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Investigating Polymer Degradation in Medical Device Production Using Inherent Viscosity Measurements

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Investigating Polymer Degradation in Medical Device Production Using Inherent Viscosity Measurements.

Commissioned by Phillips-Medisize.

In a world full of industries, quality remains the main factor that makes an industry stand out. Phillips-Medisize has a zero-defect goal that aims at continuous improvements. In addition, as for a company that manufactures medical devices made out of plastic polymers, degraded components should not be considered as a normal characteristic in a polymer nor as a usable product for the safety of the patients.

This thesis will clarify the method that Phillips-Medisize is currently utilizing to measure the molecular weight in a polymer. This method is used in order to acquire the polymer's properties that determine the degradation levels. The degradation can be visible from the polymer's behavior. This thesis will also discuss the outer elements that affect the polymers causing it to degrade.

For more accurate and reliable measurements, viscometer devices can be utilized for the sake of grasping as much beneficial information as well as actions to implement during the degradation. Viscometer devices mainly include displays that show the results in a graph form for easier interpretation and less time consumed.

The IhV method influences the determination of the degradation level. It also measures the flow time of a fluid, with and without applying stress to understand the polymer's behavior. This method has been researched according to the ASTM D4603 standard.

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ASTM D4603, Capillary Viscometer, Degradation, Dilute Solution Viscosity (DSV), Inherent Viscosity (IhV), Molecules, Polymers.

Contents

1   Introduction

This thesis is commissioned by Phillips-Medisize, a Molex company located in Lehmo, Finland. Phillips-Medisize stands as a worldwide organization comprising over 7,500 professionals renowned for their skills and knowledge in areas such as design, product development, manufacturing, tool construction, and the introduction of new products. The company provides comprehensive solutions in front-end design, development, and manufacturing tailored to industries with stringent regulatory requirements. such as pharmaceuticals, in vitro diagnostics, medical technologies, automotive and defense. It is a global leader in this field, supported by the collective resources of Molex and its parent entity, Koch Industries. (Phillips-Medisize 2023.)

Manufacturing medical devices as a company takes a lot of research, development, and studies. Most manufacturers tend to use certain kinds of unharmful polymers in their products both to prevent diseases for patients and harm to the environment. This thesis will be contributing to the plastics quality control enhancement to get the final product delivered to the customer with zero defects. Zero defect products align with one of the organizational objectives in Phillips-Medisize. (Phillips-Medisize 2023.)

Therefore, Phillips-Medisize is a manufacturer of injection devices and diagnostic tests using polymers as a raw material, some quality faults such as degradation can occur. Degradation is the process by which polymers lose their strength and stability due to exposure to heat, light, air, water, or microorganisms. Phillips-Medisize has observed material degradation during the process. This appears as cracks and fragile pieces. Phillips-Medisize has been measuring the melt flow rate. The molecular weight is comparable to the melt flow rate. A low molecular weight is associated with a high melt index, and a high molecular weight is associated with a low melt index. However, the results have not been accurate enough to know the degradation levels of a component.

This thesis aims to investigate the polymer degradation in medical device production using the inherent viscosity method. The purpose of this study is to investigate the benefits and limitations of the IhV method compared to other methods, such as the melt index, and to identify the factors that influence the validity and reliability of Inherent Viscosity (IhV) measurements. This thesis seeks to provide valuable information regarding the degradation levels and the possible causes of a material's degradation as well as suggestions for optimizing the quality control of plastics and improving their functionality. Later on in this thesis, Phillips-Medisize will be referred to as a company.

Another goal of this thesis is to clarify and assist the company in its decision making and to clarify the compatibility of a viscometrical device according to the company's specific requirements. One of these requirements is to have an efficient device that can measure the samples accurately in a short period of time with promising results.

2   Introduction to the IhV Method and its Applications

To begin with, IhV stands for Inherent Viscosity. The purpose of this method is to measure the molecular weight of a polymer and its quality. It is highly important to know the molecular weight since all polymer chains do not have the same molecular weight and chain lengths.

Hence, the molecular weight of a polymer is very useful for finding out its properties. The final form of a solid material depends on how the molecular weight influences its physical and mechanical properties. However, the goal and use of the IhV method is to keep the end properties of the polymers and control the processability in a desired range. (ASTM D4603, Pg 2.) (Hylton 2004, Pg 8.) Some questions that the IhV methods can answer are:

- What is the molecular weight of a polymer in a solution?
- How easily can a polymer chain move in a solution?
- How is the quality of a polymer solution affected by impurities, degradation, or cross-linking?

- How can the processing conditions or the formulation of a polymer solution be adjusted to achieve the desired quality and performance?

2.1 The Melt Index Method

With the method Phillips-Medisize is currently utilizing, namely the melt index as shown in Figure 1, it is not possible to determine the possible degradation of the material from the injection molded parts.
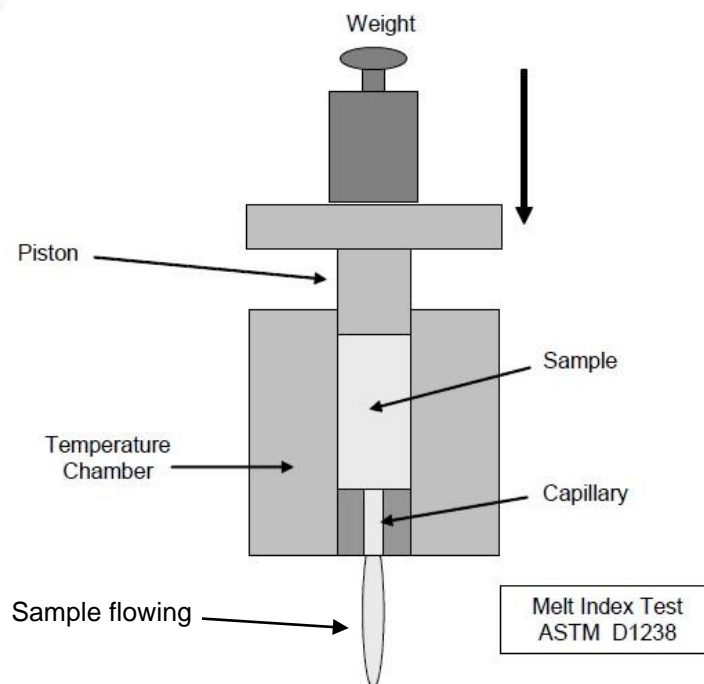
Figure 1. Typical Melt Index (Hylton 2004).

Melt index measures how fast a melted material can squeeze out of a small hole with a certain shape and size. The hole is called an orifice, and it has a fixed length and diameter. The test is done at a certain temperature and pressure according to different standards. The main purpose of the melt index test is to determine the size of the molecules in a material. (Hylton 2004, Pg 48.)

The inherent viscosity should be measured by a viscometer device or a capillary viscometer to evaluate the properties of the polymers. The reason is that the

capillary viscometer measures the viscosity of the polymer melt at different shear rates, giving a complete picture of the polymer's melt and how it responds to flow and stress. Shear rate is how fast the material changes as it flows when force or pressure is applied to it. Therefore, melt index is not as accurate as a capillary viscometer when measuring and understanding the behavior of a polymer. (Hylton 2004, Pg 49.)

2.2 Degradation in Polymer Science and its Causes

The Inherent viscosity method can determine the molecular weight of a polymer in order to understand its characteristics and behavior; it can also solve problems related to depolymerization. Depolymerization is a process that splits large molecules called polymers into smaller units called monomers. This can happen when the bonds in the polymer chain are broken by different factors, such as high temperature, chemical reactions, or biological enzymes. A polymer is a large molecular chain made of many smaller units called monomers. The scientific term that refers to the depolymerization process is known as "unzipping" (Carraher 2017, Pg 371).

