is therefore of interest to examine whether SAP Validation Method 1 produces comparable results to SAP Method 3. A mean difference of only 0,08g was observed, indicating that the methods yield very similar values and have comparable accuracy.

Through interviews, it has emerged that the SAP validation method 1 has greater potential for understanding material variation. The main focus of the method is to calculate the average SAP amount using mean values. In many cases, the use and interpretation of the data are limited to mean values only, which provides a simplified view of the data. To gain a more nuanced understanding, other statistical measures such as standard deviation and variance can also be calculated by considering the standard deviation and variance of products with and without SAP.

4.4.2 Root-Cause Analysis Using a Fishbone Diagram

As part of investigating the validation process, a fishbone diagram was developed to systematically identify potential causes of failure and variation that might happen in production. It focuses on six areas: Measurement, Materials, Machines, Methods, People and Environment. The diagram is presented in Figure 4.44 and is based upon interpretations of possible failure modes that might occur.

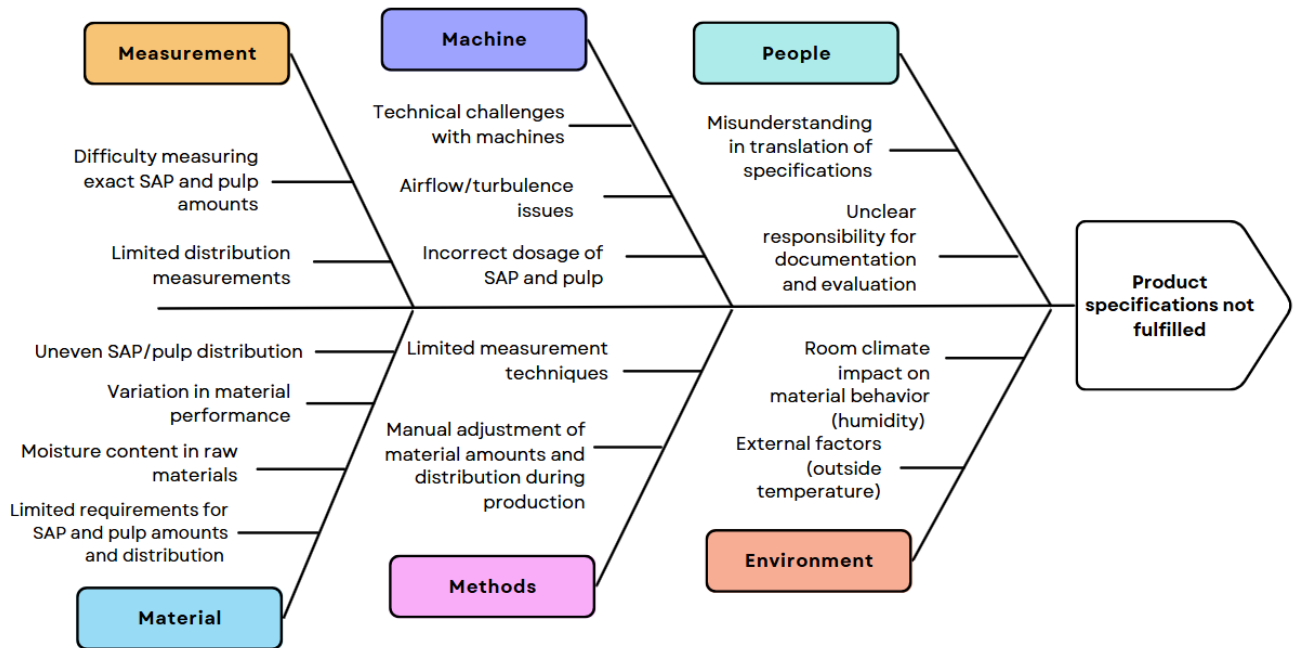


Figure 4.44: Root-cause analysis in relation to process validation (Own Illustration)

Within the measurement category, there can be potential limitations in measuring exact SAP and pulp amounts in production. From a material and environmental standpoint, factors such as humidity and temperature can influence material behavior. Another potential challenge is the turbulent airflow in the machines during the production process, potentially introducing unexpected variations in SAP and pulp amounts and distribution. Manual adjustments are used to fine-tune material dosing which could also introduce variations in production. Another potential cause of variation can be due to misunderstandings of specifications and documents, potentially contributing to inconsistent outcomes throughout different manufacturing facilities.

The fishbone diagram provides a holistic overview of the potential root causes influencing SAP and pulp integration across the value chain. This analysis underscores the importance of process validation as a key opportunity to align measurement methods, materials, staff, machine settings and environmental conditions to ensure a stable and reproducible production performance.

4.5 Running Production and Quality Control

This chapter focuses on the production of the products and the quality controls employed to measure relevant quality parameters. Additionally, the chapter also presents real-time production data collected for a number of these parameters from ongoing manufacturing processes.

4.5.1 The Manufacturing Process of Incontinence Products

A visit was made to a production facility in Gothenburg, dedicated to producing prototypes and test-variants for concepts under development. Information gathered from this visit, along with insights from the semi-structured interviews has been used to summarize the details of the processes below.

The production process begins with pulp being fed into a machine in large rolls or sheets. The pulp is broken down into fibers in a mill, transforming it to a softer tissue. At the same time, SAP is being fed through a separate pipe, merging it together with the pulp. The SAP is carefully dosed to ensure even distribution throughout the mixture. Next the mixture is sprayed onto a rotating wheel to shape the mixture into a uniform sheet. This is done by a suction vacuum drum that is attached to the wheel and ensures that the mixtures adhere uniformly to the wheel, creating a consistent absorbent layer. After this, top sheets and back sheets are applied over and under the absorbent core. These sheets provide structural integrity and additional layers for absorption and protection. For products with additional materials and/or multiple cores, the manufacturing process may differ. However, the above-mentioned steps outline the general procedure for producing these types of products. An illustration of the approximate process is presented in Figure 4.45, outlining the initial steps to the final product.

