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Techno-economic analysis of a pharmaceutical grade magnesium stearate production process

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Abstract

For many years the local economy of Oost-Groningen has been declining. An initiative called Innovatie Hub Oost Groningen has identified this problem and wants to solve it by encouraging more economic activity of the companies in the region. Two of these companies are Nedmag and Ten Kate which respectively produce magnesium hydroxide and lard stearin. These two products can be processed to a high value product; pharmaceutical grade magnesium stearate. This magnesium stearate is used in the pharmaceutical industry as a lubricant in tablet production. This research is focused on the production process of this pharmaceutical grade magnesium stearate from magnesium hydroxide of Nedmag and lard stearin from Ten Kate. First the product requirements of the pharmaceutical industry set to magnesium stearate are discussed. Then the magnesium hydroxide from Nedmag and lard stearin from Ten Kate are analyzed on their chemical composition. After which, the production process of obtaining stearic acid from the lard stearin of Ten Kate is given. Next, the production process of obtaining pharmaceutical grade magnesium stearate from stearic acid and magnesium hydroxide is stated. Lastly, the capital cost of the magnesium stearate production processes is estimated.

Contents

Introduction

Groningen is one of the most northern provinces of the Netherlands which is known for its natural gas production. However, currently the natural gas production has been diminished in the region because of the earthquakes it is causing. This decrease of gas production resulted in a diminishing local economy for the province (Duijkers et al., 2018). To compare the national economy of the Netherlands grew 2.9 % in 2017 and the local economy of Groningen diminished with 0.5 % in 2017 (Duijkers et al., 2018). Therefore, there is a need for action in the province to create more economic activity outside of the natural gas production. One company that shows to be interesting for this purpose is Nedmag. Nedmag makes magnesium compound derivatives from a high quality magnesium salt deposit below Veendam (Nedmag winningsplan, 2018). The products Nedmag currently makes are magnesium hydroxide, magnesium oxide, calcium chloride and magnesium chloride (Nedmag producten, 2019). These products are all made in bulk for several industries; however, more high value niche products are currently missing in the product assortment of Nedmag. Therefore, several magnesium salt derivatives were investigated in H.M.Bijlaard's research on magnesium salts (Bijlaard, 2019). From this research an appealing product arised magnesium stearate for its lubricating properties in the pharmaceutical industry. This industry is a high value market in comparison with the bulk industries Nedmag is currently producing for. It was concluded from this research that the magnesium stearate market is showing an expected growth in the upcoming years (Bijlaard, 2019). Furthermore, an initial production process was provided: the melt process with general production process specifics. However, currently a more in-depth production process of magnesium stearate based on the quality requirements of the pharmaceutical industry is missing.

Problem analysis

Problem statement

As stated in the introduction, H.M. Bijlaard provided the first initiation of the analysis of the production process of magnesium stearate by Nedmag. The melt process was stated here as the most suitable production process, which reacts magnesium hydroxide and stearic acid with water as reaction medium. The product that arises from this process is mainly magnesium stearate with some water and stearic acid. The general production process was presented: however, this production process is not in depth enough and was not certain to produce magnesium stearate of the expected pharmaceutical grade. Further, the costs of this production process was not presented. Therefore, the problem statement can be defined as: *Currently the in depth production process of pharmaceutical grade magnesium stearate and its associated costs is missing*.

Stakeholder analysis

Nedmag

The problem owner is Nedmag, because it will expand its production capabilities by incorporating a high value product in its assortment of products. Furthermore, Nedmag is chosen as the problem owner, because it will gain the most from the research.
The goal of Nedmag is finding out if the production of magnesium stearate will be profitable for them. To be able to know this, the costs of producing magnesium stearate should be known which can only be researched if the production process is analyzed and presented. Therefore, the primary objective is first to analyze and present the production process of magnesium stearate for the pharmaceutical industry to Nedmag. Further, Nedmag can be identified as a key player in the stakeholder analysis, because they show great interest in the research. This interest comes from the economic gains Nedmag possibly can obtain from the production of magnesium stearate. Further, Nedmag has the final decision in incorporating the production of magnesium stearate in its product assortment; therefore its influence power is great.

Innovatie hub Oost Groningen

The second stakeholder is Innovatie hub Oost Groningen. The representative for this stakeholder is dr. André Heeres. This stakeholder identified the loss of economic growth in the province and saw Nedmag as a potential player to increase this. The goal of this stakeholder is to initiate Nedmag to produce magnesium stearate. Because if Nedmag produces magnesium stearate there will be more export from the region. This will, in term, result to more economic growth in the region. Innovatie hub Oost Groningen can be identified as a show consideration stakeholder because, it shows interest in the economic growth affect the project can have. However, this player does not have too much influence in the decision of Nedmag of producing magnesium stearate.

Syncom

The third stakeholder is Syncom, which is specialized in custom synthesis solutions (Syncom, 2019). The representative for this stakeholder is also dr. André Heeres. The goal in respect to this research of Syncom is obtaining knowledge about the production process of magnesium stearate. This knowledge will result in more expertise for the company to give better service to its customers. This stakeholder shows interest in this research because, of its focus on process research. It, however, likewise does not have too much influence in the decision of Nedmag to produce magnesium stearate. Therefore, it can be classified as show consideration stakeholder.

Rijksuniversiteit Groningen

The fourth stakeholder is the University of Groningen; the representative of this stakeholder is prof. dr. ir. HJ (Erik) Heeres which supervises bachelor IP students. The main goal of this stakeholder in respect to this research is to assist and educate the bachelor IP student and provide research for the scientific community. This assistance and education is performed by meetings with the bachelor IP student. Further, this stakeholder shows interest in this research because it provides more knowledge in the production process of magnesium stearate. Concluding, this stakeholder shows interest in the research and has influence on the bachelor IP student; therefore, it can be classified as a key player.

Ten Kate

The fifth stakeholder is Ten Kate, which is an animal fat and protein producer (Ten Kate, 2019). One of the products of Ten Kate is lard stearin which can in term be used for the production of magnesium stearate. The representative for this stakeholder is a sales manager which tries to sell its products. The goal of this stakeholder is thus to make profit out of its products. It is concluded that this stakeholder has a lot of influence on the research, because it is the supplier of one of the feeds of the magnesium stearate production process. Therefore, it is a classified as a key player.

Pharmaceutical industry

The last stakeholder is the potential customer of Nedmag, the pharmaceutical industry. As was concluded by H.M. Bijlaard, magnesium stearate's high value application was found as a lubricant in the pharmaceutical industry. This industry sets certain quality standards to magnesium stearate. The magnesium stearate produced by Nedmag should meet these quality requirements in order to sell it to this industry. This industry does not have goals, because there is no gain for them in respect to this research; they already have suppliers of magnesium stearate. Therefore, it can be stated that the interest of this stakeholder is low in respect to this research. However, the set requirements are important and should be taken into account in the production process of magnesium stearate. Thus the influence power of this stakeholder is great. It can be concluded that the pharmaceutical industry can be set as a meet their needs stakeholder.

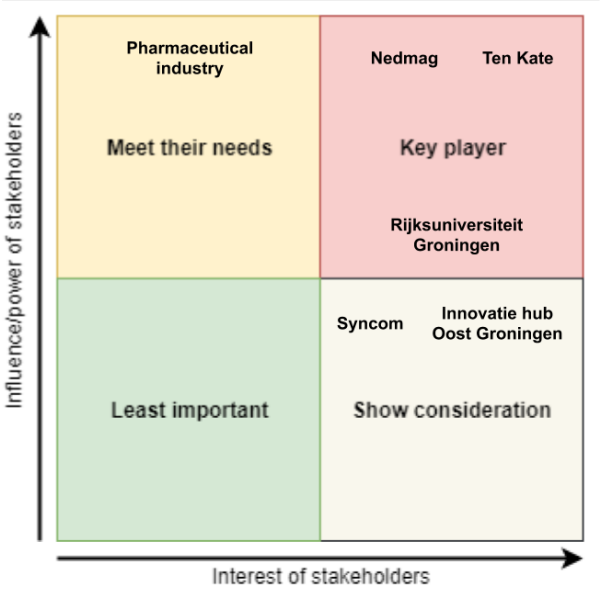

Figure 1: stakeholder analysis

Conclusion of stakeholder analysis

From the stakeholder analysis, it can be concluded that Nedmag, the pharmaceutical industry, Ten Kate and the Rijksuniversiteit Groningen are the most important stakeholders. These stakeholders influence the to be designed production process the most by their needs and decisions. Nedmag influences the production process because they want a low-cost and high yield production process of magnesium stearate. Further, the set quality requirements of the pharmaceutical industry set the desired output of the production process. Furthermore, Ten Kate is important because it is one of the companies that provides the feed for the magnesium stearate production. Lastly, the Rijksuniversiteit Groningen determines how the design of the production process follows by guiding the bachelor IP student. The rest of the stakeholders do not influence the to be designed production process. They will however, be satisfied if Nedmag start producing magnesium stearate.

System description

The system contains the production process of magnesium stearate which has as input magnesium hydroxide suspension from Nedmag and lard stearin from Ten Kate with the output being magnesium stearate. The production process is already generally known; however, the in-depth production process that produces magnesium stearate of pharmaceutical quality is unknown, therefore, this is classified as a black box. Further, this production process should output magnesium stearate which satisfies the high quality standards from the pharmaceutical industry. These quality standards are also seen as a black box. Furthermore, the system also contains a cost analysis of the

production process of magnesium stearate and an analysis of the pretreatment process of lard stearin from Ten Kate which are as well regarded as black boxes.
The system is shown in figure 2.

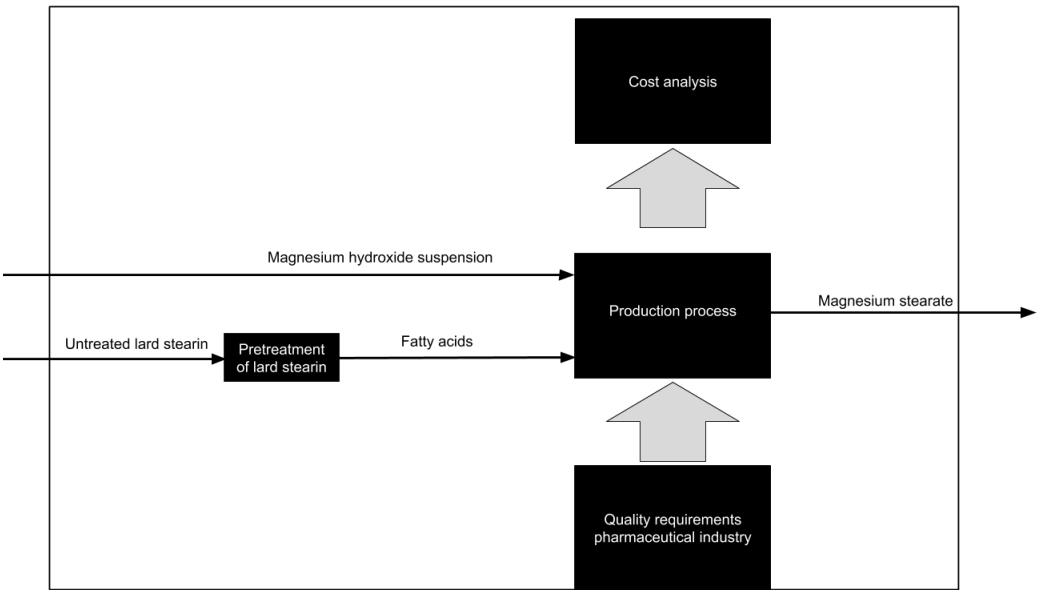

Figure 2: system

Literature review

To be able to perform the research on the production process of magnesium stearate for the pharmaceutical industry, initial literature about the general process should be provided. The production process which will be further analyzed is the melt process. This melt process is given in (Cinco, 1977), which provides this production process as a way of producing magnesium soaps such as magnesium stearate. In this patent the production of magnesium stearate is given by mixing magnesium hydroxide, stearic acid and water together in a mixing vessel at 17 °C. This mixture will react and produce magnesium stearate. Further, this reaction vessel is external cooled to ensure that the reaction is performed below 45°C. After 15 minutes, when all the stearic acid is reacted, the product is allowed to go to 53 °C. After the reaction the product is dried to remove the water present. The product that will be obtained should contain below 1 weight percentage stearic acid and pure magnesium stearate. This production process is, however, not in-depth enough to accurately produce magnesium stearate of the expected pharmaceutical quality. Therefore, more knowledge needs to be obtained about the production process. Further knowledge needs to be obtained about the quality requirements of the pharmaceutical industry. It is stated in (Wang, 2010 and Li, 2014) that it is used as a lubricating agent in the pharmaceutical industry to reduce friction of the particles between each other and between particles and the tablet manufacturing equipment.

Several product properties that alter the lubricating ability of magnesium stearate are stated such as: hydration state, particle size, particle shape and surface area (Li, 2014). The effect of these properties and other properties to the lubricating ability of magnesium stearate should be analyzed. The optimal of these properties in respect to the lubricating ability of magnesium stearate should be stated. This optimal magnesium stearate should be produced by the production process. How this production process can produce this high quality magnesium stearate should also be researched.

From the literature review, it is known that more knowledge about the production process of magnesium stearate should be obtained. This process should aim to produce the pharma grade quality of magnesium stearate that is expected from the pharmaceutical industry. Therefore, also more knowledge about the product properties that create the most optimal lubricating ability in magnesium stearate should be obtained. Further, knowledge needs to be obtained about the pretreatment process of lard stearin to be able to use it in the magnesium stearate production process. Furthermore, it should also be analyzed how the production process can optimize these product properties to create magnesium stearate which has the most optimal lubricating ability.

Research goal

Knowledge goals

First knowledge needs to be obtained about the effect the properties of magnesium stearate have on the lubricating ability of magnesium stearate. This will give the desired output requirements where the production process of magnesium stearate of Nedmag should aim for. The first knowledge goal is, therefore:
Analyzing the properties of magnesium stearate that alter the lubricating ability of magnesium stearate.