Polymers are modified in every lab or company to achieve a certain positive reaction with specific results and properties in mind. For instance, some acids can be added to the polymer to improve its strength and solubility. However, these modifications can also cause some unintended reactions that lead to some undesirable properties, thus affecting the final outcomes. For example, some polymers can degrade or cross-link, which lowers their quality.

In the field of polymer science, degradation is defined as any alteration or reduction in the characteristics of polymers due to the influence of environmental elements such as light, heat, mechanical forces, and chemicals. Some degradation agents are mostly susceptible to certain polymer types (Carraher 2017, Pg 371.) Table 1 as shown below simplifies it.

Degradation Agent	Most Susceptible Polymer Types	Examples
Moisture	Heterochain polymers	Polyesters, nylons, polyurethanes
Heat	Vinyl polymers	Poly (vinyl chloride), Poly (alphamethylstyrene)

Table 1. Primary agents that break down synthetic polymers (Carraher 2017, 371).

Table 1 shows the degradative agents that play a big role in degrading these synthetic polymers. However, this is not always the case or the main cause for these specific polymer types and their examples. Degradation can be caused by many different means such as those previously mentioned or a combination thereof.

It is crucial to know that the majority of polymers are prone to oxidative degradation. This is particularly the case when subjected to conditions such as high temperatures, plentiful oxygen, different catalysts, intense radiation (including ultraviolet and high-energy visible light), and physical strain. One way to mitigate the degradation caused by oxidants is by incorporating antioxidants. These are typically compounds that readily interact with free radicals or enticers to diminish their impact. Nevertheless, even in the presence of antioxidants, most polymers remain vulnerable to degradation under natural radiation such as sunlight and elevated temperatures. (Carraher 2017, Pgs. 371-372.)

2.3 Types of degradations and their solutions

Certain parameters might affect the quality and performance of the components in production, during processing or even after. Therefore, it is important to measure and monitor parameters such as moisture content, melt temperature and residence time, as shown in Figure 2.

H₂O
The pellets should have a moisture content
value below 0.03% (300ppm)

Temperature
Melt temperature should be between 260-280°C

Residence Time
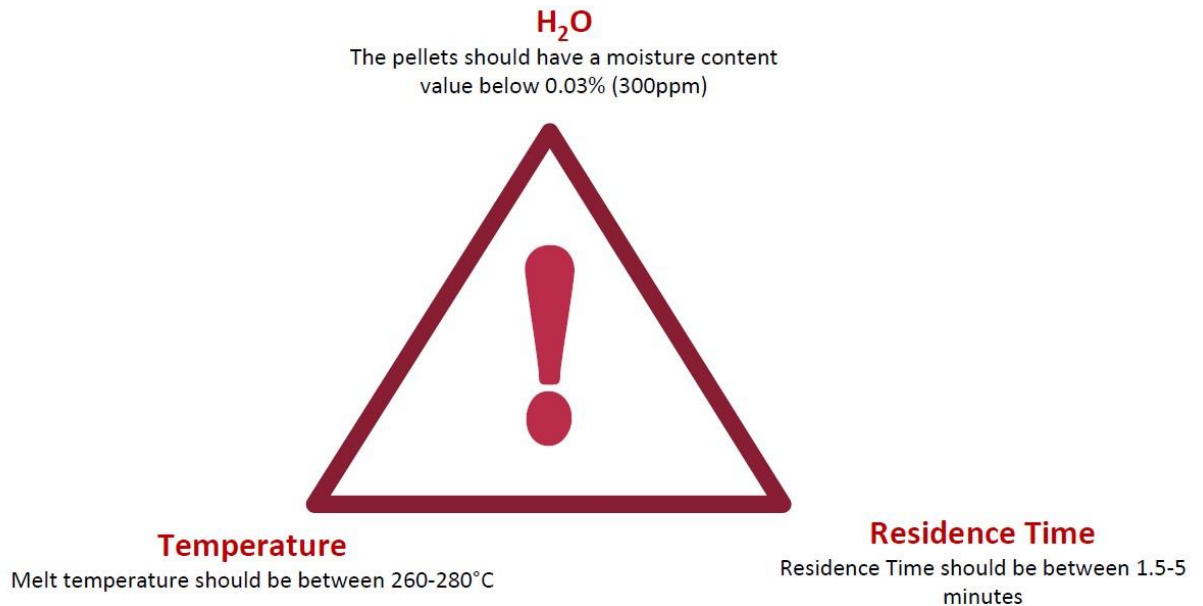Residence Time should be between 1.5-5
minutes

Figure 2. Three main reasons of material degradation (Supplier 2023).

Figure 2 shows the possible causes of the component's degradation during the drying process or during the polymer processing. The moisture content should be below 0.03% (300ppm), the melt temperature should be between 260280°C, and the residence time should be between 1.5-5 minutes. If any of the values are out of the range, it might indicate a problem or a potential cause of degradation. (Supplier 2023.)

Secondly, some possible sources of variation on error for each parameter include, for instance, that the moisture content might be affected by the storage conditions, the drying process, or the humidity level. The melt temperature might be influenced by the heating system, the extruder speed, or the ambient temperature. The residence time might depend on the screw design, the feed rate, or the die pressure. (Supplier 2023.)

Regarding residence time, leaving the polymers in the barrel for too long at processing temperature can cause the degradation of the polymers as well, not only the molded component. The supplier then recommends a residence time between 1.5 – 5 minutes. (Supplier 2023.)

2.4 Cross linking in Polymer Science

In some cases, the reason for the plastic's inferiority might be caused by something other than degradation. Cross-linking is a phenomenon that can occur in certain polymers, and it is a common characteristic of both natural and synthetic polymers, as well as vinyl and condensation polymers (Carraher 2017, Pg 373).

These cross links can maintain the polymer chain's properties, such as its shape, size, and color. For instance, if a rubber band is heated it becomes more flexible making it possible to stretch much further than before. However, when it cools down it will go back to its original size and shape. The cross-linking reaction can either be a positive or negative reaction, depending on the intended result. (Carraher 2017, Pg 373.)

There are two types of cross-linking: physical and chemical. Physical crosslinking happens when the entanglement of chains causes the intertwined chains to behave collectively, which restricts their mobility. This also occurs in crystalline formation when the material's strength increases to reduce the wholescale chain movement. However, both ways lead to the material becoming weaker, brittle, less flexible, rigid, stable, and stronger. (Carraher 2017, Pg 373.)

Chemical cross-linking is when two molecules form a bond between their double bonds, creating the chemical cross-link between them. Some molecules have double bonds, and they are more reactive since they can break easily and form new bonds with other molecules. One example of chemical cross-linking can be vulcanization. Vulcanization is the process of using sulfur to harden the rubber in order to make it more durable and elastic. In this case, the cross-link forms when rubber, which is a polymer that has many double bonds, is heated with sulfur, the rubber's double bonds break and form new bonds with the sulfur atoms in it. Therefore, the chemical cross-link occurs (Carraher 2017, Pg 373).

2.5 IhV Ranking

It is quite challenging to get a standard or a reference sheet for degradation levels to refer to when measuring the inherent viscosity. The reason is that there are a variety of different polymers for different applications and therefore for different criteria. However, the supplier has been measuring the inherent viscosity and degradation levels for Phillips-Medisize.