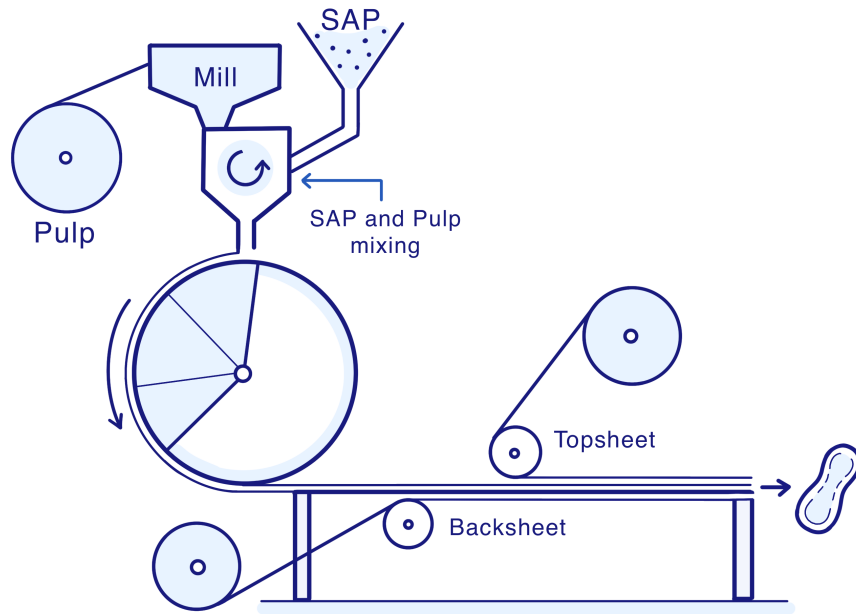


Figure 4.45: An overview of the manufacturing process (Own Illustration)

An important factor that influences the behavior and distribution of SAP and pulp is the environment. During the visit to the production facility, it was emphasized that maintaining the right humidity level is crucial to ensure that both the SAP and the pulp behaves as desired. If the humidity level is too high, the SAP will activate and start to cluster, if it is too low, it will become ineffective. The pulp is also affected, too high humidity level will cause the pulp to expand, which is undesirable. Therefore, maintaining a balanced humidity level in the factory is essential. External factors that cannot be controlled, such as weather, outside temperature and the time of day can also pose challenges in producing the cores as intended.

4.5.2 Current Quality Control Methodologies in Running Production

This section presents the methods used to monitor and assess critical quality parameters in running production such as Weight, *Thickness*, SAP amount and distribution.

Weight is one of the parameters measured in production facilities. During production, samples are periodically extracted and weighed. The standard method involves taking five samples from the same batch over a short period of time and measuring them simultaneously. This process is repeated daily to ensure consistent monitoring and control of the Product Weight.

Similar to Weight, *Thickness* is a parameter measured in ongoing production. The process is the same and involves periodically extracting and measuring five samples at the same occasion. In the factories, *Thickness* is measured using the same standardized methods as those used in the laboratory settings. This includes measuring *Thickness* in the same designated area on the product using the same type of measurement tools.

During the process validation phase, the production system is adjusted and calibrated to ensure that the specified amount of SAP is correctly applied to the product. The validation method 1, which is explained in Chapter 4.4.1, is based on Weight measurements that are consistently monitored during production. This method, that is performed in the process validation phase ensures that the right amount of SAP is correctly calibrated when transitioning into full-scale production.

There are also methods to assess the material distribution within the product in the factories. This method is similar to the one described in Chapter 4.2.4.3, where smaller sections of the product are extracted and weighed separately. This provides an indication of how even the material is distributed in different areas of the product. While this method does not specify the type of material that is uneven, it does provide an overview of the overall material distribution in the product. If the distribution is uneven, the machine can be adjusted manually to open a valve that blows more air on one side, thereby redirecting the material more towards one side.

4.5.3 Production Data Overview

Production data relating to the Weight and *Thickness* of a selected product were gathered, ranging from January 2023 to April 2025. These parameters are measured directly after manufacturing to ensure data consistency. This comprehensive data collection enables ongoing evaluation of these critical product parameters and process stability.

The production data for the Weight includes 2480 samples and is presented in a histogram in Figure 4.46. As can be seen the values are very close to target and all samples fall within the upper and lower specification limits. This can demonstrate that the Weight parameter is being maintained, and that the process is capable.