Next knowledge needs to be obtained about which process steps will produce these optimal properties of magnesium stearate. The second knowledge goal is:
Analyzing which production process steps will ensure the optimal properties of magnesium stearate in respect to lubrication.

The third knowledge goal relates to the lard stearin of Ten Kate.
The third knowledge goal is:
Analyzing the pretreatment steps that should be used to be able to use the lard stearin from Ten Kate in the magnesium stearate production process.

The last knowledge goal relates to the costs of the production process of magnesium stearate. The fourth knowledge goal is:
Analyzing the costs of the magnesium stearate production process.

Design goal

The knowledge obtained results in the design of the production process with the cost analysis. The goal of this design is:
Designing a production process of pharmaceutical grade magnesium stearate with the costs associated with producing this process.

Research problem

The research main focus is on the lack of knowledge about the production process of magnesium stearate for the pharmaceutical industry which uses magnesium hydroxide of Nedmag and lard stearin from Ten Kate. From this main problem, the main research question can be formulated.

Main research question

What are the production process steps of producing pharmaceutical grade magnesium stearate from magnesium hydroxide of Nedmag and lard stearin from Ten Kate and how much does this production process cost?

Knowledge questions

To be able to answer this main research question, first knowledge questions need to be answered. These knowledge sub-questions are:

- What are the most optimal properties of magnesium stearate that ensure the maximum lubricating ability of magnesium stearate?
- Which production process steps contribute to producing this magnesium stearate of pharmaceutical grade?
- How much does the magnesium stearate production process cost?
- What is the quality of lard stearin from Ten Kate?
- Which pretreatment steps of the lard stearin are necessary to use the lard stearin of Ten Kate in the magnesium stearate production process?

These knowledge questions will help answer the main research question and will result in the knowledge base which was required from the knowledge goals. The knowledge base will enable the design of the production process and result in the fulfilling of the design goal.

Product requirements

Introduction

As was stated in the goals first knowledge about the properties of magnesium stearate that alter the lubricating ability should be analyzed. This product requirement section is focused on this and provides a proposal of the optimal magnesium stearate properties to obtain the highest lubricating ability possible.

First some general knowledge about tablet production is provided. In the pharmaceutical industry tablets are produced by tablet presses, which presses powders under high pressure in to tablets. In this process of tablet pressing and also the tablet ejection there is much slide friction between the particles in the powders that are being pressed together and between the machinery and the particles. Further in this process particles can attach to the machinery which is not desirable. Magnesium stearate is used in these processes to reduce this friction and adhesion of the tablets to the machinery (Li, Jinjiang 2014, Moody,G. 1981, Faldu, Bhavdip 2012, Miller 1988, Dansereau, Richard 1987, Rao, K Phanidhara 2005). How magnesium stearate reduces this friction is explained in the following paragraph.

To be able to understand how friction of particles occur in tablet pressing it is first important to understand that the particles in the powder have rough surfaces with many cavities and lumps. These lumps slide against one and create slide friction (Bhavdip 2012, Moody,G. 1981). The magnesium stearate particles when mixed with these particles start by filling these cavities and creating a more smooth surface of the particles in the powder. Eventually these magnesium stearate particles (starting from the cavities) will be forming small bumps of varying sizes across the particles (Roblot-Treupel, L 1986, K Phanidhara 2005). These magnesium stearate bumps will be smeared out because of the low shear strength that magnesium stearate has which cause them to delaminate fast when being mixed (Roblot-Treupel, L 1986). This delamination of the magnesium stearate particles will form small discontinuous areas of layers of magnesium stearate of several molecular layers thick around the particles in the powder (Miller 1988, Shah, AC 1977). These layers having low shear strength act as boundary lubricants which reduces slide friction between the particles and the particles and the die walls of the machinery. Moreover, the low shear strength of magnesium stearate comes from the laminar plate like crystal structure of magnesium stearate which has lamellae that have low interactive bonding with each other (Li, Jinjiang 2014, Moody,G. 1981, Faldu, Bhavdip 2012, Miller 1988). This low interactive bonding between the lamellae in the crystal result in that they shear easily from each other. It is therefore very important that the magnesium stearate particles have this laminar plate like structure and also have low interactive bonding between the lamellae.

It was found that this crystal structure property of magnesium stearate is a function of the hydration state of magnesium stearate which alters this crystal structure and also the crystal habit and lattice d spacing (Wada,Yasutaka 1994, Miller 1988). The effect of hydration state on these properties should be analyzed and the hydration state that gives the crystal structure, crystal habit and lattice d spacing that results in the most shearing should be found. In further paragraphs the effect of hydration on these properties and the most optimal hydration state in respect to shearing is given.

Aside from these molecular properties of magnesium stearate which enable better shearing the properties of the powder also alter the lubricating ability of magnesium stearate. These properties are: particle size distribution, surface area and degree of agglomeration. In further paragraphs these properties are analyzed with their effect on the lubricating ability of magnesium stearate.

Lastly impurities in the feeds for the production of magnesium stearate are discussed and the effect of it on the produced magnesium stearate.

Furthermore, these molecular properties and powder properties also have influence on the production and the physical properties of the tablets produced with magnesium stearate in it. The properties of importance in these tablets are: dissolution rate, disintegration time, hardness and friability of the tablets(Rao, K Phanidhara 2005, Vromans,H. 1988, Ertel,K.D. 1988 A, Ertel,K.D. 1988 B). The effect of the properties of magnesium stearate on these tablet properties are also analyzed and taken in to account in the selection of the optimal requirements of magnesium stearate.

Hydration state

The crystal habit and lattice d spacing of the crystals of magnesium stearate showed to be a function of the hydration state of magnesium stearate (Ertel,K.D. 1988). Magnesium stearate has four hydration states: the anhydrate, monohydrate, dihydrate and trihydrate state. These hydration states are formed when H_2O bounds to the magnesium atoms. The effect of these hydration states on the crystal lattice spacing is described in (Wada,Yasutaka 1994). This paper describes that the H_2O molecules go into the crystal lattice between the lamellae in the crystal, these lamellae then separate slightly from each other which causes the lattice d spacing to increase. This has the effect that the interactive forces between the lamellae in the lattice decrease which enables that less shear stress is necessary to let the lamellae of magnesium stearate delaminate and slide next to each other. The magnesium stearate particles that surround the other particles in the tablet can thus easily be sheared because of this process which results in less friction between the other particles in the tablet. The effect of the delamination on the tablet properties is later described, first the optimal hydration state in respect to lubrication is analyzed.

In (Ertel,K.D. 1988) it is stated that the more H_2O molecules go between the lamellae of the crystal the more the lattice d spacing increases. From this reasoning it can then be stated that the trihydrate which has three H_2O molecules per magnesium stearate enables the most lattice d spacing which then should imply that it gives the most lubrication. However it was found in (Giron, D 2002 and Ertel,K.D. 1988 and Barra 1996 and Miller, TA 1988) that the crystal structures of the hydrates also effect the lubricating ability. The optimal crystal structure for lubricating ability was found to be the orthorhombic or monoclinic structure. This structure is found in the monohydrate and dihydrate of magnesium stearate. The anhydrous and trihydrate state are of the hexagonal structure which in comparison with the orthorhombic or monoclinic structure decrease the shearing ability of magnesium stearate (Ertel,K.D. 1988). This is because the orthorhombic and monoclinic structure form plate like crystal structures which shear more easily then the hexagonal structure which forms needle like structures.

Therefore taken in consideration the lattice d spacing and crystalline structure of magnesium stearate gives that the dihydrate of magnesium stearate enables the most shearing between the lamellae of the crystal structure (Li, 2014). This favorable shearing ensures the highest lubricating ability.

As stated before the crystals of magnesium stearate will also delaminate because of the low shear strength. These delaminated magnesium stearate crystals will form a coating over the other particles in the tablet. This coating should be discontinuous and several molecular layers thick, because this will then enhance the lubrication of the other particles according to the mechanism previously described. It can however also happen that magnesium stearate crystals form a continuous coating layer over the other particles in the tablet. This phenomena is called over-lubrication and results in that the particles are completely covered with the lubricant which leads to low adherence of particles between each other (Li, Jinjiang 2014, K Phanidhara 2005). The low adherence of the particles between each other means that the tablets break and crumble easily when pressure is applied to them, because the particles fall apart from each other. This fast breaking and crumbling when pressure is applied means the tablets have according to the pharmaceutical industry low hardness and high friability which is undesirable. Further, this continuous layer will also be very hydrophobic because of the non-polar stearic acid chain. This will imply that all the particles in the tablet are very hydrophobic which results in a low dissolution rate and disintegration time which is not preferred. This over-lubrication phenomena will happen the most with magnesium stearate that has the lowest shear strength. This low shear strength is however a requirement for the most optimal lubricant magnesium stearate. Thus a conflict arises, because the most optimal lubricant magnesium stearate has to be made but this negatively affects the

tablet hardness, friability, dissolution rate and disintegration time. It was however found in (Bolhuis, GK 1981, De Boer, AH 1978, Shah, AC 1977, Barra 1996) that the amount of lubricant used in tablets and increased mixing time have the most influence on this phenomena to happen. Which means that the magnesium stearate has to be of the highest grade possible in respect to its lubricating ability to ensure a minimal amount can be used in the tablet pressing production. Further, the mixing time of lubricant in the powder which will be formed in the tablet can also be decreased by adding the lubricant as last to the powder mixture. Further adding to this, is that there are also other compounds added in the powder mixture that enhances the mentioned tablet properties. It can therefore be stated that to be able to satisfy these tablet properties the most optimal lubricant properties has to be chosen, which already was the goal.

From the analysis of the hydration state it can be concluded that the produced magnesium stearate should be of the dihydrate state form, because this enhances the lubricating ability the most. Which eventually results in the least negative effect on the dissolution rate, disintegration time, tablet friability and tablet hardness because less of the compound has to be used in tablet production. Also because the mixing time was found to be a huge factor in the degree of coating and this is not important in the formulation of producing magnesium stearate

Particle size and surface area

As previously described the particles of magnesium stearate fill the cavities and adhere there to the other particles in the powder during the small mixing time. It can be stated that these cavities fill better and faster when the particles of magnesium stearate are as small as possible. The smaller particle size in combination with the particle shape (which will be determined by the crystal morphology) will result in a greater total surface area (Dansereau, Richard 1987). It is also important to state that every particle size in combination with its particle shape has a certain surface area. Further these greater total surface areas can be sheared in tablet pressing which results in better lubrication. It can be concluded that smaller particles thus result in greater total surface area and therefore better lubrication and this statement is supported by several articles (Dansereau, Richard 1987, Li, Jinjiang 2014, Rao, K Phanidhara 2005, Barra 1996, Leinonen, UI 1992). In (Barra 1996) the smallest particle size of commercial magnesium stearate was an average diameter of 1 micron to the biggest average diameter being 3.1 microns. Further in the patent of (Wu, Stephen H 2010) it is stated that the magnesium stearate dihydrate particles can be micronized to a particle size of an average diameter of 5 microns with an surface area ranging from 10 m^2/g to 20 m^2/g. It can therefore be concluded that the average particle size could be reduced to microscopic proportions and the smallest average diameter of (Barra 1996) of 1 microns with a surface area of around 8.5 m^2/g is the guideline for the to be produced particles of magnesium stearate.

This particle size could be realized by milling. In (Chow, Kwok 2008) it is however stated that milling could modify crystal structures which is not preferred. However in (Barra 1998 and K Phanidhara 2005) it is stated that milling does not affect the crystal structure of magnesium stearate because of the lack of heat developing when magnesium stearate is milled. This milling will be more thoroughly discussed in the production process section of this report.

For the influence of particle size on friability, hardness, disintegration time and dissolution time can be stated that bigger particles are preferred because these will fill the cavities of the films less. These bigger particles also have smaller surface areas that can be sheared. The bigger particles therefore form less of a coating around the other particles in the tablet. This will lead to more cohesion between the particles which results in better hardness and less friability of the tablets. If less coating is formed the tablets will also have a higher dissolution rate and faster disintegration time. However as was stated in the hydration state section, over-lubrication is the main contributor to these negative effects to happen. Which is mainly a factor of the amount of lubricant used and mixing time. Therefore to decrease the amount of magnesium stearate used the lubricant has to be of the highest possible quality. This highest quality in respect to lubrication is realized by having as small as particle size as possible.

Thus concluding the particle size has to be the smallest possible, which was found in (Barra 1998) to be an average diameter of 1 micron with a surface area (which is a function of the particle size and the particle shape) of 8.5 m^2/g.

Agglomeration state

For the agglomeration state it is stated that a non-agglomerated lubricant leads to better lubrication (K Phanidhara 2005). This is the case, because the particles will have more surface area in an non agglomerated state which will results in better shearing of the particles. However in (Johansson,Mats E. 1984) it is stated that agglomeration has positive effects on hardness, friability, disintegration time and dissolution rate. However more of the agglomerated magnesium stearate needs to be used to obtain the same lubricating ability as the not agglomerated magnesium stearate. This is not preferred, because the concentration of magnesium stearate in tablets should be kept as low as possible as was stated previously. Therefore it is concluded that a non-agglomerated magnesium stearate is preferred over an agglomerated magnesium stearate.