Phillips-Medisize's supplier has its own internal degradation values based on its best experience. As with any other company, the supplier always aims for the best and to maximize the quality for its consumers and clients. A certain IhV value, which is a key or usual quality control parameter for the materials, is delivered by the supplier. Therefore, the supplier studied the behavior of the materials. It also ensured that it has established internal processing brackets, which are ranges of processing conditions and factors that can cause different levels of degradation for plastic materials during injection molding and the impact they have on the properties of the material. (Supplier 2023.) An example of the supplier's IhV ranking that determines the degradation levels is shown in Figure 3.

General IhV Ranking	
0-2%	Excellent processing/drying
3-5%	Good to average processing/drying
6-10%	OK processing/drying
9-15%	Poor processing/drying
16-50%	Extremely poor processing/drying

Figure 3, IhV Ranking and degradation levels (Supplier 2023).

The less the percentage of the IhV loss, the better. A more descriptive way for the ranking numbers of the IhV rankings are:

- 0-2% - Inherent viscosity loss: mainly the same IhV measurement of the pellet– excellent as loss of original properties is minimal. No further improvement can be achieved in terms of degradation.

- 3-5% - Inherent viscosity loss: good, as it is usually the industry standard. The properties are slightly affected by the low level of degradation.

- 6-9% - Inherent viscosity loss: decent processing, maybe identified as a borderline degradation since it is too close to the high level of degradation. The material parameters have slightly decreased, but they are still suitable for the application.

- Over 10% - High degradation of the polymer causes a large decline and loss in the material properties. In some cases, if the material is more specified than needed, it can still be utilized. (Supplier 2023.)

2.6 Solvents in IhV Methods: Role and Function

In this section, the entire concept of solvents will be introduced, along with finding out how to choose solvents according to materials, and why solvents are even needed in the first place.

A solvent is a substance that can dissolve another substance. For instance, water is an example of a solvent. Water was the first substance that people thought of as a solvent (Reichardt & Welton 2011, Pg 1). A solvent is mainly used in a solution; both a solvent and a solute can form a solution. A simple example to clarify how the solution, solute and solvent are related, is by having 1 cup of sugar and 2 cups of water. In this experiment, the water plays the role of the solvent, sugar as the solute and by adding both of them in a vessel, the solution forms as a result. The solution here has the sugar diluted or dissolved in the water. Another term that can be used for this result is dilution, which can here be understood as the process of lessening the concentration of the solute in a solution.

One benefit of using diluted solutions is that their viscosity can be measured to ascertain the specific volumes of macromolecules. These volumes are directly associated with the shape and size of the molecules in the solution and have an

indirect relationship with their molar masses. In other words, the volume per gram of a large molecule can be known by measuring the viscosity of a diluted solution of the molecule and the solvent. This has a direct connection to the shape and dimension of the molecule when it is dissolved in the solvent. As a result, there exists an indirect correlation with the molecular mass of the compound since molecules sharing identical molar masses may exhibit variations in shapes, dimensions, and lengths. (Elias 1996, Pg 200.)

2.7 How Solvents Affect the Accuracy and Reliability of IhV Measurements

Polymers move very slowly in their nature, hence when dissolving polymers in a solvent, it makes the whole solution viscous therefore slow. The reason is that they have a high molecular weight, and a higher molecular weight results in a higher viscosity for the polymer solution. The dissolving of the polymers into the solvent involves the solvent's diffusion and the chain disentanglement. In addition, it is needed to ensure the solubility of the polymers with a solvent. The solvent makes the polymer swollen, which means it increases its volume, creating a gel layer with two different interfaces, one with the polymer and one with the solvent. Finally, the polymer dissolves after the induction time. The induction time indicates the slow stage period of time before the full chemical reaction occurs. (Miller-Chou & Koenig 2003, Pg 1234.)

The main idea of using solvents can be clarified in two ways:

1. The molecular weight cannot be measured if the polymers were in a solid form, and at the same time, it is not possible to only heat the polymers and get the molecular weight through the heating method. However, there are variety of different polymers that heating may be applicable in their case. (Schaller 2023, Chapter 4.1.) The reasons why it is not possible are:

a. The results are not accurate nor reliable due to the polymer's chains' interactions, forming entanglement (Schaller 2023, Chapter 4.1).

b. The polymer's long chains break, resulting in thermal degradation that leads to smaller fragments and losing mass, which makes it harder to measure the polymer's molecular weight (Schaller 2023, Chapter 4.1).

2. When polymers are diluted in a solution, the polymer chains start to react with each other and behave as independent molecules. Not all polymer chains have the same weight and length. Some polymer chains can be shorter or longer, and some can even stop growing. That is why when measuring the molecular weight accurately it becomes helpful to know how widely these individual polymer chains are distributed. The dispersity is a term that indicates how varied the molecular weights are in polymer chemistry. (Schaller 2023, Chapter 4.1.) (Miller-Chou & Koenig 2003, Pg 1228.)

In conclusion, polymers should dissolve in a substance in order to get precise and accurate results by measuring the molecular weight. However, there are a variety of different methods to dissolve the polymers, with or without using solvents and toxic chemicals.

2.8 The Importance of Solvent Selection for IhV Methods

Polymers can mix with solvents or another material that have similar solubility parameters. This is called the 'like dissolves like' rule, which means that materials that have the same chemical properties can dissolve better in each other. The compatibility of polymers with other materials for the sake of dissolution can be predicted by using solubility parameters frequently in industries. The solubility parameters of polymers can only be obtained by using methods that are not explicit usually, since polymers have high molecular weight and do not have a boiling point, they will not evaporate but instead they degrade easily. (Miller-Chou & Koenig, Pg 1234.)

One of these methods can be for example, the solubility being measured directly by using different solvents or by using lightly crosslinked polymers and measuring how much they swell or, in other words, how much the polymers can

absorb the solvent. The swelling will be the greatest when the solvent and the polymer have the same gel layer thickness value. (Miller-Chou & Koenig, Pg 1228.)

However, these parameters are only used to determine the solubility and behavior of a polymer or solvent in many industries, especially for applications such as paints, coatings, etc. Therefore, parameters may not actually be directly and explicitly helpful when determining the kind of solvent that should be used with certain types of polymers, since the parametric shows only the numerical values. (Miller-Chou & Koenig, Pg 1233.)

On the other hand, there are some useful references when choosing a solvent. One example is the chemical resistance chart, also known as the solvent selection guide. Such a guide is made by researchers, organizations or institutions involved in Chemistry studies. This is also a great way of helping to keep the environment safe due to less experiments occurring in the labs or industries in dealing with chemicals. As an observation, it has been noticed that IhV methods can measure polymers that can be soluble in a solvent or in other words, diluted. In that way, the fluid can at least flow through the capillary tube in order to get measured.

The chemical resistance of a material is the ability of the material to withstand the effects of a chemical or a mixture of chemicals without significant damage. The chemical resistance of a material depends on many factors, such as the type and concentration of the chemical, the temperature and pressure of the exposure, the duration and frequency of the contact, the surface characteristics and joining methods of the material, and the mechanical stress applied to the material.