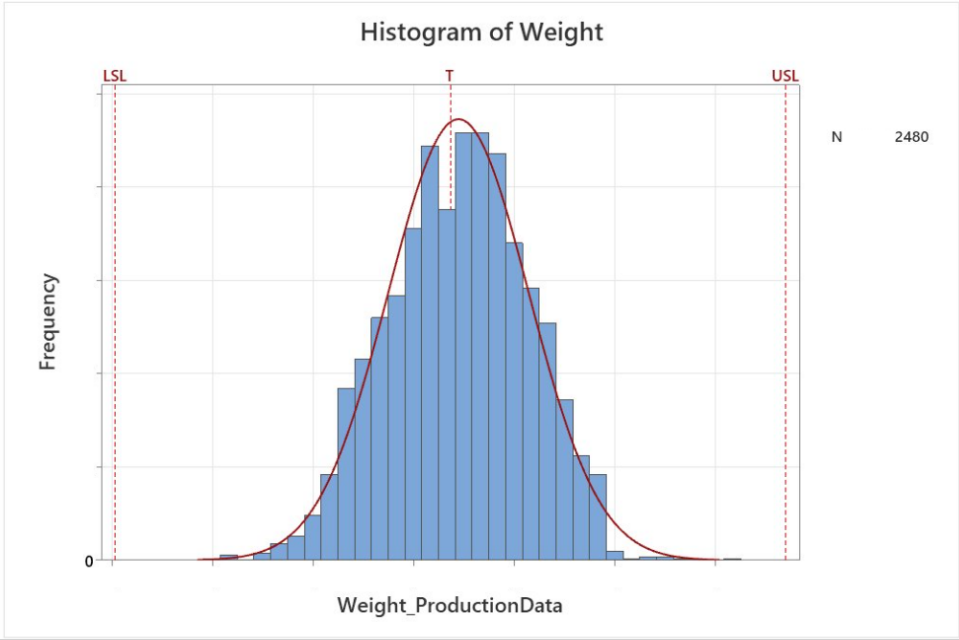


Figure 4.46: A histogram presenting the Weight measured in production for a span of two years

The data set for *Thickness* also included 2480 samples and is presented in two histograms in Figure 4.47. It is separated by Year 1 and Year 2, due to a shift in process mean after approximately a year in the collected data. As can be seen by the histogram, the *Thickness* falls within the established upper and lower specification limits, meeting variation requirements. However, there is a slight shift from the target value observed in both graphs.

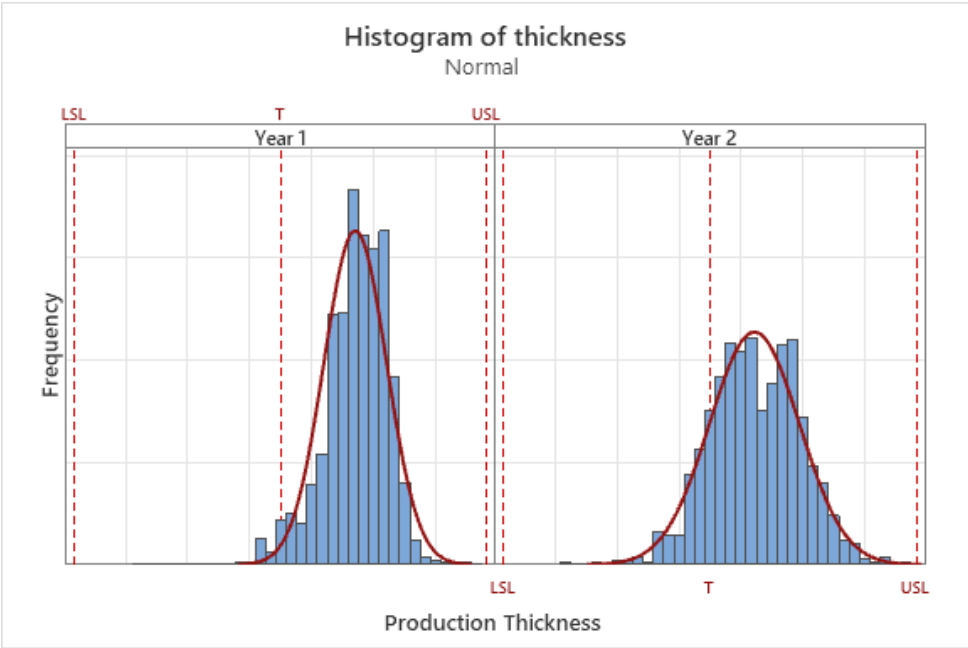


Figure 4.47: A histogram presenting the *Thickness* measured in production for Year 1 and Year 2

The production data for *Thickness* was inserted into a control chart, separated by Year 1 and Year 2 to visualize the stability of the process over time, see Figure 4.48. Initially the process seems to be stable, falling within the upper and lower control limits of the process, with some outliers falling outside of the limits, noted by the red dots. After approximately a year the data begins to show signs of instability, with increased levels of variation and a broader control limit span, which can be observed in the right side of the chart.

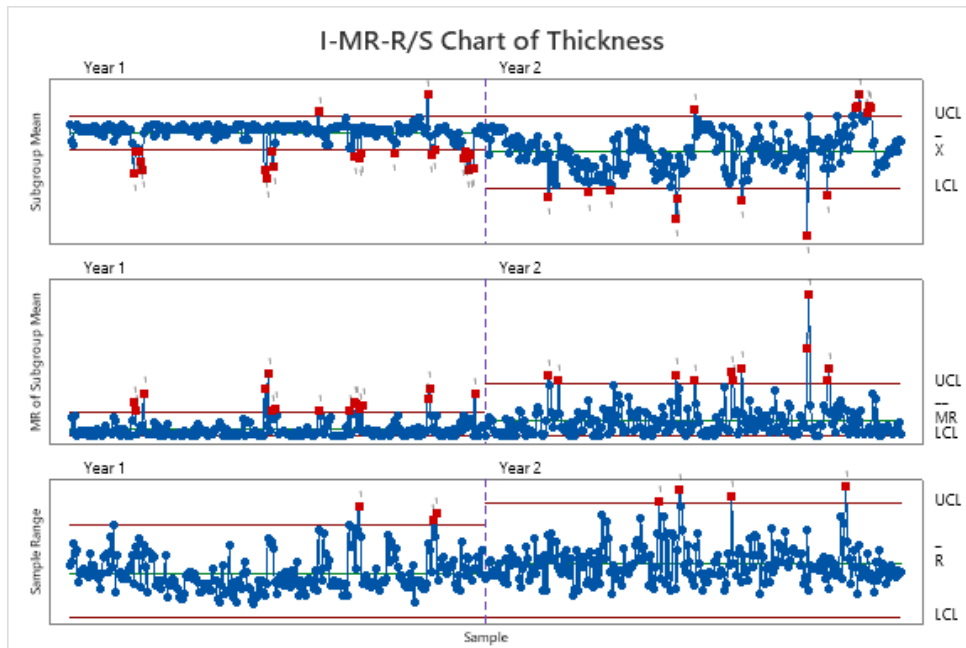


Figure 4.48: A control chart presenting the *Thickness* measured in production for Year 1 and Year 2

