DETERMINATION OF ENERGY USAGE AND POTENTIAL ENVIRONMENT IMPACT (PEI) OF A MULTI EFFECT DISTILLATION SYSTEM FOR PRODUCTION OF WATER FOR INJECTION (WFI) IN PHARMACEUTICAL INDUSTRIES

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NUR MAHIRAH BINTI HIBRAHIM

Thesis submitted in partial fulfilment of the requirements
for the award of the degree of
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JANUARY 2014

SUPERVISOR'S DECLARATION

We hereby declare that we have checked this thesis and in our opinion, this thesis is adequate in terms of scope and quality for the award of the degree of Bachelor of Chemical Engineering.

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STUDENT'S DECLARATION

I hereby declare that this thesis entitled "Determination of Energy Usage and Potential Environment Impact (PEI) of a Multi Effect Distillation System for Production of Water For Injection (WFI) in Pharmaceutical Industries" is the result of my own research except for quotations and summaries which have been duly acknowledged. The thesis has not been accepted for any degree and is not concurrently submitted for award of other degree.

Signature :
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Dedication

Special dedicated to my beloved Father, Mother
Brothers and Sister
My future Family
Professors, Lecturers and Friends…..
Special Thanks for all of you Care, Love, Encouragement and Best Wishes.

Thank you for your support.

ACKNOWLEDGEMENT

In the name of Allah, The Most Gracious, Most Merciful

First gratitude and praises goes to ALLAH, in whom I have put my trust and faith in. With the help and blesses from the Almighty, all the obstacles and problem have solved smoothly. I also would like to take this opportunity to express profound gratitude to my research supervisor, Dr-Ing Mohamad Rizza bin Othman and Madam Auni binti Idris (master student) for the noble guidance and valuable advices along the process to complete this research. His patience, time, thoughts and understanding are highly appreciated.

My sincere appreciation also extends to all my fellow colleagues; their help, support and understanding are really appreciated. Last but not least, I would like to thank my beloved family who always being supportive, helpful and listened to all my doubt and problems during my study. All their helped will always remembered.

ABSTRACT

Pharmaceuticals are emerging as a rapidly growing global industry because health is a crucially important social and economic asset whilst the cornerstone for human development. Energy in pharmaceutical industries is used to operate the unit operations and also needed to produce water for injection (WFI) as production utilities. Significantly, WFI is largely used in pharmaceutical processes. Typical process for generating WFI is through a multi effect distillation which needs temperature and therefore uses large amount of energy. The high energy consumption increase the amount of greenhouse gases in the atmosphere particularly carbon dioxide, methane and nitrous oxide. As the pharmaceutical industry expands, the industry faced more serious environmental problems arising from increasing global production. Thus aware of this fact, it is important to assess the energy consumption and its environmental impact as early as possible especially during the process design stage to avoid further harm to the future generation to meet their needs. In order to know the emission of mass and energy would emit to environmental, we used the waste reduction (WAR) algorithm methodology analysis to access the energy usage in process which is potential environmental impact (PEI) and economic impact. In this work, we used Super Pro software to gain the amount of energy used for the WFI production in pharmaceutical industry. Furthermore, the data from the research can be analysis to achieve the sustainable development of process without sacrificed our worth earth. The total energy demand is 95.29 kWh was calculated to produce 880 L/hr WFI in pharmaceutical industry. The energy produced from several equipment such as listed above. Result from the PEI value calculation suggested that the higher amount of component emission is 122 CO_2 contain.

ABSTRAK

Kertas kerja ini menerangkan tentang potensi kesan terhadap alam sekitar ataupun *"Potential Environmental*(PEI)dankajianmengenai*Impact"*penggunaan tenaga dalam penghasilan *"Water For Injection"* (WFI) menggunakan sistem *"Vapor Compression Distillaton"*(VCD). Jumlah PEI telah dianalisis menggunakan algoritma *"Waste Reduction"*(WAR) dengan mengambil kira jumlah tenaga yang diadaptasi dalam sistem simulasi. Persamaan yang digunakan telah dibina menggunakan perisiaan *"Excel"*. Terdapat lapan kategori bagi impak yang telah dikira untuk mengetahui kesan proses kimia terhadap alam sekitar. Keputusan daripada *Excel* menunjukkan bahawa potensi kesan toksik melalui pernafasan serta pendedahan pada kulit , *"Human Toxicity Potential by Inhalation/ dermal exposure"* (HTPE) adalah yang paling tinggi berbanding yang lain. Penggunaan tenaga bagi sistem VCD telah dikira dengan mensimulasikan proses aliran VCD tersebut menggunakan *"SuperPro Designer"* (SPD). Keputusan bagi model tersebut mendapati keperluan tenaga WFI daripada sistem VCD adalah 53.07kWh/h. Memandangkan system VCD menggunakan elektrik sebagai sumber tenaga, beberapa gas berbahaya seperti CO_2, SO_2 dan NOx telah dibebaskan ke atmosfera. CO_2 adalah gas yang paling banyak dibebaskan daripada proses tersebut dengan nilai 112.19. Keputusan yang diperolehi daripada hasil kerja ini mungkin berguna bagi mencegah pembebasan gas CO_2 terhadap alam sekitar. Jumlah permintaan tenaga adalah 95,29 kWh dikira untuk menghasilkan 880 L / jam WFI dalam industri farmaseutikal. Tenaga yang dihasilkan daripada beberapa peralatan seperti yang disenaraikan di atas. Keputusan daripada pengiraan nilai PEI mencadangkan bahawa jumlah yang lebih tinggi daripada pengeluaran komponen adalah kandungan 122 CO_2.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS

EP	European Pharmacopeia
JP	Japanese Pharmacopeia
MED	Multi Effect Distillation
PEI	Potential Environmental Impact
PW	Purified Water
SPD	Super Pro Design
VCD	Vapor Compressor Distillation
WAR	Waste Reduction Algorithm
WFI	Water for Injection

1 INTRODUCTION

1.1 Motivation and statement of problem

In the pharmaceutical industry, water is an essential ingredient and the water should meet the set standard (Rakesh et al, 2010).One of the types of water is WFI which used in many areas of the pharmaceutical industry for the production of medicaments and intermediates as well as for the final cleaning of equipment. Unfortunately, large amount of energy must be transferred to the water in order to achieve phase transition and this input of energy causes the water to move rapidly. When more energy used, potential environmental impact will be increases from the process to generate the energy. In Malaysia, fossil fuel was used as sources to generate the energy. In the United State alone, more than 80% of greenhouse gas emissions released were from fossil fuels which contribute to climate changes (EPA, 2009).

For future stability, sustainable development in early stage of design process play important role to considering the environmental and social impacts.As an engineer, the potential impacts to the environment when developing and manufacturing the pharmaceutical industry should be consider. Sustainable development in process is important while protecting the environment for the present and future generations. The waste reduction (WAR) algorithm methodology is used to determine the potential environmental impact. Better technology can help us study and better understand how our process is affecting the environment and prevent the impact from effecting the environment. Potential environmental impact is the unrealized effect or impact that the emission of mass and energy would have on the environment (Cabezas, Bare, & Mallick, 1999). Although the pharmaceutical industry is not considered a ‘heavy’ industry compared to chemical industry and others, it faces new challenges in controlling and preventing environmental pollution as it expands.Thus aware of this fact, it is important to assess the energy consumption and its environmental impact as early as possible especially during the process design stage to avoid further harm to the future generation to meet their needs.

1.2 Objectives

The following are the objective of this research:

This work aims to determine the energy usage and potential environment impact to produce water for injection using multi effect distillation process for pharmaceutical use.

1.3 Scope of this research

The following are the scope of this research:

i) Simulate MED process using SPD to calculate amount of energy generated per unit of time

ii) The amount of energy generated were used to calculate the amount of PEI indicator

iii) Apply Waste WAR Algorithm methods to analysed PEI indicator in an Excel spreadsheet.

1.4 Main contribution of this work

The following are the contributions of this research:

- MED process flow diagram and equation for each PEI indicator.
- Environment impact for WFI production using MED method.

1.5 Organisation of this thesis

The structure of the reminder of the thesis is outlined as follow:

Chapter 2 provides a description of the pharmaceutical industry and the process utility for Water For Injection production. A general description of applications and general design features of multi effect distillation system. This chapter also provides information of the energy usage and potential environment impact.

Chapter 3 gives a review of the multi effect distillation method applied for determine of steam generated, energy usage and potential environment impact by using waste reduction algorithm.

Chapter 4 is showed the result and discussion for an environmental assessment, total energy usage during operation, PEI indication comparison and energy comparison between MED and VCD methods.

Chapter 5 to combine together a conclusion and recommendation outlines the future work which might be derived from the model developed in this research.

2 LITERATURE REVIEW

2.1 Introduction to pharmaceutical Industry

Water is the most important natural resource in worldwide. Quality of water is the important part need consider for human being especially for drinking water. Furthermore, in the pharmaceutical industry water is the basic carrier in the pharmaceutical processes and products. Pharmaceutical industry business has divide by section such as are manufacturing, formulating and processing medicinal chemicals and pharmaceutical products. Most of product sold in various dosage delivery forms such as tablets, capsules, ointments, solutions, suspension and powders (Berry & Rondjnelli, 2002). Water is the essential and high demand expectation components in the pharmaceutical industry due to the nature of its production processes. Production of biological pharmaceutical in general requires more water than conventional drugs. WFI is one of the types of water used in pharmaceutical industry. WFI used for the preparation of medicines for parental administration when water is used as vehicle WFI in bulk and for dissolving or diluting of substance or preparations for parenteral administration (sterilised WFI).Additionally, WFI is mainly used with drugs that need to diluted or dissolved in aqueous solution for patient use. Certain biological require water for injection which must be sterile and devoid of minerals and microbes. According with World Health Organization (2005) WFI is not sterile water and not a final dosage form. The element is important for cleaning agent and ingredient in many formulations.

2.2 Water For Injection

Water is the most frequently used as a raw material in the pharmaceutical industry. It is an essential ingredient of various pharmaceutical preparations and most apply to the pharmaceutical industry which the quality of water is critical and high priority in pharmaceutical process or product (Pahwa, Piplani, & Sharma, 2010). There are two basic types of pharmaceutical water which are purified water (PW) and WFI. PW used for cleaning while WFI used for irrigation and most sterile water for inhalation. There are no chemicals, bacteria or endotoxins in it. The main difference between WFI and PW is the amount of bacterial contamination allowed, measured by colony count and endotoxin level. Generally, WFI used in injectable product preparations for dissolving or dilution substances or preparations for parental administration before use and for sterile water for preparation of injections (Scope, 2005). In the production of water for the pharmaceutical, there are few methods to produce WFI and follow the standard. Generally, methods that are used are distillation, reverse osmosis and ultrafiltration. Three types of standard and regulation method in the production of water for injection are United State Pharmacopeia (USP), European Pharmacopeia (EP) and Japanese Pharmacopeia (JP). According to Brush & Zoccolante (2009), distillation is the only WFI method of production that is approved by the EP. While EP, USP and JP have attempted to harmonize the method for production of water for injection, it strongly suggested that distillation because the robust nature of distillation process specifically as it relates to the phase change of water to steam.