Alphabetical Listing of Materials	Concentration + Weight %	ABS	Acetal	Acrylic	CAB	CPVC	ECTFE (Halar®)	Fluorosint®	HDPE	Nylon®, Type 6/6	PEEK	PET	Polycarbonate	Polypropylene	Polysulfone	PPS	PVC, Type I	PVC, Type II	PVDF	PTFE	Tecator™/Torlon®	UHMW
☑ Acetone		D	B	D	*	D	A	A	A	A	B	B	C	A	B	A	D	D	D	A	*	*
☑ Ethylene Dichloride		D	*	*	*	D	A	A	D	B	A	A	*	D	*	A	D	D	A	A	A	*
☑ Methyl Acetate		*	B	*	D	*	*	A	*	A	A	A	*	*	*	A	*	*	A	A	*	A
☑ Methyl Ethyl Ketone		D	B	D	D	D	A	A	D	A	A	A	D	D	D	A	D	D	D	A	A	A
☑ Methyl Chloride		*	C	*	D	D	A	A	D	C	A	D	D	D	D	A	D	D	A	A	*	A
☑ Vinyl Chloride		*	*	*	*	*	*	A	*	A	A	*	*	*	*	A	*	*	A	A	*	*
☑ Water		A	A	*	*	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
☑ Xylene		D	*	D	D	D	A	A	D	D	A	A	*	D	D	A	D	D	A	A	A	B

Figure 4. Chemical Resistance Chart (Plastics International 2018).

To evaluate and compare the chemical resistance of different materials, various methods and standards have been developed, such as ASTM, ISO, DIN and BS. One of the common methods is to use a chemical resistance chart or table, which provides a general guide and rating system for the compatibility of a material with a chemical or a mixture of chemicals. An example of a chemical resistance chart is shown in Figure 4. This is adapted from the Plastics International website, which also allows the users to filter the materials or solvents they are looking for according to the desired polymer or plastic. On the other hand, the chart uses a five-level rating system, which is explained in the legend below:

- A: No attack, negligible effect. The plastic material is suitable for the solvent and shows no significant damage.

- B: Slight attack, reduction in properties. The plastic material may show some signs of swelling, softening, or loss of strength.

- C: Moderate attack, limited life. The plastic material is not suitable for the solvent, and may show considerable swelling, cracking, or dissolution.

- D: Severe attack, not recommended. The plastic material is not suitable for any exposure to the solvent and will likely fail.

- *: No data available

In addition, the chosen solvents in the graph do not indicate that they are the only ones applicable to be measured in the IhV. However, the graph indicated an example in general. (Plastics International 2018.)

3   Measuring Systems and Measurement Results

Rheology, a scientific discipline concerned with the deformation and flow of materials, assesses the appropriateness of materials for specific uses and correlates the outcomes with the structure and shape of polymers. (Hylton 2004, 45).

The flow of polymers is of significant importance to the processor, material provider, end user, and polymer scientists. This characteristic categorizes materials and aids in the development of new materials. It also shows if a material can work for a specific manufacturing process. Plastics are both viscous (flow) and elastic (solid) at once, which is called viscoelasticity (Hylton 2004, 45).

In order to measure the flow behavior of a polymer or to test it, a variety of different devices and tools are used explicitly according to the polymer type, thickness and what kind of measurements or results would be preferred to have as the output.

In the case of Phillips-Medisize, continuous testing and quality control are essential as both consumers and clients prioritize their safety and adherence to specific standards. Customers have become more conscious of the products they use and the standards these products need to meet for safe and reliable consumption. Manufacturers are obligated to comply with numerous specifications, standards, and health and safety requirements, and to disclose information about their products. (Hylton 2004, 1.)

3.1 Capillary Viscometer Solution or Rheometry Solution (ASTM 2857, ISO 1628)

To meet the standards, one of the first methods for measuring molecular characteristics of polymers was dilute solution testing. This technique estimates the average molecular weight of polymers in dilute solution by using a glass viscometer (see Figure 5). Solution Rheometry with the American Society of Testing and Materials (ASTM) 2857 and ISO 1628 studies this entirely and can be also used to measure the viscosity and the behavior of the polymers especially. (Hylton 2004, 58).

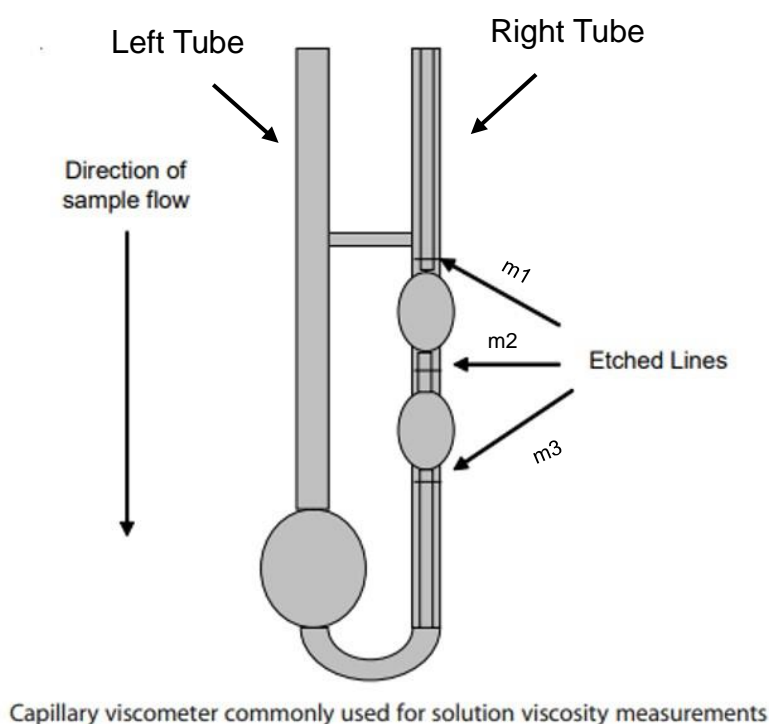Capillary viscometer commonly used for solution viscosity measurements

Figure 5. Capillary viscometer (Hylton 2004, 58).

A capillary viscometer called Ubbelohde is one type of instrument. It basically works by pouring the solution into the left tube (Direction of sample flow) as shown in Figure 3. The solution is poured into the Ubbelohde patiently until the fluid level reaches in between the two markings on the right tube (these markings will be marked in the Ubbelohde glass itself). Secondly, the fluid will be drawn upwards, for instance by a syringe that has a tube attached to it, from the tube on the right side of the viscometer. While drawing the fluid from the right tube, the left tube is closed tightly with a finger for example. This is only done by taking into

consideration the toxicity of the solvent used, and accordingly, another tool can be used. The reason for blocking the left side tube is to help the fluid can be drawn up towards the syringe when pressure is applied.

The viscosity of a fluid is determined by the duration, in seconds, it takes for a specific volume of the fluid to travel a set distance (Hylton 2004, 58). For instance, to measure the flow time between m2 and m3 as shown in Figure 5, the timer starts when the fluid completes its flow in point m2 and stops in point m3. Ultimately, by conducting this test on various polymers, the observed changes can help ascertain the molecular weight of the polymer in the samples. (Dr. Sentman 2019.)

3.2 Rotational Viscometer or Rotational Rheometer (ASTM D4440)

The Rotational Viscometer and the Cone and Plate measuring system might be efficient but indeed not in this case. The reason is that the capillary viscometer measures the diluted solutions better and more accurately than the rotational viscometer, which plays a huge role in the measurement of the inherent viscosity. By studying the schematic and the detailed theoretical explanation in Figure 6, the company can comprehend why the non-Newtonian fluids and some of the polymers they have are incompatible with this rotational viscometer device.