5

Analysis

This chapter presents a structured analysis of the four studied value phases, with a focus on understanding variation and the possible impact on product quality. By combining insights from laboratory measurements, production data, statistical evaluation and information gathered from interviews, the aim is to discover areas for improvement

5.1 Analysis of the Current Situation

Insights gathered from the interviews and the workshop reveals that there are some systematic challenges present that complicates the ability to accurately monitor SAP and pulp amounts and distribution throughout the value chain. Out of the three laboratory methods analyzed, it appears that only one is considered reliable for measuring SAP amount precisely. There is also a known recognition of sources of errors in production, like turbulent airflow and environmental distribution. One main theme that has been noted is the reliance on the assumption that the source of variation in Product Weight stems from variation in SAP amounts. However, there may be other sources of variation not accounted for or currently known, potentially impacting the reliability of that assumption. This connects back to Deming's philosophy, emphasizing the value of statistical methods in making more informed decisions, grounded in actual process data rather than assumptions or expectations.

There is also the matter of communication between different departments, particularly the transition from development to ongoing production. As Gitlow and Gitlow mention [19], when responsibilities are diluted, no single role has the accountability for ensuring that design parameters are consistently translated into reality. It should be clearly defined who is responsible for overseeing SAP and pulp data throughout the value chain from product development, through design verification and process validation, to final production. It is important to make sure efficient cross-functional communication to avoid misalignment between design intent and outcome.

There may also be a challenge of how specifications are structured and communicated. Its important that technical requirements such as Inlet and *Rewet* are properly broken down into clear design solution and design parameters. This enables better understanding for both fulfilling customer needs and avoiding misunderstandings in production. It can also be important to consider equivalence limits, and the opportunity to leverage them. Since cost is always a factor, production can potentially aim for the lowest material usage while remaining within specified requirements, rather than exceeding them. When centering requirements is not fully implemented, there is a possibility that the process mean may shift, while still remaining within specification limits. This could mean that the process operates closer to one specification limits, possibly reducing its robustness.

5.2 Evaluation of the Product Development Process

The key design parameters are analyzed with respect to technical requirements and customer needs, as well as their impact on product performance. This analysis builds on the results presented in Chapter 4.2, including QFD, laboratory tests, and defined specifications.

All design parameters are linked to technical requirements, which in turn are linked to customer needs. Therefore, it is of high priority to have good control over the design parameters in order to achieve the intended product performance. Both the presented QFD and lab tests indicated that two key design parameters are the amount of SAP and the product *Thickness*. As shown in the results, these design parameters affect the two key functions, *Inlet time* and *Rewet*. An incorrect amount of SAP and *Thickness* can lead to significant consequences for the product's performance. *Inlet time* and *Rewet* are also referred to according to EDANA [7] as two functions that are of high importance for urinary incontinence products as they minimize the risk of leakage and make the product feel drier.

As presented in the results, the amount of SAP has a significant impact on the *Rewet* of a product. The higher amount of SAP in a product, the less *Rewet* occurs, which is positive. *Inlet time* has the same relationship, where a higher amount of SAP leads to a faster *Inlet time*, which is desirable. The impact of *Thickness* also proved to be significant, for *Rewet*, the results showed that a thinner product had the lowest *Rewet*, while for *Inlet time*, a thicker product was more advantageous. This demonstrates how product developers need to consider the whole picture and optimize the design to ensure that both technical requirements meet the desired performance. There are also interaction effects between the amount of SAP and *Thickness* for the two product functions. This means it is crucial to analyze these interactions to find optimal solutions. As presented in the results for the interaction effects, the amount of SAP does not significantly affect the *Inlet times*, when the product at the same time remains thin. This means that by studying interaction effects in product development, robust design can be used to make the product insensitive to varying SAP amounts, as *Thickness* can then be used as a tool. The same reasoning applies to *Rewet*, in cases where the product is thin, the amount of SAP plays a smaller role in creating minimal *Rewet*.

Understanding the importance of SAP amount and *Thickness* is crucial. It is essential to grasp the significance and relationship of these design parameters. Additionally, ensuring that the correct dimensions are maintained in production is vital, as the consequences of deviations can be significant. In the project, it became clear that even minor variations affect performance more than expected, a lesson that reinforces the need for clear guidelines. The importance of working with well-defined specifications as technical guidelines is described according to Gitlow and Gitlow [19] as essential for maintaining quality. Variation is always to be expected, but it is important to find a way to become insensitive to incoming variation. If possible, variation requirements and centering requirements can thus serve as tools to improve quality at all levels, where specifications lay the foundation for continued quality work.

5.3 Assessment of the Design Verification Process

In this section, a combined analysis of Product Concept A and Product Concept B will be presented. Differences and similarities will be discussed and analyzed in relation to the set requirements variation and centering requirements will be reviewed.

An important observation is that the SAP amount consistently varies by approximately $\pm 30\%$ from its target across different product concepts. This range is based on calculated tolerance intervals from the tested samples. Such variation raises critical questions about its potential impact on key product functions such as absorption capacity, *Inlet time*, *Rewet*, and overall user experience. A deeper understanding of these effects could support the definition of appropriate specification limits for future product concepts. As highlighted by Sofeast [20], it is essential to define acceptable levels of variation in production in a way that maintains product quality, without setting overly tight tolerances that increase costs, or overly loose ones that risk compromising performance.