Impurities

Impurities in the feed streams of the production process could result to poor quality magnesium stearate. These impurities could be in the lard stearin from Ten Kate or in the magnesium hydroxide from Nedmag. These impurities could alter the crystal structure which could have impact on the shearing capability of the magnesium stearate particles. Further, the impurities could perhaps react with the other particles in the tablet. Reactions with the active pharmaceutical ingredients (API's) could render the tablets useless because the API's do not function or form possible dangerous compounds. Therefore a magnesium stearate without impurities is necessary. Thus the chemical compositions of the two feed streams needs to be analyzed and compared with the concentration thresholds stated in the guidelines of the European Medicines Agency. If the impurities exceed the thresholds stated they need to be filtered out by separation processes. Further in (Delaney 2017) it is stated that the fatty acid percentage in the magnesium stearate should contain at least 40% stearic acid and more than 90% of a combination of stearic acid and palmitic acid. The other 10% could contain any chain of fatty acid. It should be noted that in the 90% combination of stearic acid and palmitic acid it is preferred that it only contains stearic acid, palmitic acid is only also allowed to be present. The lard stearin of Ten Kate should be analyzed and compared if it satisfies these specifications. If it does not satisfy the specifications listed separation process should be used to filter out the excessive fatty acid chains. Concluding the feeds should satisfy the specification thresholds listed if these are not satisfied separation process should be used to pretreat the feeds to make them satisfactory. These separation processes will be discussed thoroughly in the production process section of this report.

Pre-treatment of stearic acid from Ten Kate

The stream from Ten Kate which will be used is the lard stearin stream. This stream is a triglyceride stream which contains different fatty acid chains. The fatty acid composition in this triglyceride stream is displayed in table 1. In this table it can be seen that there is a stearic acid percentage of 22.2. There are however also percentages of unsaturated acids of c-18 present these are 33.5 % of oleic acid, 8.5 % of linoleic acid and a 0.9 % of α-linolenic acid. Further the palmitic acid also has unsaturated acids present the 2.0 % palmitoleic acid. These unsaturated acids should be hydrogenated to the preferred stearic acid and palmitic acid. When all these unsaturated acids are saturated there will be a stearic acid percentage of 65.1 and palmitic acid percentage of 31.4. These percentages together will be 96.5%, the remaining percentages consist of the other fatty acids present and an unknown substance displayed in table 1. These percentages all suffice the requirements of the stearic acid present in magnesium stearate. The percentages should be that there is 40% stearic acid and 90% stearic acid and palmitic acid present in the fatty acid mixture. The other percentages are all other fatty acids chains with a percentage of 3% which is below the threshold of 10%. Which component or components the left over 0.5% consists of is unknown. However, because this percentage is so small and the composition is not given by the chemical composition sheet of Ten Kate this percentage of components is assumed to be non-reactive and nontoxic in the magnesium stearate formulation. It can therefore be concluded that the lard stearin from Ten Kate suffices the fatty acid requirements from the pharmaceutical industry after hydrogenation. After this hydrogenation step the lard stearin should also be hydrolyzed to produce the free fatty acid chains from the triglycerides.

FATTY ACID		Percentages	FATTY ACID		Percentage
Caproic acid	C-6:0	0.0	Oleic acid_trans	C-18:1T	0.0
Caprylic acid	C-8:0	0.0	Linoleic acid	C-18:2	8.5
Capric acid	C-10:0	0.0	Linoleic acid_trans	C-18:2T	0.0
Lauric acid	C-12:0	0.0	α-Linolenic acid (ALA)	C-18:3	0.9
Myristic acid	C-14:0	1.2	Linolenic acid_trans	C-18:3T	0.0
Myristic acid	C-14:1	0.0	Octadecatetraenoic acid	C-18:4	0.0
Pentadecanoic acid	C-15:0	0.0	Nonadecanoic acid	C-19:0	0.0
Pentadecanoic acid	C-15:1	0.0	Arachidic acid	C-20:0	0.3
Palmitic acid	C-16:0	29.4	Gadoleic acid	C-20:1	0.6
Palmitoleic acid	C-16:1	2.0	Eicosadinoic acid	C-20:2	0.3
Palmitoleic acid_trans	C-16:1T	0.0	Eicosatetraenoic acid	C-20:4	0.0
Palmitoleic acid	C-16:2	0.0	Eicosapentaenoic acid (EPA)	C-20:5	0.0
Hexadecatetraenoic acid	C-16:4	0.0	Uneicosanoic acid	C-21:0	0.0
Margaric acid	C-17:0	0.4	Erucic acid	C-22:1	0.0
Margaric acid_branched	C-17:V	0.0	Docosapentaenoic acid (DPA)	C-22:5	0.0
Heptadecenoic acid	C-17:1	0.2	Docosahexaenoic acid (DHA)	C-22:6	0.0
Stearic acid	C-18:0	22.2	Lignoceric acid	C-24:0	0.0
Oleic acid	C-18:1	33.5			

Saturated fatty acids	53.5
Mono unsaturated fatty acids	36.3
Poly unsaturated fatty acids	9.7

Table 1: stearic acid from Ten Kate composition

Hydrogenation process

The first pretreatment process which needs to take place is the hydrogenation process. This hydrogenation process uses nickel as catalyst which is commercially widely available for this purpose (Hughes, JP 1953). The nickel splits the hydrogen molecules in half which then both react with the double bound in the unsaturated fatty acid chains. All the double bounds in the unsaturated fatty acid chains are reacted according to this method to saturated fatty acid chains. In figure 3 oleic acid is taken as an example.

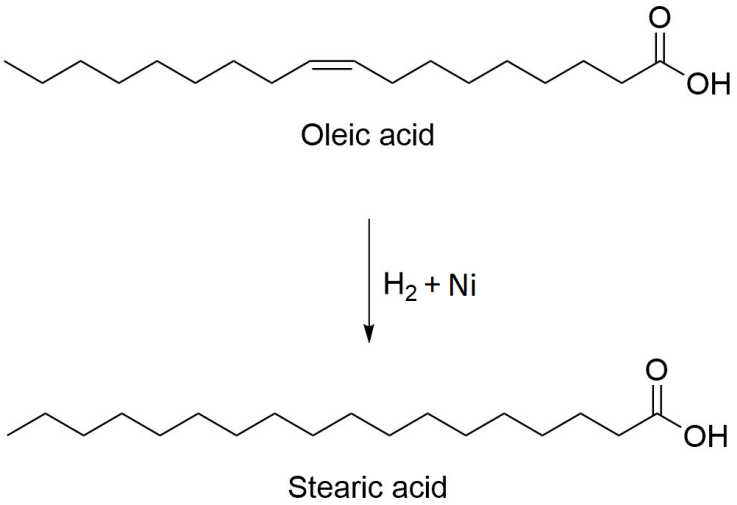

Figure 3: hydrogenation reaction

This hydrogenation process is commercially mainly done in batch processes. Two batch processes are used the dead-end system and hydrogen recirculation system (Coenen, Jacques WE 1976, Gary R 2016, Puri, Pushpinder S 1980, Sourelis, SG 1956). The dead-end system is chosen for this purpose, because it is shown in (Puri, Pushpinder S 1980**)** that it requires less energy, less operating costs and is safer in comparison with the hydrogen recirculation system. This dead-end hydrogenation system consists of several equipment steps. These equipment steps are the storage vessel, the catalyst mixing tank, the convertor vessel, the catalyst filter press, the catalyst removal mixing tank and the scavenger filter press (Sourelis, SG 1956). This entire production process will now be explained in the following paragraphs.

The storage vessel is the first production process step, here the lard stearin from Ten Kate builds up until the production process starts. When the process starts this storage vessel needs to heat up to melt the lard stearin. This is necessary to be able to transport the lard stearin through the pipes to the process equipment's. The heating temperature of this storage vessel is depended on the melting point of the triglycerides in the lard stearin. This melting point of the triglycerides in the lard stearin come from multiple aspects. These being the fatty acid composition in the triglyceride, the saturation of

these fatty acids and crystal structure of the triglycerides (Zéberg-Mikkelsen,Claus K. 1999). From (Zéberg-Mikkelsen,Claus K. 1999) it is found that the triglycerides with the highest carbon chain fatty acids have the highest melting temperature. Further it is also stated that saturated fatty acids have higher melting temperatures than unsaturated fatty acids. Thus when examining the lard stearin it can be concluded that the highest carbon saturated fatty acid is stearic acid. The arachidic acid is in such low percentages available that the likeliness of a triglyceride with three arachidic fatty acids is very low. Further, in (Zéberg-Mikkelsen,Claus K. 1999) it is found that a combination of arachidic acid with stearic acid in the triglyceride has a melting point which is lower than the melting temperature of a triglyceride which only has stearic acid. Therefore it can be concluded that the triglyceride with only stearic acid has the highest melting temperature in the lard stearin. Lastly the triglycerides have three crystal structures that have different melting temperatures. It is unknown in what crystal state the triglycerides of lard stearin are, but it is assumed that they are in the most stable form. This leads from (Zéberg-Mikkelsen,Claus K. 1999) that the triglycerides in lard stearin with the highest melting point are the triglycerides that have three stearic acids chains and are in the most stable crystal form. This melting point is 72,5 °C and the storage vessel should be heated to above this temperature to ensure that the lard stearin will be liquid and thus useable in the production process. The temperature of the heating of the storage vessel will thus be 74 °C to ensure that the lard stearin is liquid.

From the storage vessel a part of the lard stearin is transported to the catalyst mixing tank. Here this lard stearin is mixed with the nickel catalyst and kieselguhr as a filter aid (Carman, PC 1938). This kieselguhr helps with the removal of the catalyst after hydrogenation. This tank has agitators which ensure that the mixture will be well-mixed, further, heating equipment is used to heat and keep the mixture at approximately 74 °C. When this mixture is well-mixed it will be transported to the convertor.

In the convertor the hydrogenation reaction will take place. This convertor is a closed pressure vessel with a turbine agitator that has two impellers at the bottom and top of the vessel that ensure mixing in the vessel. Further a sparger is located at the bottom that creates hydrogen bubbles. The vessel also contains heating and cooling coils, baffles on the sides of the vessel and an evacuator which is a steam ejector. Lastly this convertor is vacuum to ensure that only the lard stearin and hydrogen will be present during reaction. This converter is shown in figure 4 from (Sourelis, SG 1956).

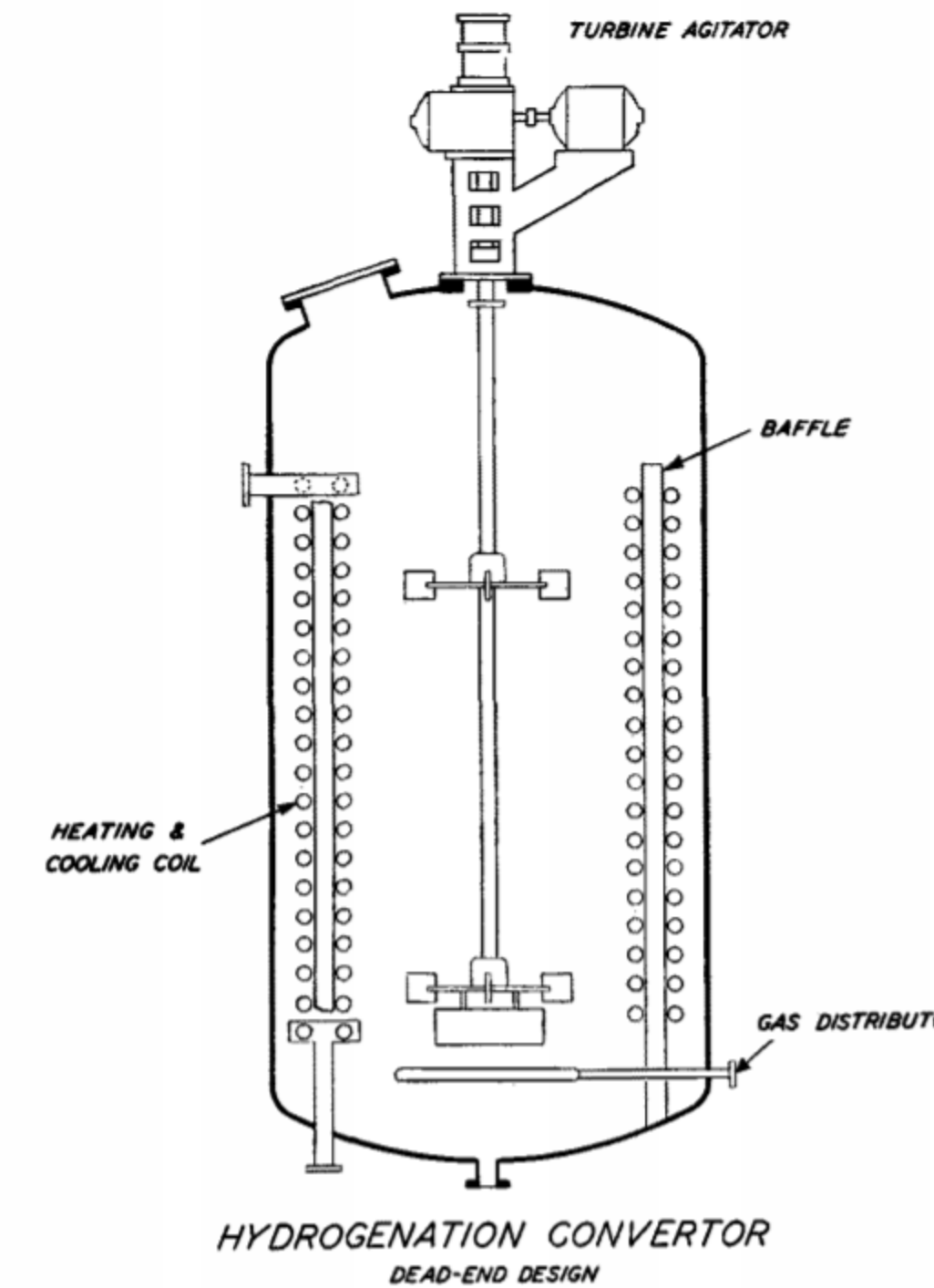

Figure 4: dead-end hydrogenation convertor

The remaining lard stearin flows from the storage vessel to the convertor. When the initial lard stearin that flows in covers the bottom impeller the agitators are turned on and the required amount of catalyst mixture from the catalyst mixing tank is added. These impellers mix the two streams together, during this mixing the mixture is also deaerated by the vacuum and this air is vented out. Further during mixing the heating

coils warm and keep the mixture to 135 °C. This heating also lets the remaining moisture vent out of the mixture by the steam ejector. When the lard stearin and catalyst mixture are well-mixed together which is after approximately 1.25 hours the coils are shut down and the steam ejector is closed.