Dynamic Plate

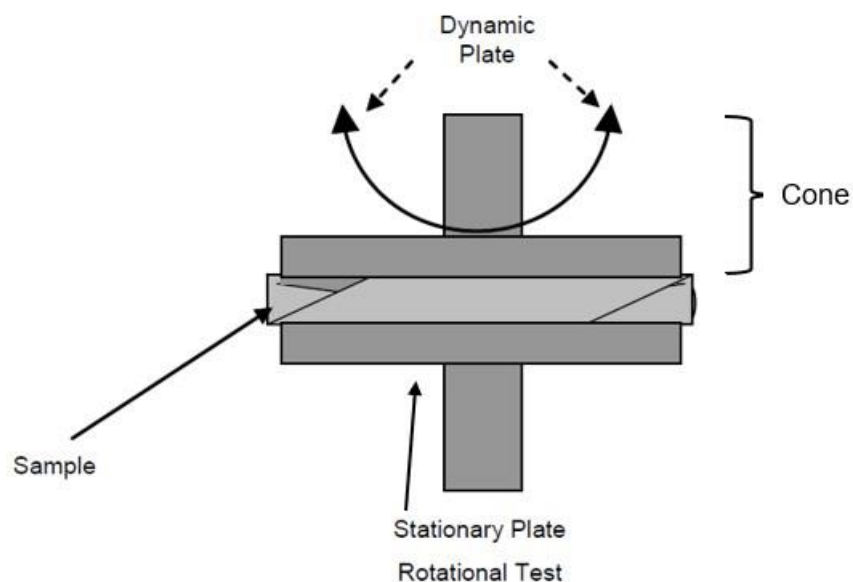Cone

Sample

Stationary Plate

Rotational Test

Figure 6. Rotational Viscometer (Hylton 2004, 53).

Often, in measuring systems the tip of the cone is truncated. Since the entire measurement depends on strain and shear, the size of the cone depends on the result of the measurement. For instance, the larger the cone angle is, the more the shear rate across the gap starts to vary. The smaller the cone angle is, the higher the possibility of errors happening becomes. This all relates to the gap setting, which is basically the gap between the cone and stationary plate where also the sample gets placed in. One of the possible risks when using a small cone angle is that the operator-to-operator gap setting easily introduces errors of over 5%, even with experienced operators.

Figure 7. Viscometer RM 100 CP2000 PLUS (Lamy Rheology 2023).

How the sample is placed in a device, for instance, the Rotary viscometer RM 100 CP2000 PLUS, is shown in Figure 7. Before starting any measurements, the device should be zeroed. Therefore, a method for each measurement is saved from the digital screen of the device with different duration, shear rate, and speed.

Afterwards, the cone plate will be installed into the device. Then the measuring head will be moved down to a point where it does not touch the lower plate. Subsequently, an attached white wire will be locked inside the spindle shaft in order for the cone plate to stay firm. The next step is to turn the brace ring clockwise until it beeps. This step is important because it confirms that the

settings chosen are in place especially regarding the measuring position. When all the specifications and requirements for the method are met, the measuring head can be raised.

When the measuring begins after the sample's preparation, the sample will be placed onto the lower plate, followed by lowering the measuring head towards the sample. From the digital screen, methods and measuring options can be selected. After the measuring process, the device will show all the results for the sample. These results can for example include, the viscosity, the shear rate, time, torque, and temperature, in addition of course to the date and time of the measurement. For clear understanding, Figure 6 illustrates all the abovementioned details in the device itself.

3.3 Interpretation and Explanation of the Measurement Results according to ASTM D4603

The test method for determining inherent viscosity, and the polymer type (PET Poly (ethylene terephthalate) can be used as an example, since this entire procedure relies on the ASTM D4603 standard. The following explanation will employ viscometry theory to explore the collaborative dynamics of solvents, solutes, solutions, and capillaries, along with detailing the computation and utilization of the IhV method. (ASTM International 2018.)

Starting with the essentials, the following will be needed:
- (PET) Polymer sample
- A suitable solvent for polymers, which is 60% phenol and 40% 1,1,2,2tetrachloro-ethane by weight.
- Safety equipment, such as safety glasses, rubber gloves, a safety apron, and a long-sleeved lab coat are required when dealing with such heavy solvents. Other instructions can be found from the solvent's safety data sheet.

The procedure starts by accurately weighing 0.2475 and 0.2525 g of the sample into a clean and dry 50-mL flask. A side note to keep in mind at this point is to check if the sample measured contains any inert material, which is not

supposed to exceed 0.5%. Inert material is a substance that does not have any chemical reaction when added to another substance, meaning it does not react. Examples include glass fiber or titanium dioxide. (ASTM International 2018.)

The amount of inert material should be determined in a special procedure, that can vary from each inert material to another. If in one case, inert material was deduced to be more than 0.5%, the amount of sample (PET) should be weighed in a way that gives the specified amount of PET. Afterwards, the TFE-fluorocarbon plastic-coated stirring bar will be placed inside the flask. (ASTM International 2018.) This is a component of a magnetic stirrer device that is used to mix liquids in a laboratory without the need of stirring the mixture by hand, as shown in Figure 8.

Figure 8. TFE- fluorocarbon plastic-coated stirring bar (Just Plastics 2023).

The magnetic stirring bar is often used in laboratory procedures. A variety of different kinds, shapes and materials of stirring bars can be found, as it all depends on the viscosity, drive magnet, vessel, or flask shape, as well as the abrasiveness of the material or the fluid to be measured. On the most basic level, opposite poles attract, and that is how stirring the bar with no hands works. A magnetic stirrer as shown in Figure 9 has a drive magnet inside.

Figure 9. Magnetic Stirrer (Biolab 2023).

The stirrer, usually in the form of a bar or U-shape and crafted from a metal alloy or ceramic, undergoes rotation propelled by a drive motor. To achieve optimal magnetic coupling, it is essential for the distance between the magnetic poles of the drive magnet and the length of the stirring bar to be identical. If not, the disproportion on both sides could increase the chances of spinouts. Hence, when initiating a process, the solution should have the magnetic stir bar placed in a flask or container. The flask should be accurately positioned over the center of the drive magnet, and the speed should be gradually increased until the desired vortex pattern is attained. (VWR 2016).
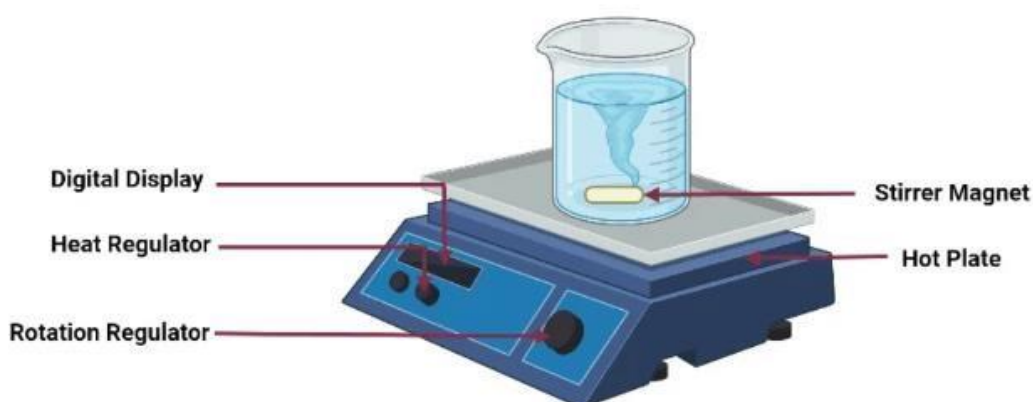

Figure 10. Magnetic stirrer and bar illustrated (Biolab 2023).

Figure 10 shows how the Magnetic Stirring bar and Magnetic Stirrer actually looks. The primary function of the magnetic stirrer is to create a magnetic field for stirring solvents with different viscosities. Consequently, it operates based on two fundamental principles: the stirring mechanism and control electronics.