2.3 MED Process for WFI

Distillation is simply the phase change from liquid to vapour, thus enabling the pre-treated feed water to be stripped of any residual ionic materials, particulates, colloids and non-volatile organic compounds. Distillation also removes bacterial endotoxins. This is crucial to the production of the WFI. The evaporation stage of the distillation process leaves the non-volatile compounds and large particulates in the feed water. The presence of demisters and separation devices removes any of these materials that may be entrained in the vapour. There are several types of distillation units in use in the processing industries such as single effect, multiple effect and vapour compression units. For larger outputs it is necessary to use multiple units in which the steam generated in the first effect is used to heat the feed water in the second effect and so on. With both types of distillation unit the distillate is typically gravity fed to the storage tank, requiring that the outlet from the unit be higher than the inlet to the tank and if possible within close proximity. In this way the need for transfer pumps or extensive piping in the system can be avoided.

MED used multiple effect still design which easily recognized by its multiple column which the flow diagram as seen in Figure 1. Function of multiple column in this process to re-use heat energy through the additional effects. The first column is heated by an external source such as plant steam with remaining columns heated by the pure steam produced form the initial evaporation process. This pure steam is utilized as both a heating source for additional columns as well as a preheating source for incoming feed water at next column. In turn, the feed water helps condense the pure steam so that the remaining pure steam produced during the process requires minimal cooling water in the final condenser. Both methods are based on the physical law that any particles, endotoxins, pyrogens or other contaminants remain in the water during the phase transition from water to steam. Unfortunately, large amounts of energy must be transferred to the water in order to achieve this phase transition and this input of energy causes the water to move rapidly. This is, in fact necessary in order to transfer the heat from the secondary medium (normally hot steam) to the water to be evaporated. These droplets may contain undesirable contaminants and must be removed from the water vapour (Solid State Technology, Pure Steam and water for injection in the pharmaceutical industry).

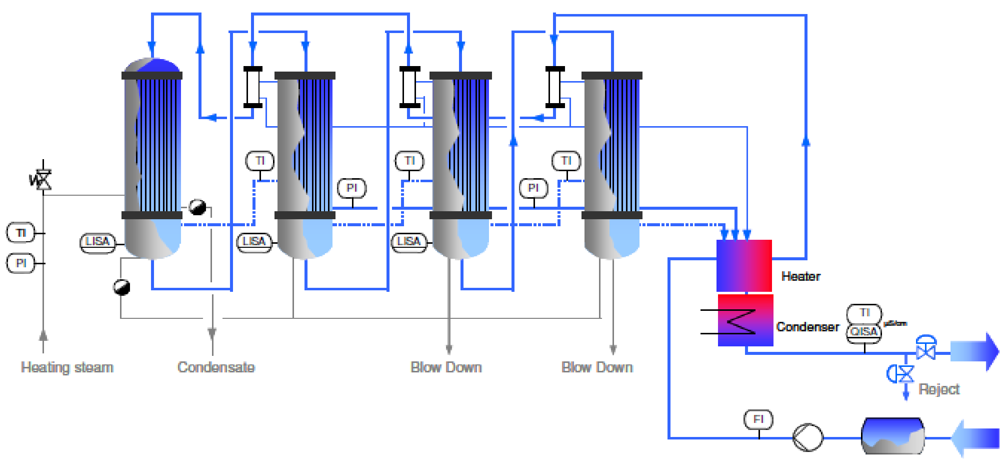


Figure 1: Process Flow Diagram using MED Method

2.4 Energy Usage

Normally, water system in pharmaceutical constantly recirculates water which consumes electricity for pumps, instruments and others devices. Often the water must be heated or cooled to maintain adequate water temperature specifications. These systems can quickly consume valuable raw water, consume electrical and steam utilities and produce a wastewater stream even if the water system is not being used in the production process. Although in the production of WFI the raw material is the water not contains any harm toxic or chemical that could impact the environment. This situation should not be over looked because WFI process consumed higher energy through equipment used such as pumps. When more energy use it means to generate energy is higher. There is gave more effect to the potential environmental impact from the process.

Energy is the fundamental to the human life and growing economy for new generation. Energy is essential in human life to give the better life but the world changing from the impact to generate the energy. An expanding population, economic growth, new technology development and changes in the nature and scope of regulations are all transforming the energy landscape. Malaysia pursue to expand the economy for the grow of citizen life, which mean Malaysia energy supply demand increase from 50 Mtoe in 2010 to 65 Mtoe in 2020(Sin, Indati, Mustapa, & Peng, 2011). Malaysia currently adopts a five type fuel such as gas, coal, hydro, oil and other sources for electricity generation. The variety of fuel power used to generate electricity impact on the environment. Fossil fuel power plants release air pollution, require large amount of cooling water and large tracts of lands during the mining process. The impact can divide to specifics category such to air, water and land impacts. The main reasons for the climate change particularly on the rise of earth temperature are industrialization and modernization, burning of oil, gasoline and coal. These activities have helped to increase the amount of greenhouse gases in the atmosphere particularly carbon dioxide, methane and nitrous oxide(Sin et al., 2011). In the industry, have a several types of chemical need to control the release because it will be the effect to the environment. Carbon Dioxide, CO_2need to avoid from discharge into soil, waterways, drains and sewers and must be control when released to the environment (Cruce, A. et al., 2012).