It would be insightful to know whether tighter limits are necessary to meet product performance targets or if the product is actually more robust than assumed. For Product Concept A, equivalence limits were set at $\pm 3\%$. These centering limits were maintained, indicating that this could be reasonable for this concept. Furthermore, no variation limits were set, which allowed individual values to stretch the distribution somewhat, resulting in a relatively large span between the highest and lowest amounts. Based on the finding that the SAP amount varied around 30% for both concepts, this could be used as a guideline for setting variation requirements.

Interestingly, no correlation was found for Concept A between Product Weight and SAP amount upon analysis. This was surprising, as many interviewees indicated that Product Weight is often used to estimate the correct amount of SAP in the product. They also suggested that the tolerances for Product Weight are expected to encompass SAP tolerances to some extent, given that SAP typically is the material that varies. However, in this case, a higher Product Weight does not necessarily indicate a higher SAP amount. This suggests that another material, possibly pulp or other components, is varying instead. For Concept B, the result was different, showing a clear correlation between Product Weight and SAP amount. This indicates that assumptions about correlations should not be applied universally, each concept needs to be analyzed separately. One possible reason why one concept shows a correlation while the other do not could be differences in SAP ratio, meaning that one contains a higher proportion of SAP relative to other core materials. Product Weight and SAP amount can correlate, but not in all cases.

Currently, material distribution is not specified very clearly. The only communicated requirement to production and development is that all material should be evenly distributed. Concept A was found to weigh more and contain more SAP than designed in the middle of the product. This raises the question of whether this is accidental or intentional. Increasing the amount of SAP in this area improves product performance. If this was accidental, the opposite could occur, with less material and reduced product performance due to uneven distribution. Distribution has proven to be crucial for product performance such as absorption, and increasing control through clear specifications would be beneficial. Most

importantly, the correct amount of material should be present at the dosing point, where the urine is expected to come. Therefore, one strategy could be to set material amount requirements on this area of the product, which could then be verified and controlled through punch out followed by the most accurate SAP amount method, for determining SAP amounts in specific areas of a product. Furthermore, the two products had an average CV of around 20%, but the significance of this value needs as an indicator of material distribution, needs to be better understood.

One of the design parameters that consistently presents a shift from the specified target value was *Thickness*. *Thickness* has also proven to be critical for product performance. Based on the results regarding *Thickness* variation, *Thickness* can be seen as a parameter that is difficult to stabilize around the target. The *Thickness* of the various products generally tends to be higher than the set target, indicating difficulties in reducing the *Thickness* to the desired level. This, in turn, affects the technical requirement, *Rewet*. Therefore, it is highly relevant to take better control over the design parameter *Thickness* for all products. For this parameter, as previously mentioned, it would be an option to study interaction effects with another parameter to find a solution where the product becomes insensitive to *Thickness* variations. As presented in the results, there were some interaction effects between *Thickness* and SAP amount. In cases where the SAP amount does not vary as much as *Thickness*, it might be possible to find combination of SAP amount such that *Thickness* does not significantly impact the product functions.

A recurring issue across all concepts was the failure to meet the set Ppk demand. The analysis was often based on a small sample size, making it difficult to draw definitive conclusions. However, cases where the sample size was increased, and reasonable tolerance intervals were maintained were analyzed. New limits were presented, and these were extended compared to the already proposed limits to meet the Ppk thresholds of 1.33 and 1.0, respectively. Therefore, it is necessary to tighten control and revise process parameters to meet capability requirements, particularly for *Thickness*, SAP amount, and *Rewet*.

In addition to considering tighter specification limits, it is valuable to evaluate the Pp value, which reflects the overall variability of the process, regardless of how well it is centered. If Pp already meets the Ppk requirement, it may be more effective to simply center the process within the specification limits using equivalence limit. This approach was demonstrated in the case of the Weight parameter for Concept B.

It is important to monitor process variation and avoid setting overly stringent requirements that are unrealistic to meet. An example is Concept A, which has a target *Thickness* with tight equivalence limits. Analysis shows that the average value falls outside these limits, indicating that the limit is too stringent for the process. One key insight from this observation is the necessity of conducting thorough statistical analysis before defining variation and centering requirements. This principle aligns with the guidance of Gitlow and Gitlow [19], who emphasize the importance of data-driven decision-making in quality management. While the quantity of available data is crucial, historical data can also provide valuable insights—for example, regarding SAP variation. A data-based approach enables the definition of more realistic and achievable limits. At the same time, as noted by Sofeast [20], setting limits that are too loose can negatively impact product quality. Therefore, defining tolerance levels requires a careful balance between manufacturability and performance to ensure product robustness.

5.4 Assessment of the Process Validation Process

Process Validation is an important part of the value chain, especially when it comes to ensuring that the production system can produce according to product specification. When it comes to validating the correct amount of SAP and pulp in the products, the SAP validation method 1 has been presented. In comparison with other methods that determine the SAP amount in products, the method was found to be as accurate and reliable as the most precise laboratory method. The measured averages were almost the same.

As previously presented, SAP Validation Method 1 shows potential for estimating the standard deviation of SAP amount, which is valuable information for determining realistic SAP tolerances. Therefore, there is an opportunity to establish clearer guidelines to optimize the use of the method.

Currently, the method is primarily used during validation but sometimes also during running production. As previously explained, it is crucial to take better control over SAP amount in the products, and therefore methods are needed to understand and measure quantities and variations. Using this SAP validation method more frequently during production is one strategy. However, as explained in the interviews, the time and cost sacrifices required for production stops and testing are a drawback to this strategy. As presented in the results, the SAP validation method 1 and SAP amount method 3 were found to be equally precise, with the measured averages being almost the same. Another strategy during production would then be to, instead of stopping production, take out a few products and send them to a lab facility to study the SAP amounts through the SAP amount method 3. This will help build an understanding of the current state of variation and enable adjustments to the production line when deviations occur, before the variations become significant enough to impact product performance. The number of products required to be tested to achieve a reliable and comprehensive understanding needs to be determined. The importance of sample size has previously been explained as crucial, so it is important to determine a reasonable number. There is also the possibility of using historical data to estimate the standard deviation, and thus the sample size does not always need to be the largest.