The stirring mechanism rotates to mix the solution, whereas the control electronics take care of all the buttons or keyboard functions, which can be adjusted according to the viscosity of the solution. (Biolab 2023.)

The initial testing procedure continues after placing the stirring bar into the flask, the next step is adding 25mL of solvent. Afterwards, an empty flask is prepared. This flask is usually called the blank or control flask and it includes only the solvent. The reason behind this is to compare the solvent's properties without any solute being added, in order to understand how the solvent behaves before and after combining it with the solute. It is a very useful method for comparisons in labs. The flasks are capped to prevent any evaporation, spillage, or contamination of liquids inside the flasks. (ASTM International 2018.)

The flasks are then placed in steel bakers and placed on the magnetic stirrer as illustrated in Figure 9. The hot plate must be preheated to 110°C (230°F), and the flasks must be heated for 15 minutes while stirred using the stirring bar. Flasks are extracted and examined for any undissolved PET. In instances where a sample fails to dissolve entirely, the stirring duration should be prolonged by an additional 30 minutes, with ongoing inspections of the sample at intervals of 10 minutes. If, for some reason, the PET still did not dissolve, this procedure is not applicable. (ASTM International 2018.)

Once the samples have fully dissolved, it is necessary to take the flasks off the hot plate and allow them to cool down to room temperature. Afterwards, the stirring bars inside the samples should be removed using the magnetic retriever, which is another component to pull the bar efficiently while making less mess. After removing the stirring bar with the magnetic retriever, it should be washed with a solvent that allows all the excess material to fall down. After this, around 1 cm of solvent should be added to the 50mL flask mark. (ASTM International 2018.)

Subsequently, the flasks are positioned within a constant temperature bath set at 30°C (86°F), allowing them to rest for 10 minutes to attain the bath temperature. The capped or stoppered flasks are then delicately inverted to rinse away solvent droplets clinging to the inner walls, ensuring the preservation

of polymer volume and concentration. It is imperative to maintain the solution at the 50 mL mark by introducing solvent as needed. (ASTM International 2018.)

Subsequently, the solution will be poured using a funnel into a clean and dry Cannon-Ubbelohde viscometer, as shown in Figure 11. This has the same shape and purpose as the one shown in Figure 5. However, the main difference is that the Cannon-Ubbelohde tolerates higher temperatures and has a rugged design. The solution passes through the filter screen which is placed on top of the larger viscometer tube, that also contains the reservoir bulb. A filter screen is used to remove any unwanted particles from the solution.
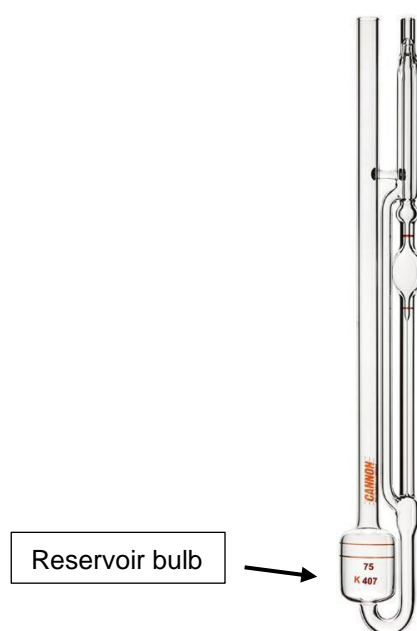

Figure 11. Cannon-Ubbelohde (CANNON Instrument Company 2023).

The viscometer should then be filled to a level in between the lines shown on the large reservoir bulb on the left side. The funnel should be removed, and the viscometer placed in the constant temperature bath preset at 30°C (86°F). Fifteen minutes should be allowed for the solution's temperature in the viscometer to reach equilibrium. Furthermore, the breather tube is to be capped. This is on the left side of the Cannon-Ubbelohde. The breather tube is then temporarily blocked with a rubber gloved finger in case of any liquid spilling. The suction is used by an aspirator to draw the solution from the right-side tube to reach a level above the top calibration mark. (ASTM International 2018.)

The solution must be filled into the viscometer with care to prevent any bubble formation or splashes from happening. The next step is to allow the solution to flow back at its normal speed by removing the rubber gloved finger from the leftside tube plus the suction from the right-side tube. This step is done in order to prevent any air bubbles from happening, since they affect the accuracy of the measurement and in other words, to wash the capillary viscometer. In this step it is ensured that the viscometer has no grease or any dirt that may interfere with the surface tension of the liquid. In addition to that, the fluid being added to the viscometer can be either the solution or the solvent. The initial flow serves as a rinse to moisten the capillary bulb and ultimately bring the sample solution to equilibrium with the bath temperature. (ASTM International 2018.)

Eventually, the same steps that have been taken in order to rinse the capillary viscometer must be done again to measure the flow time between the two higher and low calibration marks. Throughout the measurements, the bath temperature will be meticulously documented, rounded to the nearest 0.01°C (0.02°F), while ensuring that the temperature variation does not surpass 0.01°C. This flow time should be measured using an electric timer. (ASTM International 2018.)

The flow time must be recorded, and the measurement repeated three to four times in some cases; this allows averaging these results and getting within a range of 0.2 seconds. The solvent flow time will be measured the same way with the solution. The purpose of this is to obtain the relative viscosity, given that it represents the ratio of the solution viscosity to the solvent viscosity. (ASTM International 2018.)

Once the measurements are done, the viscometer is taken out from the bath, and the solution is cautiously transferred from the viscometer into a safety disposal container. (ASTM International 2018.)

4   Comparing Devices and Methods in measuring Inherent Viscosity of Plastics

Indeed, for a major company like Phillips-Medisize, these kinds of measurements and tests cannot be only implemented with the use of manual equipment or tools, since it consumes time and is usually not adequate for a large number of samples to get tested. Overall, it is not as practical.

Therefore, in this section two device will be compared in order to assist in the decision making of purchasing the suitable one that satisfies the needs of the company. The two devices are Anton Paar's Rolling-ball viscometer Lovis 2000 M/ME and Metrohm's DS2500 Solid Analyzer. The structure used to compare these two devices is to first go through the background of the company and the standards they have received as an introduction. From there, the author will comment on the products as well as the services these companies offer to their customers. Finally, the similarities between both devices, the pros and cons of each device, time consumption, etc. will be highlighted.

4.1 Rolling-ball viscometer Lovis 2000 M/ME

To begin with, Anton Paar is a company that specializes in high-precision instruments for measuring density, concentration, viscosity, rheology, etc. Anton Paar's headquarters is in Graz, Austria. There are distribution partners in more than 110 countries, including Finland. Anton Paar has implemented a quality management system aligned with ISO 9001 since 1994, encompassing environmental and safety management components. (Anton Paar 2023.)

Every device or product by Anton Paar can be chosen depending on the standard, industry, and type. That means that each device they own has its own standard plus certain instruments for each device that can be purchased later on if certain upgrades are needed. Some examples of the products Anton Paar offer are:

- Alcohol meter, which analyzes alcoholic beverages at the push of a button.
- Coating Thickness Measurement, which determines the coating thickness of a product in an inexpensive, simple, and quick way.

- Automation & Robotics, which prepares the samples 24/7, whether the preferred tailored automated solution is in the production hall or lab.

A variety of different products and devices are found on Anton Paar's website. However, as mentioned earlier each one of these above-mentioned examples has different instruments to be used depending on the cause and method of utilization.

Figure 12. Rolling-ball viscometer Lovis 2000 M/ME (Anton Paar 2023).