As conclusion to obtain the sustainable development in process design, industry activity should be transformed into a more integrated model and industrial ecosystem to optimize the consumption of energy and materials (Frosch, R,. et al., 1995).

2.5 Potential environment impact

Pharmaceutical industry less in paying attention towards the environmental impact from the manufacturing because is not consider a dirty industry compared to others which consistent with medical substances which are pharmaceutical a group of substances that until recently have been exposed to the environment with very little attention (Science, E., & Britain, G., 1998).

Waste WAR Algorithm methods used to evaluating the potential environmental impacts and the design or modification of WFI processes. There are few impacts to the environment need to manage which is air emissions and waste water discharge. As the engineer, the potential impacts to the environment when developing and manufacturing the pharmaceutical should be consider while patients will be access to the best available pharmaceutical treatment. Health care without harm provides resources to increase our understanding of the issues involving pharmaceuticals and suggests ways to reduce their environmental impact. Sustainable development in process is important while protecting the environment for the present and future generations. Better technology can help us study and better understand how our process is affecting the environment and prevent the impact from effect the environment. Potential environmental impact is the unrealized effect or impact that the emission of mass and energy would have on the environment on average. It is, essentially a probability function for the realization of a potential effect (Cabezas, Bare, & Mallick, 1999). The sustainable development with the particular indicator is important from initial stages of process design. There is the indicator presents a direct correlation among flows and reduces the requirement of complex models. In the potential environment impact (PEI), the WAR algorithm is adopted to assess the environmental performance of a process design. The reason is because of its ability to describe the environmental impact of the input-output material and energy stream in a simple approach. Moreover, it uses less extensive data which can be found in open literature and could greatly facilitate design comparison to modified or new processes (Othman, 2011).

The WAR algorithm uses eight environmental impact categories in its evaluation. The impact categories are generally divided into two categories which are to measure the effect to the environment (Heijungs et al,1992). Two categories were used to estimate the potential for human toxicity, ingestion and inhalation. There also to estimate toxicity potential because they considered all of the primary routes of exposure of a chemical. Based on the study by Othman M. R. those categories are:

Table 1: Environmental impact categories of method

Global Atmospheric	**Method**
Global warming potential (GWP)	By comparing the extent to which a unit mass of a chemical absorbs infrared radiation over its atmospheric lifetime and the extent that CO2 absorbs infrared radiation over its respective lifetimes.
Ozone depletion potential (ODP)	By comparing the rate at which a unit mass of chemical reacts with ozone to form molecular oxygen to the rate at which a unit mass of CFC-11 (trichlorouoromethane) reacts with ozone to form molecular oxygen.
Acidification potential (AP)	By comparing the rate of release of H+ in the atmosphere as promoted by a chemical to the rate of release of H+ in the atmosphere as promoted by SO2.
Photochemical oxidation (PCOP)	By comparing the rate at which a unit mass of chemical reacts with a hydroxyl radical (OH-) to the rate at which a unit mass of ethylene reacts with OH-.
Local Toxilogical	**Definition**
Human toxicity potential by ingestion (HTPI)	Calculated for a chemical if it existed as a liquid or solid at a temperature of 0^{o}C and atmospheric pressure and an exposure potential.
Human toxicity potential by inhalation/dermal exposure (HTPE)	Determined for that chemical if it existed as a gas at those conditions. However, some chemicals were assigned values for both categories if it was warranted.

Aquatic toxicity potential (ATP)	The toxilogical level the lethal dose (LD50) was used as estimate for the ATP.
Terrestrial toxicity potential (TTP)	The toxilogical level lethal concentration (LC50) was used as estimate for the TTP.

3 PROCESS SIMULATION AND MODELLING

3.1 Overview

In this chapter, it will discuss about the methodology flow on energy usage for WFI process and waste reduction (WAR) algorithm. To achieve the above stated objective, the methodology employed in this research. First step is modelling MED process in SPD to simulate the process for gain the amount of energy usage. From that, the PEI value was calculated used WAR Algorithm.

3.2 Environmental assessment using WAR algorithm

The concept of the potential environment impact (PEI) in the WAR algorithm is based on the conventional mass and energy balance on Figure 2. The waste reduction algorithm (WAR) was developed by EPA scientists so that the environmental impacts of designs could easily be evaluated. The goal of WAR is to reduce environmental and related human health impacts at the design stage. WAR algorithm has been developed to describe the flow and the generation of potential environmental impact through a chemical process (Young, Scharp, & Cabezas, 2000). Potential environmental impact theory is the quantity of material and energy balance would have effect if they were to be emitted into the environment.