5.5 Assessment of Running Production Process

The production process of light incontinence products involves multiple challenges related to both material behavior and environmental conditions. One key issue is the difficulty in achieving uniform distribution of the SAP and pulp mixture within the core, due to the turbulent airflow in the machines. The varying humidity levels also pose a challenge in getting the material to behave right. All of these factors represent common causes of variation, that are inherently built into the process.

When reviewing the production data, it is observed that the *Thickness* is relatively high but still falls within the established specification limits. This connects back to the topic that focus is placed mostly on process capability and staying within the specification limits.

If centering is not given the same attention, the process might potentially drift high and low within the specification limits without triggering any corrective action.

When examining the control chart over a two-year period of time, it can be observed that the process initially seems stable with very little variation. After approximately a year, the data starts to shift, introducing an increase in data points falling outside the control limits. This might suggest an intentional adjustment in an effort to center the process, or it could be due to changes in the product specification, but the real underlying reason is currently unknown. However, this led to an increase in variation, causing the process to become show signs of instability. An important question is raised regarding why the shift led to greater instability. One possible explanation is that in the attempt of centering the process, a full understanding of the causes of variation was not established beforehand, as mentioned by Gitlow and Gitlow [19], this could be factors that potentially increases instability in a process.

Another observation is that, while production demonstrates a good control over SAP and pulp dosing, both through manual adjustments and the use of the SAP validation method in the Process Validation process, it could be beneficial to also monitor SAP and pulp levels in real time. Expanding the control strategy can provide an overview of these design parameters and potentially enhance product consistency.

5.6 Opportunities for Improvement

Based on the comprehensive analysis of all data, results, interviews and information gathered, several opportunities for improvements have emerged. One fundamental recommendation is to include a broader use of statistical methods across the development chain. Tools like Minitab, or similar software can be utilized to higher extent during product development to gain even more information about SAP and pulp levels and distribution. With statistical tools, better understanding of how design parameters affect technical requirements can be established, using correlation and interaction studies. This ensures that when specification limits are set, they are based on realistic values so that both product performance and processability can be assessed. This is also something that Deming emphasizes in his philosophy for quality improvement where he explains the importance of making decisions based on statistics. The use of statistical tools can also enhance internal communication. Teams can present data clearly and visually, generating a shared understanding across all departments, including R&D, Technology and Manufacturing. This ensures that decisions made throughout the chain are based on what is actually happening in production, not just what is assumed to happen.

One topic that is mentioned both in meetings, interviews and during the workshop is that if there is unexpected variation in SAP amounts, it will be detected through a corresponding change in Product Weight. There is a possibility that this assumption may not always reflect actual conditions, suggesting that expanding the monitoring of real-time SAP and pulp levels could present opportunities for further improvement. An idea could be to implement Validation Method 1 for monitoring SAP amount in running production, as mentioned earlier. However, this might not be the most time- and cost-effective approach. The company could instead consider implementing periodically lab testing of a smaller set of samples, using SAP method 3, as it proved to be a good representation of actual

conditions. Even if the sample size is limited, this strategy could provide snapshots of the SAP levels in production over time, helping to identify trends and shifts before they become too large.

Currently production data that falls within specification limits is often seen as acceptable, even though the process mean is shifted from the target. In the current production process, turbulent airflow and mechanical factors like uneven dosing of SAP could probably be identified as common sources of variation. When a process is allowed to drift close to a Control Limit, common causes of variation may frequently produce defects that appear to be due to special causes, leading to incorrect reactions. A more robust approach would be to utilize centering requirements further in specifications, either by tightening the equivalence limits or set them equal to target value. The latter means that the process mean value should be centered on target and that the control limits are locked symmetrically around target. This approach offers the benefit of constantly steering the process towards intended design targets. This focus can help to reduce false alarms or avoid unnecessary costly adjustments since only meaningful deviations will trigger intervention.

5.7 Quality Control Measures

The following control measures aim to sustain the mentioned improvements, prevent the process from drifting and maintaining consistent quality for all products.

5.7.1 Laboratory-based Product Testing

To gain an even better understanding of real-time SAP levels and distribution, a monthly routine could be implemented. This routine would involve sending a small number of samples to the laboratory each month to assess the SAP amount and distribution. However, the testing interval needs to be evaluated to determine the most optimized approach. Monthly testing was chosen to enable the monitoring of variation trends over time and to detect any seasonal or time-dependent changes in the process. By using the SAP method 3 in a laboratory setting, both entire products and smaller sections of products can be analyzed, providing insights into overall SAP content as well as the evenness across the product. An outline of the details of this control measure is presented in Figure 5.1

Purpose	Ensuring SAP amounts and distribution meet defined product specifications
Parameters to test	SAP content, SAP distribution
Method (sample & frequency)	Send six samples per month to the laboratory for testing using SAP method 3
Reference for Control	Product specification limits and targets
Who performs	Laboratory Engineer
Responsible roles	Product developers and product owners (data review and follow-up)
Training needed	Laboratory Engineer trained in laboratory SAP method 3

Figure 5.1: Table of control measure related to laboratory-based product testing

The data obtained from these tests can be logged and a statistical summary can help indicate potential trends and deviations. When deviations occur, the manufacturing department can be responsible for performing root-cause analysis and implementing corrective actions if needed. To ensure that these control measures are sustained, the

company can include monthly reviews where the evaluation of this data collected are presented and analyzed, ensuring ongoing monitoring of SAP levels. This provides a cost-effective alternative to halting production, but still offering a valuable quality control. The company can gain insight into the product performance, enabling faster problem solving, addressing signs of instability before they come to large.