The rolling-ball viscometer Lovis 2000 M/ME, as shown in Figure 12, It functions as a rolling-ball viscometer, gauging the time it takes for a ball to roll through liquids, whether transparent or opaque, employing Hoeppler's falling ball principle as the underlying mechanism. Hoeppler's principle stands as a recognized and dependable approach for determining the viscosity of a specific liquid. This involves measuring the time it takes for a ball to descend, under the influence of gravity, through a tube filled with the sample and inclined at an angle. Utilizing the Lovis 2000 M/ME allows for the extraction of various measurements, including dynamic viscosity, intrinsic viscosity, the molar mass of a polymer, and more. Table 2 shows some certain characteristics of the device.

Rolling-ball viscometer: Lovis 2000 M/ME	
Number of samples required	• Small sample amount (starting from 100 μL)
Sample Volume	• 0.1 mL to 0.8 mL
Accuracy	• High Accuracy, up to 0.5 %
Temperature range	• Extensive temperature spectrum (5 °C to 100 °C / 41 °F to 212 °F) achievable without the need for counter-cooling. • Possibility of conducting measurements with counter-cooling, extending to as low as -30 °C (-22 °F).
Viscosity Range	• Wide viscosity range (0.3 mPa.s to 10,000 mPa.s)
Resolution	• 0.001s intervals
Standard	• ISO 12058-1
Measuring Time	• Less than a minute

Table 2. Rolling-ball viscometer Lovis 2000 M/ME device characteristics.

Anton Paar offers a couple of different services for its clients and customers whether before or after purchasing the product. Anton Paar offers a visit to the company with demo devices for real life testing. In addition, after purchasing the device, Anton Paar offers a couple of different services to the consumer:

• Competent assistance provided in the native language

- Safeguarding the investment across its entire lifecycle

- Three-year warranty, all new instruments will include repair for three years and an option to extend the warranty

- For a minimum of ten years after the discontinuation of a device, services and spare parts that might be required for the client's operations are provided.

- Certified service engineers who assist the client with excellent service provision. Training and certification are carried out at the company's facilities.

- Maintenance including repair coverage and functional checks. (Anton Paar 2023).

4.2 Metrohm DS2500 Solid Analyzer

Metrohm is a company with headquarters is in Herisau, Switzerland. Metrohm has its distributers and subsidiaries in more than 80 countries, including Finland. Metrohm is certified according to ISO 9001:2008, with 2008 standing for the year the standard was updated in. It was the fourth edition of the standard.

Metrohm mentioned that it is a reliable supplier that offer Swiss quality products and services to its customer. It offers a variety of different products and devices for customers' analytical challenges. These include, for instance:

- Titrators like OMNIS Titrators, which are all in one potentiometric auto titrators that are able to be customized depending on the applications needed, number of titrators, data export, titration mode, etc. One example of what OMNIS Titrators can measure is ammonia and ions in water or soil samples.

- Fluid Handling like the 846 Dosing Interface, which can automate dosing, pipetting, diluting, and dispensing tasks. The 846 Dosing Interface can

measure the volume of a liquid added or removed from a sample, for
instance.

Despite the fact that Metrohm offers great products and devices to utilize,
Metrohm's DS2500 Solid Analyzer device as shown in Figure 13 can be
beneficial in case of plastic degradation.

Figure 13. Metrohm's DS2500 Solid Analyzer (Metrohm 2023).

By applying the near-infrared spectroscopy (NIR) method, the DS2500 Solid
Analyzer device can quickly and easily determine the intrinsic viscosity of
polymers without any sample preparation. This avoids the use of any dangerous
or toxic solvents or liquids. The samples are exposed to a special light that has
only one wavelength or color, which is called monochromatic light. The device
has a sample holder where the samples are put. The light travels through the
samples, which have different molecular structures. The molecular structures
determine how the samples absorb, reflect, or transmit the light. The light that
gets through the samples is detected by a sensor, which changes the light into
an electrical signal or data. The device processes the data to create an
absorption spectrum, which is a graph that shows the amount of light that the
samples absorb at each wavelength.

The device makes a graph that shows the level of light that the sample absorbs at each wavelength. This is called an absorption spectrum. The absorption spectrum is a unique fingerprint of the sample. This reveals information about its composition, structure, and properties. The device can produce the absorption spectrum very quickly and accurately and display it on an external screen connected to the device. However, the device needs to be calibrated using the sample's reference method from the laboratories for a more accurate measurement of the sample's concentration. After that, the device will be able to learn the relationship between the absorption spectrum and the concentration of the substances in the chosen set of samples. Table 3 shows certain characteristics for the device.

Metrohm's DS2500 Solid Analyzer	
Number of samples required	• 1 sample • Using The MultiSample Cup accessory, 9 samples.
Sample Volume	• 1g of solid samples
Accuracy	• Intrinsic viscosity measurement of 0.02 dL/g
Temperature range	• Wide temperature range (5 to 95 ℃ for operation) • -20 to 60 ℃ for storage
Viscosity Range	• Viscosity range of polymers (0.1 to 40000 mPa.s)
Measuring Time	• Less than one minute

Standard	• ASTM E 1655
Resolution	• 0.0001 mPa.s

Table 3. Metrohm DS2500 Solid Analyzer device characteristics.

Metrohm provides different services as well as testing the sample in its demo device for extra assurance to the clients. Metrohm also offers a range of services to support customers who want to purchase the DS2500 Solid Analyze, such as:

- Setting up and verifying the device based on the requirements and needs.

- Training and assisting for the use, maintenance, and care of the device and the software.

- Calibrating and validating the methods and models for specific applications.

- Service and repair of the device in case of any problems or faults.

- Software Updates and enhancement to keep the device current with the latest features and functionalities. (Metrohm 2023.)

4.3 The Selected Device for Inherent Viscosity Measurement

In this thesis, the aim is to understand the polymer's properties by its molecular properties and behavior, and from that the degradation levels in the components. For this purpose, a reliable and versatile instrument that can handle different types of samples, operate in a wide temperature range, and provide accurate and reproducible results is needed. After reviewing the available options and comparing the two devices, it seems that the Metrohm

DS2500 Solid Analyzer could be chosen over the Lovis M 2000 Anton Paar rolling-ball viscometer for the following reasons, in my point of view:

1. Metrohm supports the idea and development of green chemistry. Therefore, DS2500 Solid Analyzer reduces the usage of solvents or any other toxic and chemical substances in the company.

2. DS2500 Solid Analyzer can measure the samples of wide viscosity range (0.1 to 40,000 mPa.s) compared to Lovis M 2000 that can only measure (0.3 to 10,000 mPa.s). In other words, DS2500 can measure both Newtonian and non-Newtonian liquids, where Lovis M 2000 measures mainly Newtonian liquids, which are liquids that have low viscosity.

3. Metrohm contains a system robustness, which is a system that handles different types of environmental change. This includes for instance, high humidity or dust load, especially when the device is placed in a production line.

4. Unlike Lovis M 2000 that only measures the viscosity measurement, the DS2500 Analyzer can also sense the changes in the color of the sample, for example, due to aging.

In this section, the following questions were answered: Which device is more suitable for measurements of samples that have different viscosity ranges? What made DS2500 Analyzer stand out more than Lovis 2000 M? Which one is more sustainable and less toxic?

5   Evaluating the Cost Effectiveness of DS2500 Solid Analyzer

5.1 Overview of the Payback Calculation

In this section, the cost calculation of Metrohm DS2500 Solid Analyzer will be analyzed for the sake of possibly reducing the valuable time wasted on shipping

and results waiting time and future money expenses. The cost analysis will include the following aspects:

- The price of the device, in addition to the calibration, maintenance and warranty.
- The price of the software that supports the device.
- Phillips-Medisize's potential savings.