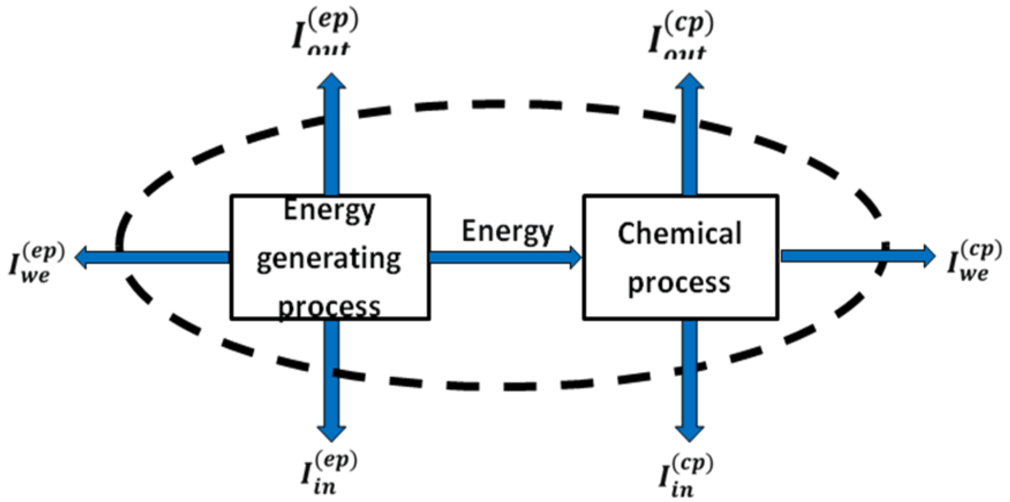


Figure 2: Mass and energy balance for the calculation of the PEI

3.3 *Energy usage to generate steam*

A process flow diagram to generate steam and Figure 3 shows the calculation to produce 1 kg of heating steam by using Excel spreadsheet whereas Table 2 shows the heat transfer agent (steam) demand for MED process.

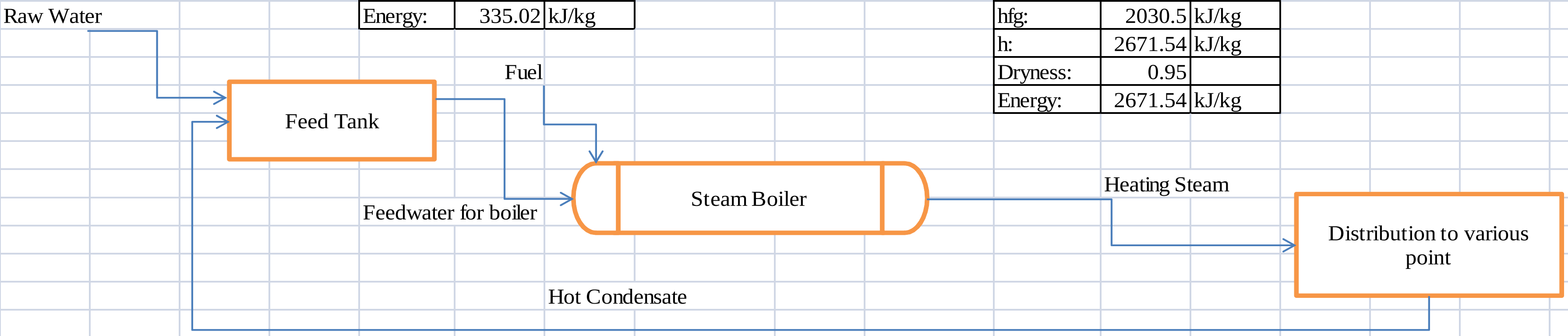
Calculation to produce 1 kg of heating steam

Feedwater

Pressure:	1	bar
Temp.:	80	C
hf:	335.02	kJ/kg
Massflow:	1	kg
Energy:	335.02	kJ/kg

Heating Steam

Temp.:	175	C
Pressure:	9	bar
Massflow:	1	kg
hf:	742.56	kJ/kg
hfg:	2030.5	kJ/kg
h:	2671.54	kJ/kg
Dryness:	0.95	
Energy:	2671.54	kJ/kg



Boiler

Fuel:	Natural gas	
LHV fuel:	49967.7	kJ/kg
Efficiency:	0.82	
Boiler energy:	2336.52	kJ/kg(steam)
Fuel energy:	2849.41	kJ/kg(steam)
Fuel required:	0.05703	kg fuel

Figure 3: Process flow and calculation to generate 1kg steam

Table 2: Heat transfer agent demand

1.1b Heat transfer Agent Demand			
Steam	kg/yr	kg/h	kg/kgMP
Steam	675661.70	85.31	N/A
TOTAL	675661.70	85.31	N/A

Source: Adapted from SPD result under Utilities & Labor report at Appendices, A2.

The calculation for lower heating value (LHV) can be reviewed at Appendices, A3.

3.4 Development of PEI

Potential environmental impact is the unrealized effect or impact that the emission of mass and energy would have on the environment on average. It is, essentially a probability function for the realization of a potential effect (Cabezas, Bare, & Mallick, 1999).