The hydrogen is then transported from a hydrogen storage tank to the spargers located at the bottom of the converter. These spargers create hydrogen bubbles which flow through the mixture and are dispersed by the impellers. The hydrogen gas will mainly solve in the mixture and react with the unsaturated fatty acid chains with the help of the catalyst. The remaining gas accumulates at the headspace in the top of the vessel where it also slightly diffuses to the mixture and reacts with the unsaturated fatty acids (Puri, Pushpinder S 1980). This reaction is exothermic therefore continuous cooling during reaction by the coils is necessary, the temperature should be kept around 163 °C. Eventually all the hydrogen gas reacts with the unsaturated fatty acids to saturated fatty acids which is after 2 hours approximately. When this state is reached the hydrogen flow is shut off and the remaining hydrogen is vented of. The mixture is now also cooled to 85 °C and after cooling send to the catalyst filter press.

The mixture goes at the catalyst filter through a plate and frame filter press which with the filter aid filters the bigger catalyst particles out. The catalyst that accumulates is re-used in the catalyst mixture tank for several iterations after which it is discarded.

After the initial filtration of the bigger catalyst particles, the mixture is proceeded to the oil mixing tank. Here bleaching clay (montmorillonite type) and phosphoric acid is added and this mixture is mixed for 20 minutes (Charles E Morris Frank P Khym 1952, Opie, Joseph W 1957, Richardson, Louis L 1978), during this mixing the temperature in the mixing tank is kept around 85 °C by heating coils. The bleaching clay and phosphoric acid help remove the small left over nickel particles in the saturated fatty acid mixture.

After mixing the mixture is passed through the last plate and frame scavenger filter press which filters out all the remaining small nickel particles with the help of the bleaching clay and phosphoric acid. This mixture should now contain only triglycerides with saturated fatty acids which can be used in the magnesium stearate production. This saturated fatty acid mixture is then sent to the hydrolysis process.
This entire process is displayed in figure 5.

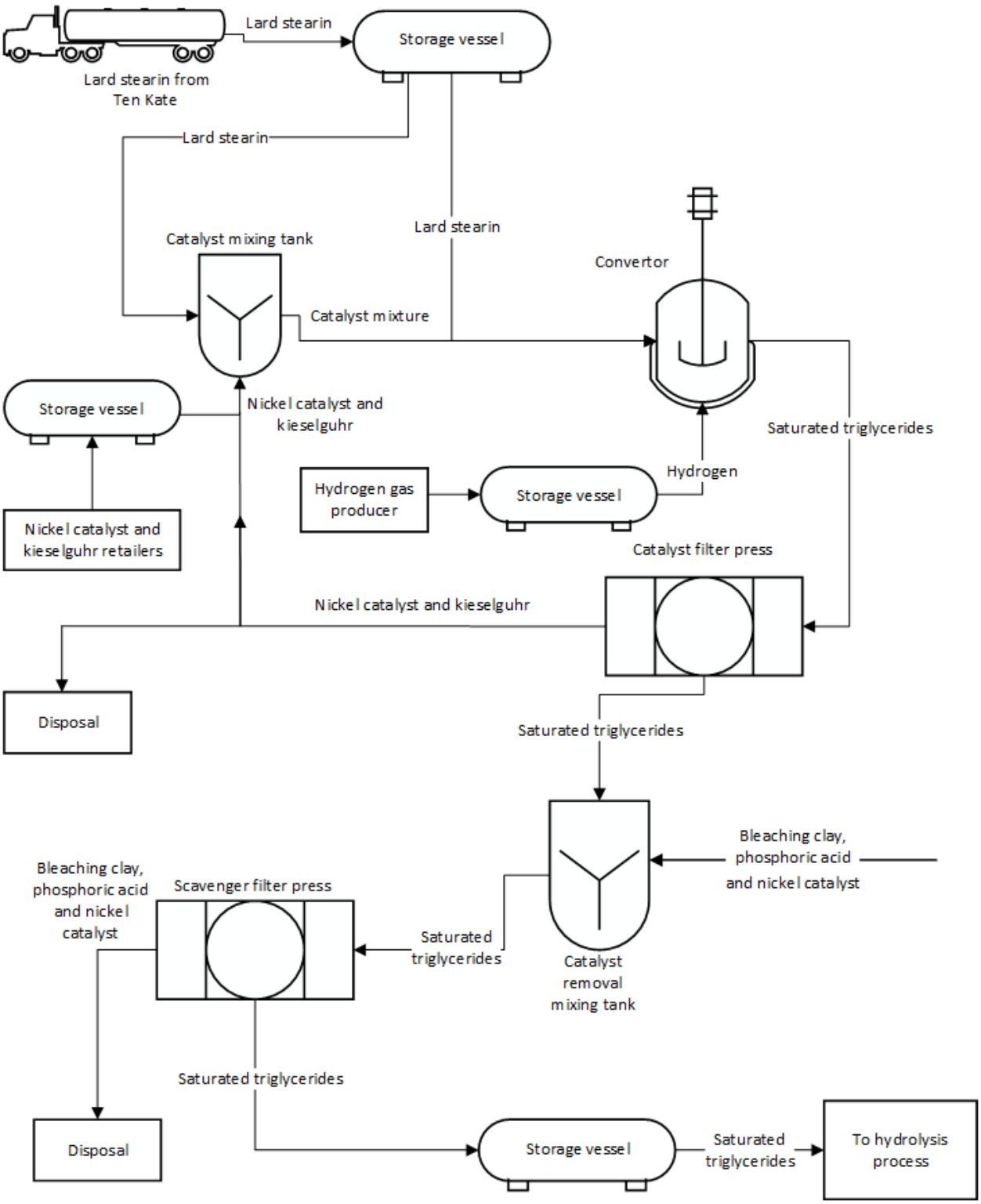

Figure 5: hydrogenation process

The materials used can be obtained according to the following ways:
The hydrogen can be bought from suppliers and stored in a storage vessel. The nickel hydrogenation catalyst, kieselguhr filter aid, bleaching clay and phosphoric acid can all be bought from suppliers.

Hydrolysis reaction

To be able to isolate the saturated fatty acids the hydrolysis reaction should be used. This reaction reacts triglyceride with water to glycerol and 3 fatty acids, this reaction is displayed in figure 6. In this figure the Ra, Rb and Rc mean carbon chains of several lengths.

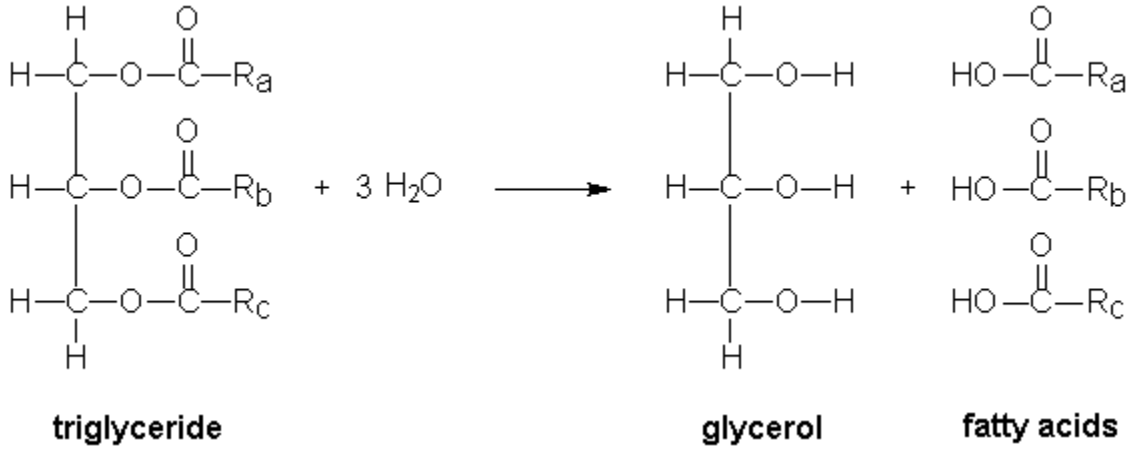

Figure 6: hydrolysis reaction

The hydrolysis reaction is commercially performed by the continuous Colgate-Emery Process. This process converts triglycerides to fatty acids with no catalyst and is cost-effective. The other hydrolysis production processes use catalysts and are less cost-effective generally (Riegel 2003, Sonntag 1979, Barnebey, HL 1948, Satyarthi,J.K. 2011, Holliday, Russell L 1997). These processes are mainly batch processes. It could be stated that a batch hydrolysis would be more efficient after the batch hydrogenation process. However, because of the high conversion rate, no catalyst usage and cost-effectiveness this process is chosen. The batch hydrogenation process and the continuous hydrolysis process should be well adjusted to each other to prevent bottlenecks though. These adjustments can be done by changing the sizes of the batch and the continuous production process until the processes flow well and no bottlenecks occur. The general Colgate-Emery process based on Riegel 2003, Barnebey, HL 1948 will be given, and the flowsheet of this process is shown in figure 7.

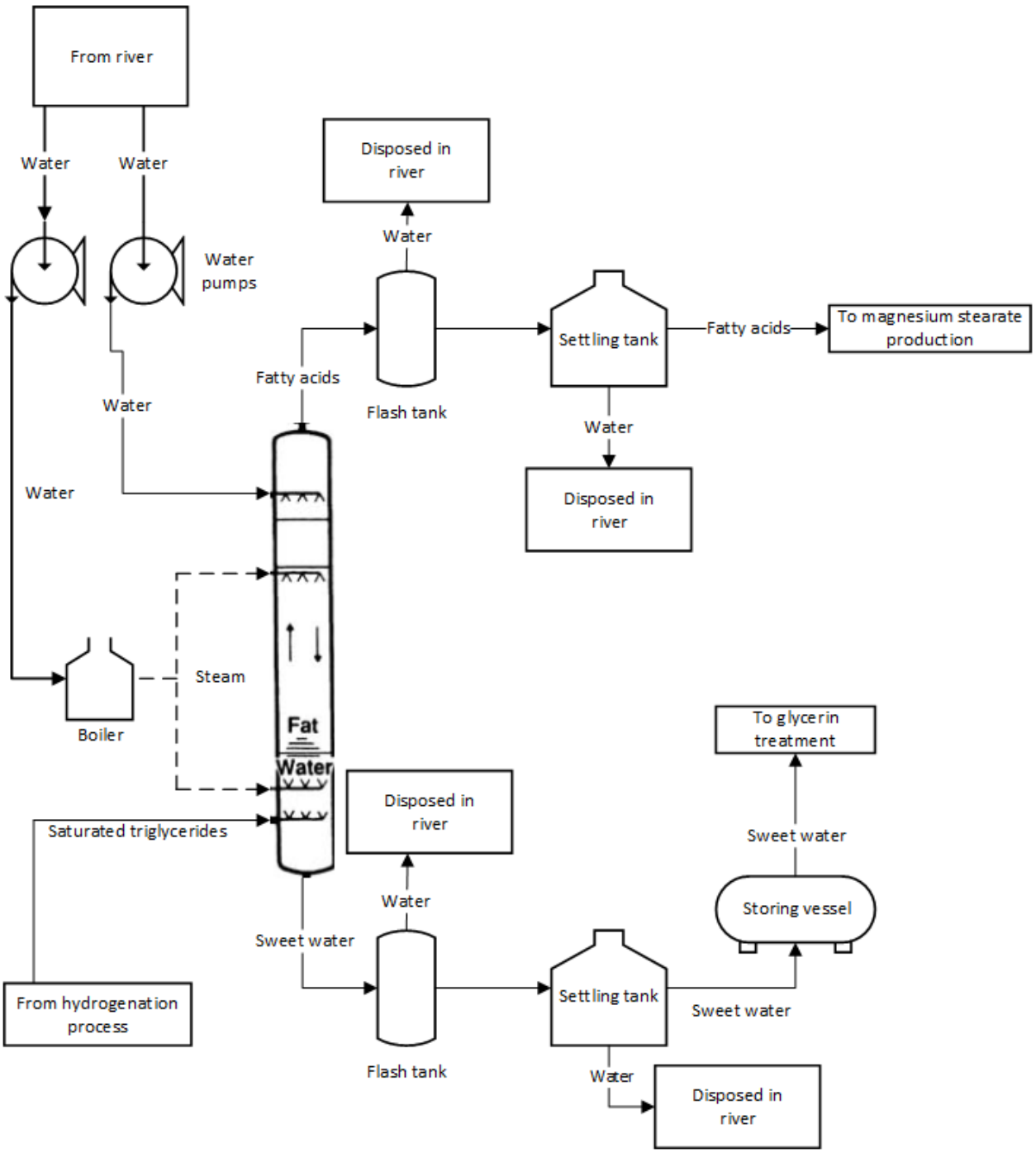

Figure 7: Colgate-emery process

Description of the Colgate-Emery process (Riegel 2003, Barnebey, HL 1948):
The saturated lard stearin from the hydrogenation process enter this continuous process from the bottom of the splitting tower and water is added from the top. This water is pumped from a nearby river or other water location. The splitting tower lets water and fat flow counter-current from each other. Further steam is added in the middle part of the splitting tower to heat the splitting tower. This steam is obtained by a boiler and the

water for this boiler is obtained by a pump which pumps water from a river or other water location to the boiler. Further, this generated steam heats the central section of the splitting tower to about 260 °C. The splitting tower has a pressure of 60 bar, which is to ensure no vaporization of water happens and therefore only liquids are present in the splitting tower.