The data collection method used for the cost analysis was interviewing a Phillips-Medisize's representative. This was the manager in charge of the management of the degraded components. In addition to Metrohm's product manager, interviews were conducted with the managers, using a set of openended and closed-ended questions. The questions covered topics such as the current situation, the needs and expectations, the preferences and opinions, the possible risks that may occur, device prices, and services.

The data analysis software used for the payback period analysis was Microsoft Excel, which helped in calculating the costs and the payback period. The payback period is the amount of time it takes to get the money invested back; it also used in capital budgeting to assist businesses in their decision making when investing in a new project, for instance (Chen 2015).

As a background of why the device is under decision making, is that there is a probability that Phillips-Medisize will face a production stoppage once every ten years based on the data provided by the Project manager of Phillips-Medisize. Phillips-Medisize usually sends its components to the supplier for measuring the degradation levels; the average waiting time for the results is two weeks. The first production stop happened only once since the initial opening of the production line.

Therefore, due to the uncertainty cause of the degraded parts and components, the production stopped for 14 days, until the cause of degradation was determined by the measurements. Phillips-Medisize then adjusted for instance, the melt temperature as an example according to these measurements. Nevertheless, Phillips-Medisize is always aiming at continuous improvement

and innovating its products and services as well as stopping risks from happening.

5.2 Payback Calculation

Tables 4 & 5 show the calculation of the payback period for the investment in the Metrohm DS2500 Solid Analyzer Device, which is a near-infrared spectroscopy system for fast and accurate quality control of solid samples. The investment aims to reduce the risks and rework costs of a production stop in the company, which could result in significant losses of revenue and customer satisfaction.

Investment Device	69 000 €
Investment Software	9,000 €
Cost of Investment	78 000 €

Table 4. Metrohm DS2500 Solid Analyzer.

The costs of the device investment as shown in Table 4 are costs given by Metrohm's product manager. Metrohm's product manager has provided the data relying on pre calibrated devices, including the services and tools, which is an estimate of 69,000€. Included additionally is the software, which displays the measurement results on the screen and comes at a total of 9,000€.

Production stop probability in 10 years	0,03 %
Production stop impact	
Downtime in Days	14
Daily Downtime Cost	85 000 €
14 days downtime loss	1 190 000 €
Impact of Downtime Occurrence	119 000 €
Payback period in years	0,66

Table 5. DS2500 Solid Analyzer Device Payback Period Calculation.

To explain the theory behind the calculation, the table is divided into the following columns and rows:

- Production stop probability in 10 years: The estimated chance of a production stop occurring in the next 10 years which also equals to 3650 days, expressed as a percentage. In this case, it is 0.03%, which means that there is a possibility of production stopping once every ten years.

- Production stop impact: This row is a subheading that groups the rows below it, which share the same topic. It shows the consequences of a production stop for the company, and its impact in terms of downtime and cost.

- Downtime in days: This is the number of days that production would be halted due to a production stop. In this case, it is 14 days on an average, which means a production stop would cause a 14-day delay in output.

- Daily downtime cost: This is the estimated amount of money that the company would lose per day due to a production stop. In this case, a production stop would cost the company 85,000 € per day in lost revenue.

- 14 days downtime loss: This is the total amount of money that the company would lose due to a production stop of 14 days, while the production operates 24 hours a day and 365 days a year in 10 years. In this case, it is 1,190,000€, which means that the production loss for one day is 85,000€ throughout a 14-day course of time.

- Impact of Downtime Occurrence: This is the expected annual cost of a production stop, calculated by dividing the 14 days downtime loss which is 1,190,000 € by 10. This represents the average amount of money that the company would lose each year due to the risk of a production stop. In this case, the company would lose 119,000€ each year.

- Payback period in years: This is the number of years that it would take for the investment to pay for itself, calculated by dividing the initial cost of

the investment by the impact of downtime occurrence. This indicates how long the company would have to wait before the investment starts to generate net savings or profits. In this case, it is 0.66, which means the investment would pay for itself in less than a year.

5.3 Payback Period Calculation's Conclusion

This section aims to address the following questions: What are the benefits and costs of investing in the Metrohm DS2500 Solid Analyzer Device for PhillipsMedisize to prevent production stops and reduce the waiting time when the components are sent to the supplier? How long will it take to get the money invested in the device back? These questions are important and relevant for the field of industrial engineering and for Phillips-Medisize as it explores the feasibility and profitability of a novel solution to a common and costly problem in the manufacturing sector.

The payback period calculation showed that the investment in the Metrohm DS2500 Solid Analyzer Device would pay for itself in less than a year, with a payback period of 0.66 years and an investment of 78,000€. This result exceeded the expectation of a payback period of less than a year, and confirmed the hypothesis that the investment would be profitable and worthwhile.

In addition, without the 78,000 € device worth of investment, Phillips-Medisize would incur an annual cost of 119,000 € and a total cost of 1,190,00 € throughout the 10 years. The payback period calculation also revealed that the investment would avoid production stops and cut down the waiting time of 14 days when the components are sent to the supplier, resulting in significant savings and efficiency gains. The investment would also enable the in-house measurement of the samples in less than a minute, according to the device's characteristics.

The payback period calculation has several implications and limitations that should be considered. The implications of the payback period calculation are

that Phillips-Medisize should invest in the Metrohm DS2500 Solid Analyzer Device, as it would increase its profitability, performance, and innovation, while for the limitations of the payback period calculation are that it is based on several assumptions and estimates that might not reflect the actual situation or the future changes.

6   Discussion

By measuring the inherent viscosity, this thesis investigated polymer degradation in medical device production. This thesis studied how the polymer properties can be determined by the inherent viscosity method and the molecular weight in a polymer. It also indicated the main causes of degradation, which are moisture and heat. Furthermore, this thesis also indicated the method that Phillips-Medisize currently uses and its inaccurate inherent viscosity results. Also, other measurement devices, like the Rotational Viscometer for instance, are very accurate for measurements, but are not suitable for nonNewtonian liquids and hence are not reliable for inherent viscosity measurements.

The result of this study indicates that the inherent viscosity method according to ASTM D4603 is reliable and accurate for determining the degradation levels and thus the possible cause of degradation. However, a standard like ASTM E 1655 in Metrohm DS2500 Solid Analyzer can be utilized for the degradation levels measurement and give the same results. DS2500 Solid Analyzer Device is also sustainable and does not require the use of toxic chemicals. Therefore, it is recommended that Phillips-Medisize invest in the Metrohm DS2500 Solid Analyzer Device, as it would increase its profitability, performance, and innovation.

The payback calculation had positive results and outcomes that can assist Phillips-Medisize in gaining its money back in less than a year when investing in the Metrohm DS2500 Solid Analyzer Device. The limitations of the findings are that they are based on several assumptions and estimates that might not reflect the actual situation or future changes.

Due to the limited time frame of this study, the results of the working phase using the viscometer devices could not be obtained. This is a major limitation of the current research, and future work should aim to complete this phase and compare the findings with the theoretical predictions. Companies and universities were contacted for their help in testing the plastic pellets and degradation levels in reality.

In the end, the aim of this thesis was to study the inherent viscosity method, the causes of the degradation of polymers, the payback period when investing in the device, and what device is suitable for accurate measurements. Eventually the results that the thesis aimed at were explained thoroughly. However, the main working phase of this thesis will be implemented within further studies and practical measurements.

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