5.7.2 Integrating and Training in Statistical Methods

From both the qualitative and quantitative analysis, it has become evident that the a broader integration of statistical tools and methods can be very helpful in the development process. Establishing reliable specification limits and target values, grounded in real production data and variation, enables informed and precise decision-making. Additionally, statistical tools can be used to understand interaction effects between different parameters. This has been demonstrated previously with SAP levels, where thinner products have shown less sensitivity to variations in SAP amount. Designing solutions that are insensitive to variations is crucial and statistical tools can be key in understanding interactions and supporting more robust design.

Incorporating these practices in each step of the development process not only offers the potential to enhances the overall control but may empower staff and product developers. With the right tools and understanding they can take greater ownership of their designs, reducing risk for out-of-spec products and improving the quality of their work. The details of the control measures are presented in Figure 5.2

Purpose	Ensuring robust product design in order to reduce waste
Method (sample & frequency)	Integrating statistical tools in development, performing statistical analysis, capability studies and control charts
Implementation	During development, design verification and process validation
Responsible roles	Product developers, quality engineers (training) and product owners
Training needed	Training in statistical measures and tools

Figure 5.2: Table of control measure related to integrating and training in statistical methods

The company can use internal quality experts to train staff in these areas. To ensure that the staff utilizes the information they’ve learned, regular follow-up can be made after training sessions. It can also be beneficial to include annual refresher courses to help staff retain and reinforce their learning. The benefits for this control measure can be that by improving design reliability and robustness, the company can reduce production waste, maintain product performance closer to target and ultimately enhance overall product quality.

5.7.3 Accelerating the Implementation of Centering Requirements

The current process is allowed to fluctuate within the specification limits. However, introducing centering requirements in production allows for a narrower range for the process mean to vary between. Centering requirements can be established in the development

phase, where developers are responsible for finding reasonable limits using lab data and production data to guide decisions, linking back to the benefits of the control measure regarding training staff in statistical efforts. The details of the control measures are outlined in Figure 5.3

Purpose	Establishing more accurate process control by maintaining the process mean around target
Method (sample & frequency)	Design and monitor centering requirements using equivalence limits in production
Implementation	Product development phase and ongoing production monitoring
Responsible roles	Process engineers (sending data). Product developers and product Owners (follow-up)
Training needed	Training in statistical tools to define centering requirements
Data source	Laboratory testing and production data to achieve reasonable equivalence limits

Figure 5.3: Table of control measure related to accelerating the use of centering requirements

As mentioned earlier, the product developers already receive reports from the ongoing production involving data of design parameters such as Weight and *Thickness*, so the developers can see whether these parameters stay within defined specification limits. This control measure proposes a simple extension of this existing routine, to also include regular reviews of the compliance with centering requirements. Adding the control of alignment with defined equivalence limits poses minimal effort to the already established routine. By monitoring and maintaining the process close to its target, the risk of design parameters drifting towards specification limits is reduced. Moreover, a well-centered process may even reduce the need for intensive control measures, as improved process predictability allows the company to rely more confidently on achieving consistent product performance. Over time, this increased stability can lead to financial savings, making the implementation of centering requirements valuable for long-term improvement.

6

Discussion

The discussion reflects on the findings of the study, connecting them to the research questions and evaluating the reliability of the result. It includes a discussion regarding the methodologies used, followed by an assessment of social, ethical and environmental aspects. Lastly the chapter outlines further investigations needed and recommendations for change management to ensure sustained improvements.

6.1 Discussion of Result Compared to Research Questions

An assessment is made of how well the research questions have been addressed, along with a discussion on the reliability of the results.

The study identified that the amount and distribution of SAP and Pulp has a direct impact on product performance, specifically *Rewet, Inlet time*. As a result, the product may not meet key customer needs, such as Leakage security, Dryness and Discretion, which could lead to customers not buying the product. Factors were identified that could potentially contribute to the variation of SAP and pulp levels and distribution, including technical factors from the machine, environmental influences and a set up of control systems. Control measures aimed at increasing insight into SAP levels and distribution have been proposed based on findings from laboratory tests. It should be noted that a sample size of six products per month may only represent a smaller portion of the total output. While it may be sufficient to identify trends over time, it may rarely detect significant deviations. In terms of practical applicability, the laboratory infrastructure already exists, and the method is known internally. However, there is a need to assign clear responsibility for this measure, which would require allocating resources, such as a laboratory engineer for conducting the test and a product developer responsible for evaluating the result.

The findings show that centering a process around its target value can reduce the potential risk of performance loss and defects. Rather than relying only on specification limits, centering the process around its target can promote further process capability. The process of implementing centering requirements is already ongoing within the company and by confirming its benefits such as better alignment with targets, the transition can gain further support. These arguments are based upon the findings from laboratory tests on test concepts. These were conducted over the course of a few months and with a limited number of samples. If these tests are to be conducted on real produced products, it can be beneficial to test over a longer period of time to include broader trends and batch-to-batch variation. Due to the limited sample size, controlled conditions, and the fact that full-scale production processes were not used, all of the results on the test concepts should be seen as indicative rather than conclusive. They provide a valuable foundation for further investigation and validation under more realistic conditions.

Statistical tools do not only offer insight into the current process capability, but also help reveal correlations between design parameters and technical requirements. This supports the development phase by helping to set realistic targets and specifications. By analyzing existing data, statistical methods can help in understanding variation and detect early signs of process shifts. The proposed control measures highlight the opportunity to train staff in statistical thinking. Initiatives for training in statistical tools already exist in the company, and it is important to make sure the right roles have relevant statistical training to benefit the business.