The saturated lard stearin that enters from the bottom of the splitting tower is sparged in small droplets. These droplets travel through the tower upwards where they are heated to 260 °C by the superheated steam and sweet water which is accumulated at the bottom of the splitting tower. When travelling upwards the lard stearin reacts with water to fatty acids and glycerol. This glycerol solutes in the water and the fatty acids remaining travel in the droplets upwards. These fatty acids droplets accumulate at the top of the splitting tower where the liquid fatty acids are discharged. The water enters the splitting tower at the top and is also sparged in small droplets. These water droplets are also heated to 260 °C by the superheated steam and fatty acid accumulated at the top of the splitting tower. When travelling downwards the water droplets react with the lard stearin. The glycerol produced from this reaction solutes in the water and the sweet water created accumulates at the bottom of the splitting tower. Further the 0.5 % of unknown components in the lard stearin from Ten Kate are also assumed to accumulate here with the sweet water. It can be discussed that this percentage can also be discharged with the fatty acids, however this is not considered in this report. This accumulated sweet water with the 0.5% of unknown components are discharged at the bottom of the splitting tower.

The discharged fatty acids are passed through a flash tank, where the temperature is dropped by evaporating most of the water left in the fatty acids. After this flash tank the fatty acids are passed to the settling tank where the remainder of the water is separated. When reaction is just started the settling tank output can be recycled back in the settling tower. However when reaction is in steady state the output of this process is assumed to consist of 100% fatty acids. The fatty acids are after the settling tank assumed to be around 75 °C. After the settling tank they are pumped to the magnesium stearate production process.

The discharged sweet water with the 0.5% of unknown components are also passed through a flash tank where part of the water is evaporated. This sweet water is then also send to a settling tank where the remaining lard stearin is skimmed out. This sweet water can be further processed to produce glycerol, which can be sold. This is however not considered in this report.

Analysis of the MgOH2 from Nedmag

After visiting Nedmag the chemical composition of the Mg(OH)2 suspension was obtained. The chemical composition can be seen in table 2.

Chemical composition		
Components from dry basis:	Typical value dry basis (%):	Specification value dry basis (%):
Mg(OH)2	98.5	97.5 minimum
Ca(OH)2	0.65	0.90 maximum
Mn	0.05	0.08 maximum
Fe	0.25	0.30 maximum
Si	0.06	0.08 maximum

Table 2

According to the threshold lists of the European Medicines Agency (EMA) these percentages of impurities are not considered toxic or not considered in the thresholds list of the EMA. Therefore the Mg(OH)2 suspension from Nedmag can be used in the production process of magnesium stearate.

Production process of magnesium stearate

Patent searching and determining

Multiple patents were considered for the production of magnesium stearate. Patent from (Pietralla, Norbert 1981) was initially considered, because it could react the molten stearic acid with Mg(OH)2 powder with water as a catalyst. This was initially considered as ideal, because the Mg(OH)2 from Nedmag is an aqueous suspension therefore the water was already present. Further the stearic acid is after the pre-treatment process in the molten state. Therefore both Mg(OH)2 and the stearic could easily be used in their states by the process according to the patent. Furthermore, this process also produced a fine granular product which was also necessary. However this reaction is conducted at temperatures from 90 to 110 °C. These temperatures could result in that the water already present and formed evaporates and does not stay bound in the magnesium stearate as crystal water. In the patent it is also stated that after reaction all this water is

drawn of, which result in that there is no water present in the formed magnesium stearate. This should conclude that the anhydrous crystal magnesium stearate will be formed when these production steps are followed.
Even when this water is not drawn off and the product is cooled the water could condense as surface water not as crystal water in the magnesium stearate crystals. The water could however also condense as crystal water in the magnesium stearate crystals. Both theories could be true, but both are not supported by literature. Therefore it is not possible to determine the state of magnesium crystals formed by the process suggested in the patent. This meant that this patent was not usable.

Patent from (Wuest, Willi 1993) was also considered but this patent reacts stearic acid and Mg(OH)2 without water. This is not possible when considering that the Mg(OH)2 is an aqueous suspension. This meant that this patent was also not usable.

Eventually patents from (Hirsch, Albrecht 1990) and (Cinco, Salvatore A. 1977) were considered as the best possible patents for the production of magnesium stearate. These patents react stearic acid and Mg(OH)2 in water at low temperatures. These low temperatures do imply that the stearic acid should be used in powder form. Which means an extra stearic acid powder formation process should be added. However when examining example 5 of (Cinco, Salvatore A. 1977) the produced magnesium stearate here after overnight drying contains 3.5 % water. According to patent from (Heider, Todd P 2008) this implies that the produced magnesium stearate mainly consists of the dihydrate form. Because according to this patent when the magnesium stearate product has a water content between 3.5 to 6.0% it comprises of a significant amount of dihydrate. Further patent from (Heider, Todd P 2008) suggests that if the magnesium stearate has a pH at around 7 the dihydrate will be formed. When examining the produced magnesium stearate it is concluded that it only consist of water and magnesium stearate therefore according to this composition the pH should be 7 (from chemicalbook pH of magnesium stearate in water is 7). This is another argument that the magnesium stearate produced according to patent (Cinco, Salvatore A. 1977) consists of a significant amount of dihydrate. Further in (Heider, Todd P 2008) it is stated that the drying conditions of magnesium stearate influence the hydration state production. According to this patent drying at 65 °C will ensure mainly the dihydrate will be remaining. Therefore this drying temperature will also be taken into the process design.

In patent (Cinco, Salvatore A. 1977) it is further stated that a free flowing white powder is formed, which suggests that the obtained product is in powder form. It is therefore concluded that the process of (Cinco, Salvatore A. 1977) produces a powdered magnesium stearate in a mainly dihydrate form, which was required. This product will be dried at 65 °C to ensure that the dihydrate will be formed.

Stearic acid powder formation

To be able to use the stearic acid in the magnesium stearate production the stearic acid needs to be converted from the molten state to a powder. This means that the molten fatty acids produced by the hydrolysis process need to be pumped to a spray dryer (Santos, Daniel 2017, Tashiro, Yoichi 1989). This spray drying process pumps the molten stearic acid through nozzle orifices which create stearic acid droplets. These spray drying processes are done in vertical cylindrical vessels where the nozzles are located at the top part of the vessel. The nozzles spray the stearic acid droplets from the top of the vessel, which then fall down the cylindrical vessel. This vessel is continuously fed with ambient air by a blower which cools the droplets when they are falling down. The droplets then become solid particles when falling through the cooled air medium. The bigger formed particles fall down and are conveyed to a storage silo and the smaller particles flow with the air to a cyclone which separates the stearic acid particles from the air. These smaller particles are after separation from the air flow also conveyed to the storage silo. From the storage silo the powder can be conveyed to the magnesium stearate production reactor.

Magnesium stearate production process

The process according to patent (Cinco, Salvatore A. 1977) is now described and proposed as the process to be used. This patent uses a batch process which starts by adding powdered stearic acid and the aqueous suspension of Mg(OH)2 to the reactor vessel. According to the patent the Mg(OH)2 and stearic acid can be added in stoichiometric amounts or in a molar excess of Mg(OH)2 from 5% to 100%. The stoichiometric amounts are used in this process, because of the high amount of water in the Mg(OH)2 suspension. The stoichiometric amounts of Mg(OH)2 and stearic acid can be obtained from the chemical equation.

Chemical equation:
$Mg(OH)_2 + 2\ C_{17}H_{35}COOH \rightarrow Mg(C_{17}H_{35}COO)_2 + 2\ H_2O$

From this chemical equation is found that for every mole of Mg(OH)2 two moles of stearic acid should be added. The amount of water added according to the patent should be between 0.1 to 8.0 % of the total weight of components added. The Mg(OH)2 suspension delivered from Nedmag contains 53% weight solids. This translates according to the calculation in table 3 seen below that the water in this suspension when mixed with stearic acid accounts for 7.95% of the total weight of components. This is between the requirement from the patent and therefore the aqueous suspension does not have to be changed. This should also conclude that if the proposed excess of Mg(OH)2 from the patent would be used the water in the reactor would exceed the 8.0

% water content threshold, which is not desirable. Further, if the excess of Mg(OH)2 is still requested to be used the water content of the Mg(OH)2 suspension from Nedmag should be altered which requires changes in their production process of Mg(OH)2. Furthermore, the added excess Mg(OH)2 should also be filtered out afterwards. This all conclude that the usage of the molar excess of Mg(OH)2 all lead to more process steps, which is undesirable therefore the stoichiometric amounts are used.

The fatty acids are conveyed from the storage silo to the reactor vessel and the Mg(OH)2 suspension is transported from a storage tank to the reactor vessel. The Mg(OH)2 suspension and the fatty acids powder are both added to the reactor vessel according to their molar stoichiometry's. This reactor vessel is a mixing vessel that operates at atmospheric pressure with a high speed agitator, a cooling jacket and a thermometer. After addition of the fatty acids and Mg(OH)2 suspension to the reactor the mixture is continuously stirred by the agitators at 3600 rpm. The continuous agitation of the mixture causes reaction and magnesium stearate is formed. Further, the continuous agitation and exothermic magnesium stearate reaction result in heat generation. This heat generation is wanted to a certain extent, but for ideal reaction the mixtures temperature has to be maintained between 40 and 45 °C. This means that the mixture has to be cooled by the jacket with cooling water. This cooling water is pumped from a nearby river or other water location to the cooling jacket. The mixture is reacted for 45 minutes after which the produced magnesium stearate is discharged out of the vessel and the next batch of magnesium stearate can be produced. The total residence time of the batch reactor consists thus of the loading of the components in the reactor, the reaction of the mixture and the discharging of the magnesium stearate out the reactor. The total assumed residence time is then: 45 minutes + 10 minutes (assumed loading and discharging time) = 55 minutes. However, the obtained product after reaction is magnesium stearate it still has too high water content to be considered a dihydrate. Therefore the product is conveyed to a series of drying operations where the unbound water is evaporated. After this drying procedure it is assumed that only 3.5% of the weight of the total powder is present as crystal water. This should indicate from (Heider, Todd P 2008) that the dihydrate magnesium stearate is formed.

Calculation:

Average molecular weight stearic acid calculation					
Fatty acid:	Percentage fatty acid after pretreatment with 0.5 % unknown components in it (%):	Percentage fatty acid after pretreatment without 0.5 % unknown components in it (%):	Fatty acids (grams):	Molecular weight fatty acid (gr/mol):	Fatty acids (mol):
Stearic acid:	65.1	65.43	65.43	284.48	0.2300
Palmitic acid:	31.4	31.56	31.56	256.4	0.1231
Margaric acid:	0.6	0.60	0.60	270.45	0.0022
Myristic acid:	1.2	1.21	1.21	228.37	0.0053
Arachidic acid:	1.2	1.21	1.21	312.53	0.0039
Total moles fatty acids (mol):					0.3644
Total weight fatty acids (grams)					100
Average molecular weight fatty acid composition (gr/mol):					100/0.3644 = 274.39 grams/mol
Molecular weight of Mg(OH)2 (gr/mol):					58.32

Assume 2 moles of fatty acid is reacted with 1 mole of Mg(OH)2 means that 274.39 *2= 548.79 gr fatty acid and 58.32*1= 58.32 gr Mg(OH)2 react with each other. Mg(OH)2 dry basis composition consists of 98.5 % Mg(OH)2 therefore complete amount of solids is: 58.32/0.985= 59.21. According to physical properties, Mg(OH)2 suspension consists of 53% solids therefore complete weight of Mg(OH)2 is: 59.21/0.53= 111.71 gr of Mg(OH)2 suspension. Amount of water in Mg(OH)2 suspension: 111.71*0.47= 52.51 gr of water in Mg(OH)2 suspension. Calculating the total amount of water in the mixture of the suspension Mg(OH)2 and stearic acid powder gives: 52.50/(548.79+111.71)= 0.0795= *7.95%* water.

Table 3: calculation

Magnesium stearate drying

The drying has to be performed according to patent (Heider, Todd P 2008) at temperatures from 60 to 65 °C. This will ensure that mostly dihydrate crystal magnesium stearate will be present with remainder being anhydrous crystal magnesium stearate. The continuous fluid-bed dryer is suggested in (Heider, Todd P 2008) as potential drying equipment. This equipment is generally used for pharmaceutical products, because it can operate at temperatures between 50 to 80 °C (Kuelling, Walter 1969). Thus this dryer can dry at the requested temperatures between 60 to 65 °C. In this continuous fluid-bed dryer the moist magnesium stearate powder has to be continuously fed in, therefore before the dryer a hopper has to be placed. This hopper functions as a holding vessel which results in that the batch production from the reactor can be temporary hold. This hopper then discharges the moist magnesium stearate powder in a continuous matter for the continuous fluid-bed drying. In this fluid-bed dryer the moist magnesium stearate is thus continuously fed in and conveys over a porous plate through the drying zone in the dryer. The transporting of the powder horizontally through the dryer is done by two conveyor worms which push the powder through the dryer. The powder does not fall through this porous plate because the plates holes are smaller than the powder particles. The holes are however big enough to let hot air at 65 °C pass through vertically which then passes through the horizontal moist powder. This hot air is heated by heating equipment and a fan blows this hot air at high velocity through the powder particles. The high velocity of the hot air results in that the powder particles float in the hot air. The floating of the particles results in the formation of a horizontal fluidized bed where the particles float in and hot air passes through. The fluidized bed of magnesium stearate particles are dried by this hot air passing past the particles. The fluidized bed moves horizontally by the two conveyor worms through the dryer and is at the opposite side of the inlet discharged out the dryer. The product that flows out of this dryer is the dried dihydrate magnesium stearate. Further, the hot air

moving vertically through the fluidized bed picks up smaller dust particle from it. These dust particles are filtered out by a cyclone. The dried smaller particles from the cyclone and bigger particles from the dryer are all conveyed to the hammer mill.

Magnesium stearate milling

After drying the product consists of smaller and bigger particles in an agglomerated state, these particles need to be micronized and de-agglomerated to be sold in the pharmaceutical industry. The wanted average particle size of the magnesium stearate product is 1 micron as stated in the particle size product requirements section. To be able to produce particles that are of such small size the particles first need to be ground by a hammer mill (Helms 1975).