There are four main environmental indicators will calculate and evaluate from WAR algorithm;I^{t}_{gen},I^{t}_{out},$\hat{I}^{t}_{gen}$ and $\hat{I}^{t}_{out}$. Here some equations use to calculate these indicators. The total rate of PEI generated,I^{t}_{gen} and total PEI output,I^{t}_{out} can be expressed as:

$$I^{t}_{gen} = I^{cp}_{out} - I^{cp}_{in} + I^{ep}_{out} \qquad \text{eq. (1)}$$

$$I^{t}_{out} = I^{cp}_{out} + I^{ep}_{out} \qquad \text{eq. (2)}$$

The indices presented to this end are in terms of rate PEI/h. To evaluate on a product basis (PEI/kg), a simple transformation can be made to the index by,

$$\hat{I}^{t}_{gen} = \frac{I^{cp}_{out} - I^{cp}_{in} + I^{ep}_{out}}{\sum M_p} \qquad \text{eq. (3)}$$

$$\hat{I}^{t}_{out} = \frac{I^{cp}_{out} + I^{cp}_{out}}{\sum M_p} \qquad \text{eq. (4)}$$

The symbol M_p is the mass flow rate of product *p*. The value of total rate of PEI output,I^{t}_{out},enables us to identify an appropriate site for a plant and $\hat{I}^{t}_{out}$measures the efficiency of material utilization by a specific process per unit mass of products; it decreases when the mass rate of PEI. On the other hand, $\hat{I}^{t}_{gen}$ is used for comparing processes and products based on the amount of new potential environmental impact generated in product manufacturing. Then, I^{t}_{gen} is an indicator useful in comparing processes based on how fast they generate impact.

Table 3 till Table 5 shows the PEI calculation and it is developed in excel spreadsheet whereas Table 6 shows the emission factor and specific PEI of component from energy consumption.

Table 3: Impact factor (energy) with hazardous gases value for each PEI indicator

Gases / Component	SOx	NOx	CO_2	CO
HTPI	1.2	0.78	0	0
HTPE	0	5.6	9000	29
ATP	0	19.6	0	0
TTP	1.2	0.78	0	0
GWP	0	0	1	0
PCOP	0	0	0	0
AP	1	1.77	0	0
ODP	0	0	0	0

Table 4: Specific PEI value calculation

Gases / Component	SOx	NOx	CO_2	CO
HTPI	0.8333333	1.2820513	0	0
HTPE	0	5.6	9000	29
ATP	0	0.0510204	0	0
TTP	0.8333333	1.2820513	0	0
GWP	0	0	1	0
PCOP	0	0	0	0
AP	1	1.77	0	0
ODP	0	0	0	0

Table 5: Normalized PEI value from energy consumption

Gases / Component	SOx	NOx	CO_2	CO
HTPI	0.787878	1.2121212	0	0
HTPE	0	0.0018595	2.988511	0.009629
ATP	0	0.0510204	0	0
TTP	0.787878	1.2121212	0	0
GWP	0	0	1	0
PCOP	0	0	0	0
AP	0.722022	1.277978	0	0
ODP	0	0	0	0

Table 6: Emission factor and specific PEI of component from energy consumption

Component	Emission Factor (kg/kWh)	Specific PEI of component
SO_X	0.0005	0.11
NO_X	0.0009	0.40
CO_2	0.5300	122.00
CO	0.0005	0.00

3.5 Super Pro designer

Super Pro Designer facilitates modelling to evaluation and optimization of integrated processes in a wide range of industries such as Pharmaceutical, Water Purification, Wastewater Treatment, Air Pollution Control and etc. The more detail results can access from SPD as seen in Appendices, A1.

Process Simulation software is used to perform the following tasks (Intelligen, Inc): Represent the entire process on the computer such as perform material and energy balances of process, calculate demand for utilities as a function of time, estimate the cycle of the process and assess the environmental impact.

The basic steps to using Super Pro (Shawna et al., 2011):

1. Specify Mode of Operation
2. Set Default Physical Units
3. Register Components and Mixtures
4. Add Unit Procedures
5. Add Input and Output Streams

6. Specify Operations
7. Schedule Process
8. Specify Labor Requirements
9. Perform Cost Analysis
10. Perform Environmental Impact Assessment

The flow diagram in Figure 4 is shows modelling of MED process in SPD.