6.2 Discussion of Methodology

Through the DMAIC framework, a clear process structure was obtained, where each phase built on the results from the previous steps, strengthening the logic of the implementation.

In this project, a combination of quantitative and qualitative methods was used. The method choice aimed to capture both measurable effects through laboratory tests and experience-based perspectives through interviews and workshops. This combination of qualitative and quantitative methods has enabled a broader understanding of the problem area.

A central challenge during the project has been the small sample sizes in the laboratory execution. When it comes to analyzing data statistically, a significant number of data points are required to draw general conclusions. This has resulted in caution in drawing general conclusions and only emphasizing that indications can be seen. Trends and deviations can still be drawn from the analyzed data, and statistical tools have been used to predict results such as tolerance limits with larger sample sizes. The limitation of the sample size was mainly due to practical factors such as time and resources.

The qualitative parts of the project, such as the interviews and the workshop contributed to the understanding of the problems and the current situation. The selection of participants for the interviews and the workshop was based on both availability and targeting individuals knowledgeable in the relevant subject. Many of the interviewed individuals could contribute knowledge about the different phases. However, there is a risk that certain perspectives were not fully captured, as no one working in ongoing production was interviewed, this area was instead described by others. It would have been interesting to interview individuals working in running production to hear their views on variation and challenges. The credibility of the general results is strengthened through triangulation, where recurring themes from different sources together create a comprehensive picture. This is achieved through both qualitative and quantitative data collection.

6.3 Ethical, ecological and social aspects

A reflection on the ethical, ecological, and social implications of the project is presented, considering its overall impact.

Incontinence products are essential for maintaining dignity, comfort and quality of life

of individuals living with urinary incontinence. Ensuring that the incontinence products function reliably is ethically important, as poor performance can lead to discomfort, social isolation and reduced well-being. This project contributes ethically by improving the quality control of two key materials, SAP and pulp which impacts key functions such as leakage security. By integrating statistical tools and better understanding material variation and setting more precise specifications, the chance of consistent product performance increases.

From an ecological perspective, incontinence products present notable sustainability challenges. Most products are single-use and contain plastic-based materials, which are not biodegradable and contribute to long-term environmental impacts. Product development and design verification are two phases which involves extensive laboratory testing to assess functional performance, material consistency, and safety. While necessary, such testing also consumes materials and generates waste. It is therefore important to ensure that testing activities are optimized and environmentally justified. This project contributes to ecological sustainability by promoting the use of statistical tools to better understand material variation. By using historical data and applying variation analysis, it becomes possible to reduce the number of physical tests required. In many cases, smaller sample sizes can be used without compromising the reliability of results.

Incontinence is a condition that affects people across all ages, genders, and social groups, often carrying significant psychological and social consequences. Incontinence products of high quality play a crucial role in enabling user independence. When users can trust their products, they are more likely to engage in work, education, and social activities which improves overall well-being. This involves ensuring that product design and communication strategies minimize social discomfort for individuals. By improving quality, this project, contributes to a socially inclusive approach to product development, where the focus is not only on technical performance but also on real-world impact for users. Furthermore, it is important that the measures resulting from the thesis project do not compromise the pricing, ensuring a balance between quality and economic accessibility, so that the products are affordable for anyone who may need them.

6.4 Further investigation

While the result provided valuable insights, further investigations are necessary to strengthen some of the findings made. To improve the reliability of the result the future work should include testing both on real product concepts and including a broad range of different product concepts that differ in design. It is also recommended to perform tests over a longer period of time to capture batch-to-batch variations and to increase the samples size to support a more robust statistical evaluation. These extended investigations could provide a more solid foundation for implementing control strategies across the whole development chain.

In order to ensure that the improvements are sustained over time, further investigation is needed into how the proposed changes can be implemented effectively within the organization. A crucial aspect will be to understand how these changes can be embedded into daily operations and supported through ongoing follow-up processes. An initial step could involve defining and assigning clear roles and responsibilities. The suggested control

measures already indicate potential role distributions. Clarifying these roles will be central to a successful implementation. Further exploration is also needed on how to best integrate the control measures into current routines and systems. Some measures may require adjustments to existing documentation, such as updated datasheet or new fields in reports. For instance, to support faster centering requirement processes, new types of follow-up routines may be necessary. Moreover, it is essential to investigate how changes will be communicated across departments such as R&D, Technology, and Innovation. Effective cross-functional communication is critical to avoid knowledge silos and ensure alignment around the improvements.

Conclusion

The master thesis has thoroughly examined the product development chain for light incontinence products, focusing on two of the most critical materials SAP and pulp. By identifying sources of variation in material amounts and distribution, the study has highlighted key areas for improvement in quality assurance processes. The investigation into design parameters and technical requirements has underscored their significant impact on product performance, emphasizing the necessity for reliable and robust specifications.

The use of statistical tools and analysis has proven to be invaluable in setting more robust targets and enhancing process control across the studied phases of the value chain. Statistical tools can be used to understand material variations, thereby setting more reasonable and credible specification limits. Interaction effects have also been shown to enable designs where certain parameters become insensitive to incoming variations. Key findings also include the importance of defining centering requirements in production to maintain process mean values close to target. Furthermore, it is recommended to allocate R&D efforts toward monitoring the SAP levels of launched products during production control, as such monitoring is currently infrequent due to time and cost limitations.

In conclusion, this thesis has laid the groundwork for more consistent and reliable incontinence products, ultimately contributing to a better quality of life for individuals with urinary incontinence. The findings and recommendations presented here offer a pathway for ongoing improvements and innovations in the field.

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