The hammer mill described is of patent (Helms 1975). This hammer mill consists of a cylindrical grinding chamber where an axis in the middle of the chamber spins with double profile hammers. This cylindrical grinding chamber is a screen with holes in it which let small particles through. The hammers spins inside this grinding chamber at high rpms, with the rotation diameter of the hammers slightly smaller than the diameter of the cylindrical grinding chamber. The magnesium stearate particles are fed in this grinding chamber and collide with the hammers reducing the particles in size. The magnesium stearate particles also get high velocities by the collision with the hammer mills smashing the particles against the grinding chamber interior. The collision of the particles with the hammers and grinding chamber interior reduces the magnesium stearate particles in size. Through size reduction the smaller particles are able to pass through the holes in the grinding chamber. The smaller particles passing through the grinding chamber screen are collected and accumulated in an exterior chamber where the cylindrical grinding chamber is in. The exterior chamber lets the accumulated powder of small magnesium stearate particles fall down interior by gravity. The smaller particles falling down from this interior of the exterior chamber are discharged at the bottom of the hammer mill. This hammer mill uses feed of bigger particles and mills them to particles of a diameter average of 1 millimeter (Liu, G. 2017).

After this initial grinding by the hammer mill the particles are conveyed to a fluidized bed jet-mill. This fluidized-bed jet mill micronize the particles to the requested 1 micron size (Liu, G. 2017, Jet, 2019).

The fluidized bed jet mill described comes from (Nied, Roland 1986) and consists of a grinding chamber, this grinding chamber has at the bottom a nozzle which brings air at a high velocity in a vertical direction through the grinding chamber. The high velocity air provided too this mill comes from a blower (Liu, G. 2017). Further, the magnesium stearate which is supplied at the top of the grinding chamber falls down to the bottom part of the grinding chamber. At this bottom section the magnesium stearate powder

forms a horizontal fluidized bed by the high velocity of air passing through the powder. Further, at this bottom section of the grinding chamber there are three nozzles equally distributed along a horizontal circle just below the surface of the fluidized bed. These three nozzles also deliver air at a high velocity by the same blower to the grinding chamber. This high velocity air emitted from these nozzles let the floating particles in the fluidized bed collide with each other. The collision of the particles with each other result in size reduction of the particles. When the particles reduce in size they rise easier with the upwards flowing air in the grinding chamber. The rising particles meet a classifier at the top of the grinding chamber. This classifier has a classifier wheel which spins and only lets through small particles. The classifier in this case should only let through particles with an average particle diameter of 1 micron or smaller. The bigger particles bounce of and fall back below in the grinding chamber where they are subjected to reduction again until they are small enough. The small particles below 1 micron in average diameter that went through the classifier flow with the air to two bag dust collector where the particles are separated from the air. These two bag dust collectors are needed because the magnesium stearate particles accumulate at the inside of the bag dust collector. Which means that after some time the formed accumulated powder on the inside of the bag filter have to be removed. This cleaning time of the bag dust collector means that for some time the dust collector is not functional. However, the production process cannot be idle therefore two equally sized bag dust collectors are used where air flow is switched between. This results in that continuous production is still possible. The micronized dihydrate magnesium stearate particles collected from the bag dust collectors are then conveyed to a storage silo. The storage silo is the final equipment were the powder is collected. This powder can then be sold to the pharmaceutical industry as lubricating agent. The complete magnesium stearate production process can be seen in figure 8.

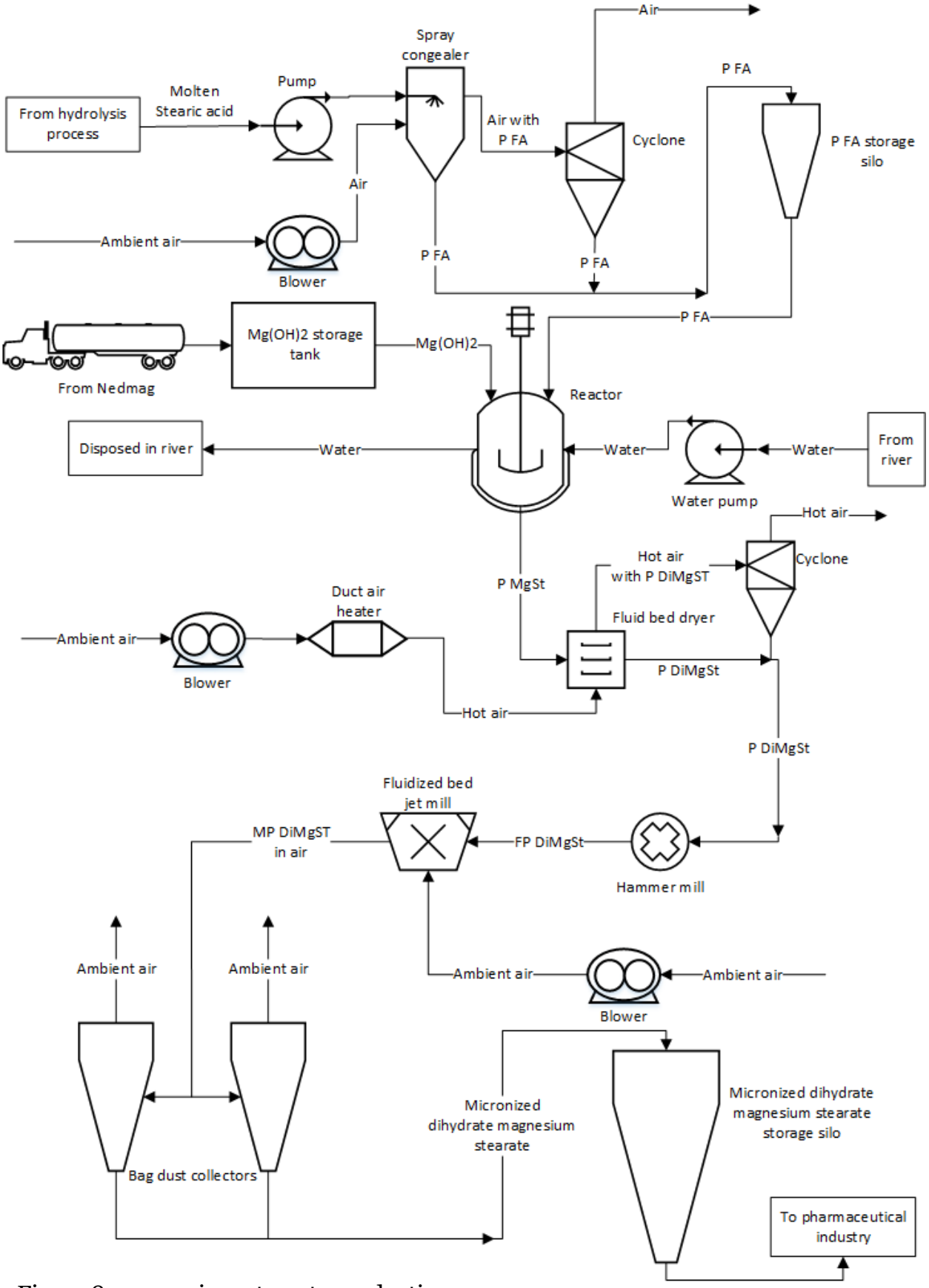

Figure 8: magnesium stearate production process

Legend magnesium stearate production process:

P FA= powder fatty acids
P MgSt = powder magnesium stearate
P DiMgSt = powder dihydrate magnesium stearate
FP DiMgSt = fine powder dihydrate magnesium stearate
MP DiMgST = micronized powder dihydrate magnesium stearate

Costs of magnesium stearate production process plant

To be able to know how much needs to be invested to build the magnesium stearate production process the capital cost of the production plant needs to be estimated. It should be noted that only the capital cost of the magnesium stearate production process plant will be estimated. This is chosen to limit the length of the research and because the hydrolysis and hydrogenation process are already known production processes. For clarification the hydrogenation process described is known as the fat hardening production process. And further, the hydrolysis process described is known as the continuous fat splitting production process. Therefore, because these processes are well-known the capital costs are also already known. Which means that for this research it is now only interesting to known how much the magnesium stearate production process plant costs, because this is a relatively new and specific production process.

Capital cost estimate method

The capital cost of the magnesium stearate production processes plant will be calculated according to a cost estimate classification made by the American Association of Cost Engineers (AACE) (Turton, R. 2008). From the AACE the preliminary cost estimate method is chosen for the magnesium stearate production process plant. It should be noted that this preliminary cost estimate method has an accuracy range of -15 % to 30 %. According to this cost estimation method all the major equipment purchasing costs should be estimated at their respective capacities. These respective capacities of the equipment will be described in the next section of this report, first the method of obtaining the capital costs of the production plant will be described. These major equipment purchasing costs at their needed capacities will be obtained by:

- Cost estimation charts (from cost estimation charts in the references)
- The Dutch Association of Cost Engineers (DACE) booklet
- Fact sheets on air emission abatement techniques from Infomill in references

These sources will together give the purchasing prices of all the major equipment's used in the magnesium stearate production process at their wanted capacities. The cost estimation charts are however from 1987 therefore they need to be adjusted to account for inflation and obtain an estimate for the cost of the equipment at 2019. The method

for updating equipment costs that were applicable in past years to equipment costs that are useful for later years is the cost index method. The cost index method uses dimensionless numbers that represent certain years of equipment costs and when combined in the following formula can estimate current equipment costs. The formula being:

$$C_2 = C_1\left(\frac{I_2}{I_1}\right)$$

where,
C_1 = Estimated cost at previous time
C_2 = Cost at expected time
I_1 = Index value at expected time
I_2 = Index value at previous time

The index dimensionless number from the Chemical Engineering Plant Cost Index (CEPCI) is used for this cost estimation section. The CEPCI number of 1987 is 320 and for 2018 is 603.1. The index number for 2019 was not available therefore the index number of 2018 was concluded to be sufficient. Thus when using the cost index method on all the obtained equipment purchasing costs from the cost estimation charts the purchasing costs of the equipment in 2018 will be obtained. When all the purchasing costs of the major equipment at the needed capacity in 2018 are calculated and estimated they need to be added up. This total then has to be multiplied by the Lang factor for solid-fluid processing plants to obtain the capital cost of the production process plant of magnesium stearate (Turton, R. 2008). The Lang factor for solid-fluid processing plants is 3.63. This Lang factor accounts for:

- Installation costs of the equipment.
- Material transportation mechanisms between the equipment. This includes: screw conveyors for solid material transportation, pipes for liquids and ducts for air.
- Measuring and sensory equipment that are needed for the complete production process.
- Supporting equipment around the major equipment. Under supporting equipment falls all the minor equipment around the major equipment were the costs are not given for, this includes hoppers for the solids as well.

The Lang formula:
*Capital cost of production process plant = 3.63 * all equipment purchase costs*

The obtained capital cost total will then include:

- The purchasing costs of all the major equipment.
- The installation costs of all the major equipment.

- The costs of piping and other material transportation mechanisms between the equipment.
- The measuring and sensory equipment costs.
- The supporting equipment costs.

This obtained capital cost total however does not contain the land costs of the production plant and the building costs where the production plant is located in. Therefore these costs also have to be added up to get the total complete capital cost of the magnesium stearate production process plant.

In the following paragraphs first the flow rates in and out all of the major equipment are calculated. These flows are then used to obtain the needed capacities for all the major equipment's. With the capacities of the major equipment's the purchase costs are estimated by the described methods. These costs are then multiplied by the Lang factor and after this the land costs and building costs are estimated and also added up to the total. The obtained total is the total complete capital cost of the magnesium stearate production process plant.

Flow rates of the magnesium stearate production process

To be able to calculate the costs of the equipment the wanted production quantity of the magnesium stearate production plant has to be stated. The wanted production of magnesium stearate is 10,000 tonne per year. From this wanted production quantity the flows in and out the major equipment can be calculated with the help of several calculations. These made calculations can be seen in appendix A.

Mg(OH)2 storage tank

The storage tank should be able to hold enough Mg(OH)2 suspension before it is pumped to the magnesium stearate reactor. It is assumed that it should be able to hold enough Mg(OH)2 suspension for a week of continuous magnesium stearate production. The volume of Mg(OH)2 suspension that is needed each week is thus the volumetric flowrate of Mg(OH)2 per hour that is need for reaction times the amount of hours in a week. The volumetric flowrate of Mg(OH) suspension needed for reaction per hour is 0.15 m^3/hr from appendix table A5. The volume of Mg(OH)2 suspension that is needed each week is thus: 0.15 m^3/hr * (24 * 7) = 25.1 m3 per week.
This means if a week of supply has to be available the tank should have a volume of 26 m3. Converting this to gallons to be able to use it in the equipment cost chart gives a rounded volume of 6,900 gallons. From the equipment cost chart a small storage tank with a volume of 6,900 gallons costs: 4,500 dollar.
Converting the costs of the equipment in 1987 to costs of the equipment in 2018 with the cost index formula, gives:

$C_2 = C_1 * (I_2/I_1) = 4{,}500 * (603.1/320) = 8{,}481$ dollar

Spray congealer

The spray congealer has to spray the molten fatty acid from the hydrolysis process to a fatty acid powder. First the molten fatty acid has to be pumped to this congealer. The mass flow rate of fatty acids that is needed for reaction is 1,058.6 kg/hr from appendix table A5. This mass flow rate has to be converted to volumetric flow rate by dividing the mass flow rate by the density of the molten fatty acids. The density of the molten fatty acids mainly comes from stearic acid and palmitic fraction having mass percentages of 65.1 % and 31.4 % respectively. The mass ratio of these two compounds is then 2.07 : 1 for stearic acid to palmitic acid. Using the densities of molten stearic acid and palmitic acid from appendix table A5 and the mas ratio of stearic acid to palmitic acid should give an estimate of the density of the molten fatty acid mixture. The density of the molten fatty acid mixture is then calculated as such: ((2.07 * 847) + 852.7) / (1+2.07) = 848.9 kg/m^3. The volumetric flow rate of molten fatty acids needed can now be calculated as following: 1058.6 kg/hr / 848.9 kg/m^3 = 1.25 m^3/hr. The molten fatty acid pump thus needs to be able to pump 1.25 m^3/hr. From DACE a single-stage centrifugal pump at 1,450 rpm made from AISI 316 is chosen. However, the cost of this pump is only given at a capacity of 6.3 m^3/hr with a water pressure of 12.5 m. Therefore to be able to know how much the pump would cost at the desired volumetric flow rate of 1.25 m^3/hr the six-tenth rule formula of equipment cost attribute has to be used. This six-tenth rule formula of equipment cost attribute can give an estimate of equipment purchasing cost at different operating capacities.