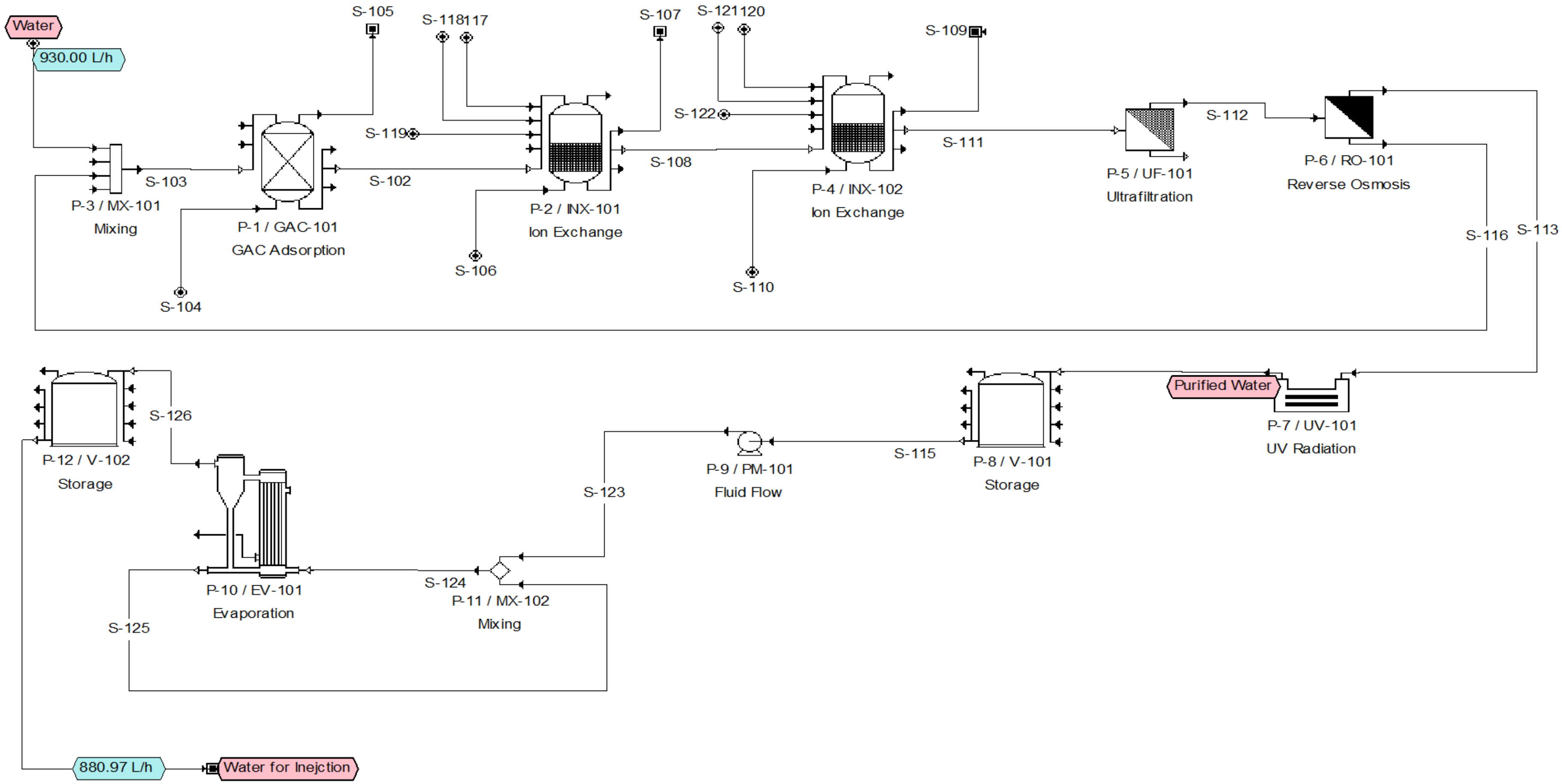


Figure 4: Process Flow Diagram of MED from SPD simulation

4 RESULTS AND DISCUSSION

4.1 Overview

In this chapter, focus will be more show the result based on PEI balance were drawn the manufacturing process to incorporate environmental effects into process design. The calculation PEI used WAR algorithm methodology on the conventional mass and energy balances (see eq. 1). PEI for energy is calculated by summing up all the energy requirements used for the system by compressor, reboilers, heat exchanger, pump and etc. In this research, electrical energy and steam was used as energy source in the MED process. Consider the energy lost from steam that is used for generating electrical energy before being used for heating purposes in the plant. Energy demand for major equipment during MED process was shows in Table 7 and Figure 5.

Table 7: Energy demand for major equipment during operation

Unit procedure	**Equipment name**	**No. of unit**	**Energy [kWh/h]**
P-5	Ultrafiltration	1	2.6
P-6	Reverse Osmosis	1	1.24
P-7	UV Radiation	1	0.33
P-9	Pump No.1	1	0.63
	Unlisted equipment	-	0.3
	General load	-	0.9
	Steam Boiler	-	89.29
		TOTAL	95.29