The six-tenth rule formula:
Cost of wanted equipment= ((wanted capacity of equipment/ available capacity of equipment)^0.6)* cost of existing equipment.

Filling in this formula gives the following equation:

Cost of the pump at the needed 1.25 m^3/hr flow rate = ((1.25/6.3)^0.6)* 6,650 = 2,516 euro.

The described pump needs to pump the molten fatty acids to the spray congealer. This spray congealer therefore has to be able to handle the outflow of the pump which is 1.25 m^3/hr which conversed to ft^3/min is 0.73 ft^3/min. However, from the equipment cost chart only much higher capacities are displayed for the spray congealer. There is however a formula given below the chart to calculate the price of the spray congealer. In this formula the minimum price of a spray congealer is also given which is 65,000 dollar. Converting this equipment cost in 1987 to costs of the equipment in 2018 with the cost index formula, gives:

$C_2 = C_1 * (I_2/I_1) = 65{,}000 * (603.1/320) = 122{,}504$ dollar.

The ambient air that cools the molten fatty acids in the spray congealer needs to be pumped in by a blower. The volumetric flow rate that is necessary for the cooling of the molten fatty acids can however not be calculated therefore it has to be estimated. This estimated needed air flow rate is assumed to be 20,000 m^3/hr which is 11,771 ft^3/hr. From the equipment cost chart a blower with a volumetric flow rate of 11,771 ft^3/hr costs around: 280,000 dollar.
Converting the costs of the equipment in 1987 to costs of the equipment in 2018 with the cost index formula, gives:

$C_2 = C_1 * (I_2/I_1) = 280{,}000 * (603.1/320) = 527{,}713$ dollar

Lastly, the air passing through the spray congealer picks up fatty acid dust particles which need to be separated from the air flow. A cyclone is used to filter out the dust particles from this air flow. In : (Fact sheets on air emission abatement techniques) cyclones are described with their costs as a factor of their capacity. From this reference the purchasing cost of the cyclone is 1,200,- euro per 1,000 m^3 air that flows through it per hour. Thus given 20,000 m3 air is flown through the cyclone each hour gives the cyclone purchasing cost to be: 20 * 1,200 = 24,000 euro.

The output of the spray congealer and cyclone is the fatty acid powder which can be used in the reactor. The produced powder is continuously collected by a hopper after which the powder is continuously conveyed to a powder stearic acid storage silo.

Powder fatty acid storage silo

The powder fatty acid storage silo should be able to hold enough powdered fatty acid to use in one throughput of magnesium stearate production. For one throughput of magnesium stearate production 1058.6 kg/hr * 0.92 hr (throughput time) = 970 kg of powdered fatty acid is needed. This mass needs to be converted to volume by dividing it by the density of the powdered fatty acids. The density of the powdered fatty acids from appendix table A5 is 934 kg/m^3. The needed volume of powdered fatty acids for one throughput of magnesium stearate production is then: 970 kg /934 kg/m^3 = 1.04 m^3. This is however only the volume of the fatty acids without the air pockets between the particles of the powder. Therefore, to account for the air pockets between the fatty acids particles and to insure that the storage silo will not overflow the silo's volume is increased to 1.5 m3. However, from DACE the costs of a 1.5 m^3 vertical storage silo made from aluminum with a plate thickness of 4 mm is not available, but a 10 m^3 size is available. Therefore the six-tenth rule formula of equipment cost attribute has to be used.

Filling in the six-tenth formula with the values for the vertical storage silo gives:
Cost of vertical storage silo = ((1.5/10)^0.6)* 20,000 = 6,407 euro.

Reactor vessel

The reactor vessel should be able to produce the requested 10,000 ton magnesium stearate per year. From appendix table A5 it was found that to be able to produce this yearly amount of magnesium stearate the reactor vessel should output a mass flow rate of 1,274.09 kg of unprocessed magnesium stearate per hour. The volumetric flow rate of this output is 1.24 m^3/hr from appendix table A5. To be able to calculate the needed amount of product produced each batch the throughput time per batch should be multiplied by the volumetric flow rate. The throughput time is 0.92 hour and the volumetric flow rate 1.24 m^3/hr thus 1.24 * 0.92 gives 1.14 m^3 product is needed to be produced each batch. However, considering that a batch reactor has a surface level and is thus never completely filled with product means that the actual volume of the reactor is slightly larger. Hence, the actual volume of the reactor is estimated to be 1.25 m^3. Further the reactor vessel has a high speed agitator which operates at 3,600 rpm and a cooling jacket which regulates the reaction temperature. However, no costs could be found of a reactor vessel that has an agitator that runs at that high rpm. Thus for the cost estimation the mixing vessel from DACE is used which operates at a maximum of 120 rpm. The mixing vessel with the high speed agitator is probably more expensive then the mixing vessel described in DACE however, because this is a cost estimation the cost of the mixing vessel described in DACE is concluded to be sufficient. From DACE a mixing vessel with jacket made from AISI 316 L with a volume of 1.25 m^3 costs around: 55,500 euro.

Further, the reactor vessel has to be cooled to keep the temperature range between 40 and 45 °C. The amount of water needed for cooling has to be assumed, because the amount of heat generated by agitation and reaction is unknown. First it is assumed that it takes 10 minutes for the mixture to get to 45 degrees. This then leaves 25 minutes of necessary water cooling. It is further assumed that a mass flow rate of 12.5 m^3/hr of ambient water is needed and a water pressure of 12.5 m in this cooling period. Thus a pump that can provide 12.5 m^3/hr of water with a water pressure of 12.5 is necessary. From DACE a pump made of AISI 316 that has a capacity of 12.5 m^3/hr and provides 12.5 m of water pressure costs: 7,150 euro.

The magnesium stearate powder output of the reactor vessel is first conveyed to a hopper. This hopper serves as a holding vessel from which the formed powder is continuously discharged to the fluid bed dryer.

Drying

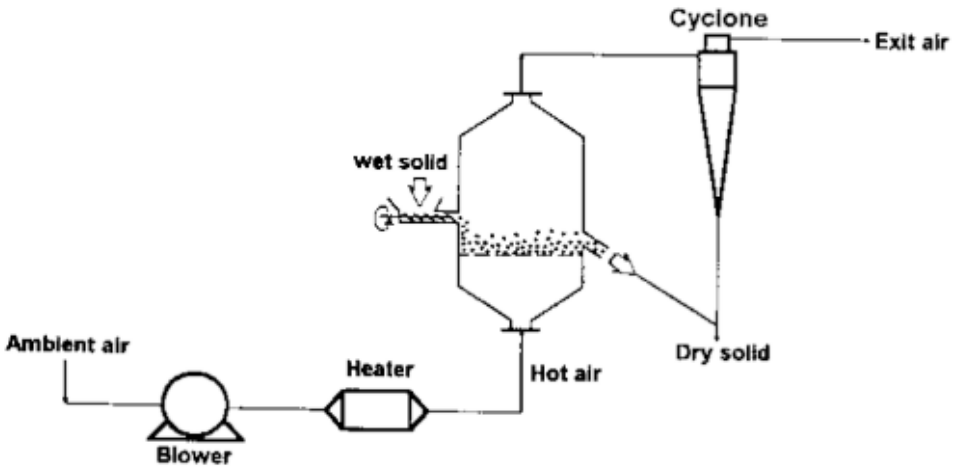

Figure 4 A schematic flow diagram of the whole fluidized bed drying system.

Figure 9: fluidized bed drying system

The fluidized bed drying system displayed in figure 9 from (Mujumdar, Arun S 2003) is used as the fluidized bed drying system. This system consists of the fluid bed dryer, an air heating equipment, a blower and a cyclone.

To be able to calculate the fluid bed dryers volume first the drying time of the magnesium stearate to be able to get the required 3.5% moisture content product should be assumed. The average drying time generally for fluidized bed dryers is between 0 to 60 minutes therefore a drying time of 30 minutes is assumed for the drying of magnesium stearate. Using the volumetric flow rate of magnesium stearate output from the reactor which is: 1.24 m^3/hr (from appendix table A5) times the average drying of 0.5 hr time gives a needed volume of magnesium stearate in the dryer of 0.62 m^3. This is however only the volume of magnesium stearate in the dryer and total volume of the dryer is larger. To be able to calculate the total drying vessel volume it is assumed from figure 9 that the volume of solids coming in the vessel should only account for 10 % of the total volume of the vessel. This then gives a total volume of the drying vessel of 0.62/0.10 = 6.2 m^3. This volume has to be converted to ft^3 to be able to use it in the equipment cost chart. Volume of 6.2 m^3 * 35,315 = 218.95 ft^3. From the equipment cost chart a fluid bed dryer with a volume of 220 ft^3 costs: 28,000 dollar.
Converting the costs of the equipment in 1987 to costs of the equipment in 2018 with the cost index formula, gives:

$C_2 = C_1*(I_2/I_1) = 28{,}000*(603.1/320) = 52{,}771$ dollar

The blower which pumps hot air to the fluid bed dryer needs an adequate air flow rate to be able to dry the magnesium stearate to the desired water content, this calculated air flow rate is 21,878.41 m^3/hr from appendix table A8. Further the blower should provide air at a high enough velocity to be able to fluidize the magnesium stearate. This velocity needed for fluidization of the magnesium stearate particles can however not be calculated, because the particle properties of the magnesium stearate particles is unknown. Therefore it has to be assumed that if the blower pumps air at 21,878.41 m^3/hr at 2 bar pressure the magnesium stearate will be fluidized and dried properly in the dryer. The calculated air flow rate has to be converted to ft^3/hr thus 21,878.41 m^3/hr * 0.589 = 12,877.15 ft3/hr. From the equipment cost chart a blower with a capacity of 12,877.15 ft^3/hr and providing 2 bar or 30 psi of pressure costs: 293,333 dollar. Converting the costs of the equipment in 1987 to costs of the equipment in 2018 with the cost index formula, gives:

$C_2 = C_1*(I_2/I_1) = 293{,}333*(603.1/320) = 552{,}841$ dollar

The heater has to heat up air at ambient temperature (assumed to be 20 °C) to hot air of 65 °C to be able to use it in the fluidized bed dryer. Further the heater has to be able to handle 21,878.41 m^3/hr of air passing through at 2 bars of pressure. In industrial drying operations electrical duct air heaters are usually used for the heating of air for fluidized bed drying. The pricing of these heaters is usually performed by the amount of kW they need to operate. The estimated amount of kw needed for the electrical duct air heater for this process can be calculated by the following formula obtained from a duct air heater vendor (Belthermal):

Power needed = (cubic feet per min air flow * air temperature rise in Fahrenheit) / 3,193

Power needed = (12,877.15 * (149 – 68)) / 3,193 = 327 kW

The pricing of the duct air heater at the given power requirement was however not available, but the price of the air duct heater at 180 kw was available from (Alibaba). Using the six-tenth rule of equipment cost attribute gives:

Cost of duct air heater at wanted capacity = ((327/180)^0.6)*4,550

Cost of wanted equipment = 6,510 dollar.

The last equipment is the cyclone which removes the dust particles that flow with the air out of the dryer. In : (Fact sheets on air emission abatement techniques) cyclones are

described with their costs as a factor of their capacity. From this reference the purchasing cost of the cyclone is 1,200,- euro per 1,000 m3 air that flows through it per hour. Thus given 21,878 m^3 air is flown through the cyclone each hour gives the cyclone equipment: 21.878* 1,200 = 26,253 euro.

Hammer mill

The dihydrate magnesium stearate produced from the dryer is processed through a hammer mill which reduces the particle size. The hammer mill reduces the larger dihydrate magnesium stearate particles to particles with an average diameter size of 1 millimeter. The hammer mill should be able to handle the output of the dryer which is 1,141.6 kg of dihydrate magnesium stearate per hour from appendix table A6. This amount has to be converted to imperial ton/hr to be able to use in the cost estimation. This gives (1141.51 kg/hr / 1000) *0.98= 1.1 tons/hr rounded. From the equipment cost chart it was found that the estimated cost of a hammer mill that can handle 1.1 ton/hr is 4,500 euro. Converting the costs of the equipment in 1987 to costs of the equipment in 2018 with the cost index formula, gives:

$C2 = C1*(I2/I1) = 4,500 *(603.1/320) = 8,481$ dollar

Fluidized bed jet mill

The powdered dihydrate magnesium stearate from the hammer mill is processed in the jet mill to obtain the 1 micron average particle diameter dihydrate magnesium stearate. This jet mill has to be able to handle the output from the hammer mill which is 1,1 tons/hr. From the equipment cost chart it was found that the estimated cost of the jet mill that can handle 1.1 tons/hr is 36,000 dollar. Converting the costs of the equipment in 1987 to costs of the equipment in 2018 with the cost index formula, gives:

$C2 = C1*(I2/I1) = 36,000*(603.1/320) = 67,848$ dollar.

Further, air at high velocity has to be pumped through the jet mill to be able to fluidize and mill the dihydrate magnesium stearate. This needed air flow for fluidization and milling in the jet mill is assumed to be the same as the fluidized bed dryer air flow rate. Therefore the necessary air flow rate to the jet mill is estimated to be 21,878.41 m^3/hr at 2 bar pressure. The blower described at the fluidized bed dryer can provide this air flow rate at the required pressure.
The cost of this blower at the given capacity in 2018 is: 552,841 dollar.

Lastly, two bag dust collectors have to be used to filter out the made micronized dihydrate magnesium stearate particles from the air flow. The two bag dust collectors need to be able to manage the volumetric air flow rate from the jet mill of 21,878.41 m^3/hr. From the equipment cost chart a bag dust collector with a capacity of 21,878.41 m^3/hr costs: 41,000 dollar.

Converting the costs of the equipment in 1987 to costs of the equipment in 2018 with the cost index formula, gives:

$C2 = C1*(I2/I1) = 41,000*(603.1/320) = 77,272$ dollar.

The two bag dust collectors thus costs 2 * 77,272 = 154,544 dollar.

Micronized dihydrate magnesium stearate storage silo

The produced micronized dihydrate magnesium stearate coming from the bag dust collectors have to be stored in a storage silo after production. This storage silo needs to hold enough product before it can be sold to the pharmaceutical industry. It is concluded that this storage silo needs to hold at least one week of magnesium stearate production. The volumetric flow rate of the produced micronized dihydrate magnesium stearate powder is 1.1 m^3/hr from appendix table A9. This amount needs to be multiplied by 7 * 24 = 168 hours. Then 1.1 m^3/hr * 168 hours = 186.8 m^3 is the volume of one week of magnesium stearate production. This is however only the volume of the solid micronized dihydrate magnesium stearate particles, the powder obtained also consists of air pockets between the solid particles. It is assumed that the volume of the air pockets in the powder account for 10 % of the total volume of the powder. Thus the total volume of the produced powder in a week is: 186.8 / 0.9 = 207.5 m^3 rounded up to 208 m3. From DACE only a storage silo made from aluminum with a plate thickness of 7 mm and a volume of 200 m^3 is available. Therefore the six-tenth rule has to be used.

Cost of storage silo at wanted capacity = ((208/200)^0.6)* 74,000 = 75,762 euro.

Building costs and land cost

The magnesium stearate production process has to be located in a building. This building has to be large enough to hold the entire magnesium stearate production process. The size of the building has to be estimated, this estimated size of the building is 30 meters long, 40 meters wide and 15 meter high. This gives an area of 20 * 30 = 1,200 m2 and volume of 1200 * 15 = 18,000 m3. In DACE the cost of an industrial building that consists of one floor and has basic installation (heating, air conditioning and lighting) is calculated by the area of the wanted building. From DACE the building

costs is 835 euro per m2 which then leads to the cost of the magnesium stearate production process building being : 1,200*835= 1,002,000 euro.

This building has to be located on a land area, this parcel should be larger than the building. It is presumed that this parcel should be at least three times as large as the production process building. Thus the area of the parcel should be: 3 * 1200 = 3,600 m2. The location of the building should be near Nedmag and Ten Kate because these two companies provide the feed for the magnesium stearate production. These two companies are located in the area of Groningen called: Westerwolde en Groninger Veenkoloniën. The price for one hectare of building land in this area costs: 60,975 euro (Misset). Thus the cost of the wanted parcel area of 3,600 m2 in the Westerwolde en Groninger Veenkoloniën area costs: 0.36 hectare * 60,975 euro/hectare = 21,951 euro.

Capital cost total

To obtain the total capital cost of the magnesium stearate production process first all the major equipment purchasing costs need to be added up, which is displayed in table 4. The sum of all the major equipment purchasing costs needs to be multiplied by the Lang factor to obtain the total production process capital cost. To this production process capital cost the building and land cost need to added. The obtained total cost is the capital cost of the complete magnesium stearate production process. This amount is also the amount of capital which needs to be invested to make the magnesium stearate production process plant. This total capital cost of magnesium stearate production process plant is: 8,403,561,- euro. The derivation of this total cost can be seen in table 4 and 5.

Table 4: equipment purchasing cost total:		
Equipment:	Cost (euro):	Cost (dollar):
Mg(OH)2 storage tank:		8,481.-
Molten fatty acid pump:	2,516.-	
Spray congealer:		122,504.-
Spray congealer blower:		527,713.-
Spray congealer cyclone:	24,000.-	
Powder fatty acid storage silo:	6,407.-	
Magnesium stearate reactor:	55,500.-	
Water pump for reactor cooling:	7,150.-	
Fluid bed dryer:		52,771.-
Fluid bed dryer blower:		552,841.-
Fluid bed dryer duct air heater:		6,510.-
Fluid bed dryer cyclone:	26,253.-	
Hammer mill:		8,481.-
Fluidized bed jet mill:		67,848.-
Fluidized bed jet mill blower:		552,841.-
Two bag dust collectors:		154,544.-
Magnesium stearate storage silo:	75,762.-	
Total purchasing cost of major equipment (dollar):		2,054,534.-
Conversion dollar to euro:	2,054,534.-* 0.893323 = 1,835,362.-	
Total purchasing cost of major equipment (euro):	2,032,950.-	

Table 5: total capital cost of magnesium stearate production process plant:	
Lang factor for solid-fluid processing plants:	3.63
Capital cost of production process (euro):	2,032,950.-* 3,63 = 7,379,610.-
Building cost (euro):	1,002,000.-
Parcel cost (euro):	21,951.-
Total capital cost of magnesium stearate production process plant (euro):	7,379,610.- + 1,002,000.- + 21,951.- = 8,403,561,-

Discussion and recommendation

The production processes described in this report are made on the basis of several assumptions this was done to limit the size of the research. However, for future research it is recommended to find out the precise operating parameters of the production processes. When the precise operating parameters of all the production processes are known more accurate production processes can be designed. These more accurate production processes will then also lead to better descriptions of the wanted capacities of the equipment. With these more accurate capacities the purchasing costs of the equipment in the production processes can be better estimated which will lead to a better estimation of the capital costs of the production processes.
Further, in this report only the capital costs of the magnesium stearate production process was estimated. This was done because the fat hardening production process and the fat splitting production process described are already very well-known production processes. Moreover, this was also chosen to limit the size of the research. However, to get a more accurate total capital cost of the complete production process plant the capital costs of the fat hardening process and fat splitting process should also be estimated.
Furthermore, in this report the operational costs of the complete magnesium stearate production plant were also left out, because first the capital cost of the magnesium stearate production process had to be estimated. However, for future research it is recommended to estimate the operational costs of the complete production plant. Because these costs in combination with the total capital cost of the complete magnesium stearate will determine if the magnesium stearate production plant will be profitable or not.

Conclusion

It can be concluded that the stated design goal is reached, this design goal was: *Designing a production process of pharmaceutical grade magnesium stearate with the costs associated with producing this process.*

This can be concluded because the complete production process of producing pharmaceutical grade magnesium stearate is designed in the figures: five, six and seven. Further, the capital cost of the magnesium stearate production process plant is also estimated to be: 8,403,561,-. This means that the associated costs with producing the magnesium stearate production process is also given.

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Appendix A:

Table A1: average molecular weight of fatty acids after pretreatment calculation		
Saturated fatty acids after pretreatment:	Weight percentage of fatty acids before 0.5 % unknown taken off (%):	Weight percentage of fatty acids after 0.5% unknown taken off (%):
Stearic acid:	0.651	0.651 / 0.995 = 0.6543
Palmitic acid:	0.314	0.314 / 0.995 = 0.3156
Margaric acid:	0.006	0.006 / 0.995 = 0.0060
Myristic acid:	0.012	0.012 / 0.995 = 0.0121
Arachidic acid:	0.012	0.012 / 0.995 = 0.0121
Total:	0.995	1

Table A2: average molecular weight of fatty acids after pretreatment calculation second part			
Saturated fatty acids after pretreatment:	Fatty acids weights assuming 100 grams of fatty acid (gr):	Molecular weights of fatty acids (g/mol):	Molar weight fatty acids (mol):
Stearic acid:	0.6543 * 100 = 65.43	284.48	65.43 / 284.48 = 0.230
Palmitic acid:	0.3156 * 100 = 31.56	256.4	31.56 / 256.40 = 0.123
Margaric acid:	0.0060 * 100 = 0.60	270.45	0.60 / 270.45 = 0.002
Myristic acid:	0.0121 * 100 = 1.21	228.37	1.21 / 228.37 = 0.005
Arachidic acid:	0.0121 * 100 = 1.21	312.54	1.21 / 312.54 = 0.004
Total:	100		0.364
Average molecular weight of the fatty acids (g/mol):	100 / 0.364 = 274.39		

Table A3: average molecular weight of the produced magnesium stearate	
Average molecular weight of the fatty acids (g/mol):	274.39
Molecular weight Mg (g/mol)	24.305
Molecular weight H (g/mol)	1.00784
Average molecular weight produced magnesium stearate (kg/kmol):	(2 * 274.39 + 24.305) - (2 * 1.0078) = 571.08

Table A4: calculations of mass flows and molar flows of the products	
Wanted production of plant (tonne/year):	10,000
Hours in year	8760
Dihydrate magnesium stearate wanted production (kg/hr):	(10,000 / 8,760)*1,000 = 1,141.6
Weight percentage of magnesium stearate without water:	0.965
Magnesium stearate production (kg/hr):	1,141.6*0.965 = 1,101.6
Magnesium stearate production (kmol/hr):	1,101.6 / 571.08 = 1.93
Water produced by magnesium stearate production (kmol/hr):	1.93 * 2 = 3.86

Table A5: reactor in- and outflows and other important information:	
Molecular weight Mg(OH)2 (kg/kmol):	58.32
Molecular weight of H2O (kg/kmol):	18.02
Saturated fatty acids needed for reaction (kmol/hr) :	1.93 * 2 = 3.86
Mg(OH)2 needed for reaction (kmol/hr) :	1.93 * 1 = 1.93
Water produced by magnesium stearate production (kmol/hr):	1.93 * 2 = 3.86
Water produced by magnesium stearate production (kg/hr):	3.86 * 18.02 = 69.50
Saturated fatty acids needed for reaction (kg/hr):	3.86 * 274.39 = 1,058.61
Density of molten palmitic acid (kg/m3):	852.7
Density of molten stearic acid (kg/m3):	847.0
Mass ratio of stearic acid to palmitic acid:	1 : 2.073
Density of molten fatty acid mixture (kg/m3):	((2.07 * 847) + 852.7) / (1+2.07) = 848.9
Density of powder stearic acid (kg/m3):	940.8
Density of powder palmitic acid (kg/m3):	852
Density of powder fatty acid mixture (kg/m3):	((2.07*940.8)+852)) /(3) = 934
Mg(OH)2 needed for reaction (kg/hr):	1.93 * 58.32 = 112.50
Mass fraction of Mg(OH)2 of total solids:	0.985
Mass fraction of solids in the suspension:	0.53
Mg(OH)2 suspension needed for reaction (kg/hr):	((112.50 / 0.985) / 0.53) = 215.49
Water in Mg(OH)2 suspension (kg/hr):	215.49 - 112.50 = 102.99
Water outflow of reactor (kg/hr):	69.50 + 102.99 = 172.50
Mass outflow of the reactor (kg/hr):	215.49 + 1058.61 = 1274.09
Volumetric flowrate out of the reactor (m3/hr):	(1,101.6 / 1028) + (172.50 / 997) = 1.24
Density of Mg(OH)2 suspension from Nedmag (kg/m3):	1,440
Volumetric flow rate of Mg(OH)2 suspension to the reactor (m3/hr):	215.49 / 1,440 = 0.15

Table A6: dryer in- and outflows and other important information	
Volumetric flowrate in to the dryer (m3/hr):	(1,101.6 / 1028) + (172.50 / 997) = 1.24
Mass flow rate in to the dryer (kg/hr):	215.49 + 1058.61 = 1,274.09
Mass flow out of the dryer (kg/hr):	(10,000 / 8,760)*1,000 = 1,141.6
Water needed to be released by dryer (kg/hr):	1,274.09 - 1,141.60 = 132.54
Mass flow of water in to the dryer (kg/hr):	69.50 + 102.99 = 172.50
Mass flow of dry magnesium stearate in and out of the dryer (kg/hr):	1,274.09 - 172.50 = 1,101.59
Mass flow of water out the dryer (kg/hr):	1,141.6 - 1101.59 = 39.95
gr of H2O per kg dry basis inlet per hour:	(172.50 / 1,101.59) * 1,000 = 156.59
gr of H2O per kg dry basis outlet per hour:	(39.95 / 1,101.59) * 1,000= 36.27
gr of H2O needed to be absorbed by kg dry air per hour:	156.59 - 36.27 = 120.32

Table A7: data obtained from psychometric chart	
Air at 20 degrees celsius with 30% humidity gr of H2O per kg dry air:	4.2
Air at 65 degrees celsius with 3% humidity gr of H2O per kg dry air:	4.2
Air at 65 degrees celsius assume 20% humidity gr of H2O per kg dry air:	10

Table A8: dryer air mass and volumetric flow rate	
Air at 65 °C flow rate needed for drying (kg/hr):	((1,101.59 * 156.59) - (1,101.59 * 36.27)) / (10 - 4.2) = 22,852.00
Density of air at 65 °C (kg/m3):	1.0445
Air at 65 °C flow rate needed for drying (m3/hr):	(22,852.00 / 1.0445) = 21,878.41

Table A9: micronized dihydrate magnesium stearate storage silo	
Magnesium stearate density (kg/m3):	1028
Water density at 20 degrees celsius (kg/m):	998
Dry magnesium stearate produced (kg/hr):	1,274.09 - 172.50 = 1,101.59
Water in dihydrate magnesium stearate (kg/hr):	1,141.6 - 1101.59 = 39.95
Micronized dihydrate magnesium stearate produced (m3/hr):	(1,101.59 / 1028) +(39.95 / 998) = 1.11