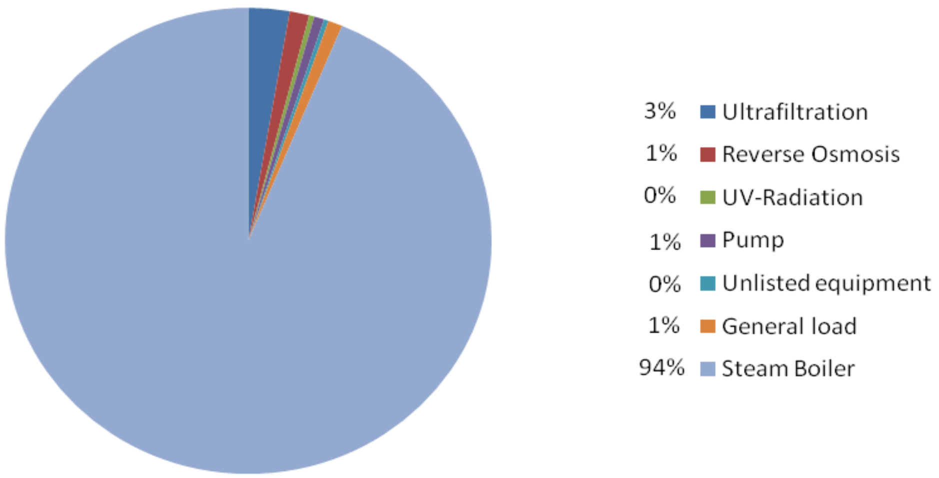


Figure 5: Percentage of energy demand during operation

4.2 Impact Factor (Energy Usage)

The amount heat energy added to the atmosphere by the greenhouse effect is controlled by the concentration of greenhouse gases in the Earth's atmosphere. The amount of gas emitted must be considered, which contains SO_2, NO_x, CO_2, CH_4 and Hg. Based on the Figure 6 at below, the amount of PEI shown the 122 CO_2 contribute the highest of gas emitted during production of WFI. Next components followed by the 0.40 NO_X, 0.11 SO_X and CO for gas emitted release in process. The burning of coal, natural gas and oil for electricity and heat is the largest single source of global greenhouse gas emissions was be proven based on the obtained result. Greenhouse gas emissions from industry primarily involve fossil fuels and natural gas burned on site at facilities for energy. As CO_2 levels have higher, so have its responsible on air pollution to the environment. The results which are consistent with the research about the change challenges of $CO_{2,}$ the power generation sector was higher emitters of CO_2 (47%) in the power generation sector (Leong, Y. et al., 2011).

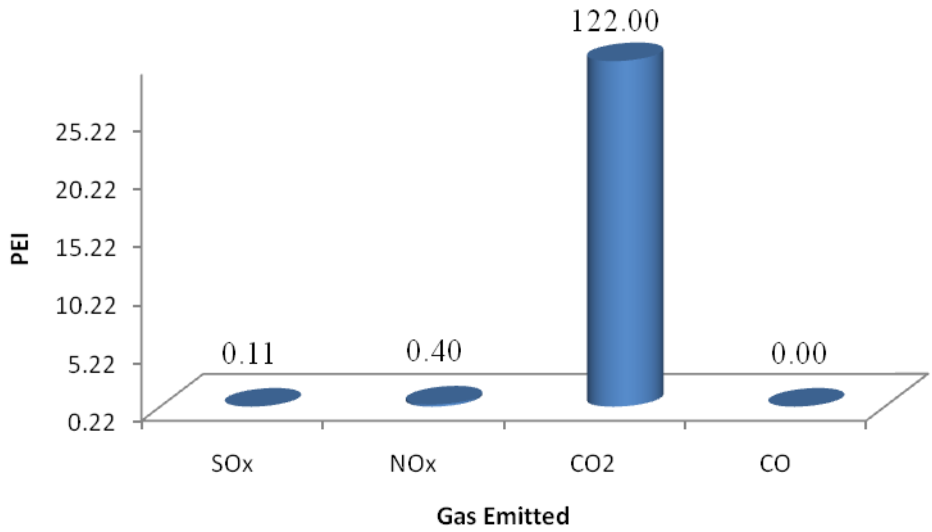


Figure 6: Specific PEI of Gas Emitted by kWh

4.3 Specific PEI Value

Based on the results shown in Figure 7 at below suggest that global warming potential (GWP) which contribute the higher impact to the environment for the WFI production in pharmaceutical industry followed by human toxicity potential by inhalation (HTPE). According with Cabezas et.al (1999), HTPE know as determined for chemical if it existed as a gas at those conditions. GWP is the extent to which a unit mass of a chemical absorbs infrared radiation over its atmospheric lifetime and the extent that CO2 absorbs infrared radiation over its respective lifetimes.

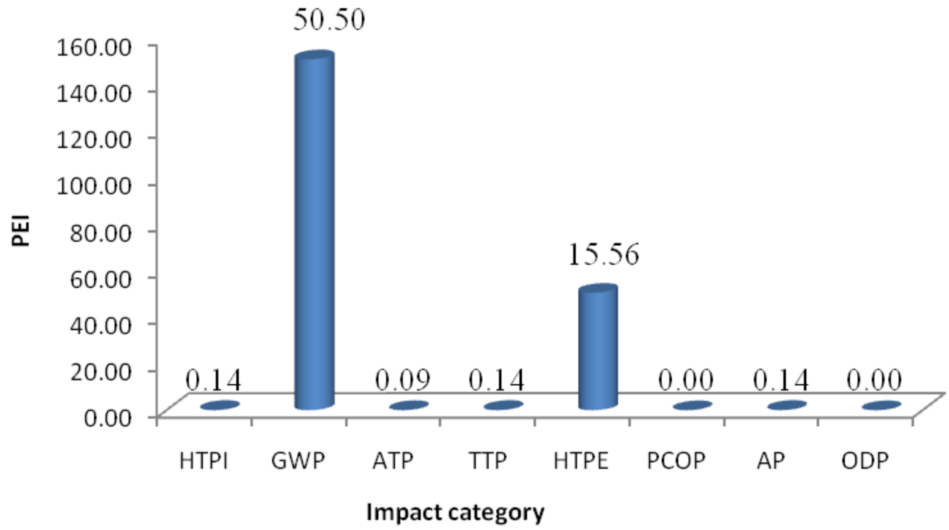


Figure 7: Specific PEI by Impact Category

4.4 Comparison of Method between MED and VCD

Based on the result in Figure 8 shown the energy usage based on equipment between MED and VCD method. In the MED process, the steam boiler was used the higher energy which the value of 95.29 kWh followed by ultra filtration, reverse osmosis, general load, pump, UV radiation and unlisted equipment in order. While in the VCD process, the steam boiler is 50.66 kWh which refer from others research. It shows that the MED process was used high steam compared with VCD process which consistent with George V.Gsell which the process VCD has a relatively high economy as compared to the ME process. Steam boiler required higher energy to change different temperature for generates steam. While steam is a principle energy source for industrial process because it's many advantages which transportability, high efficiency, high heat capacity and low production costs.

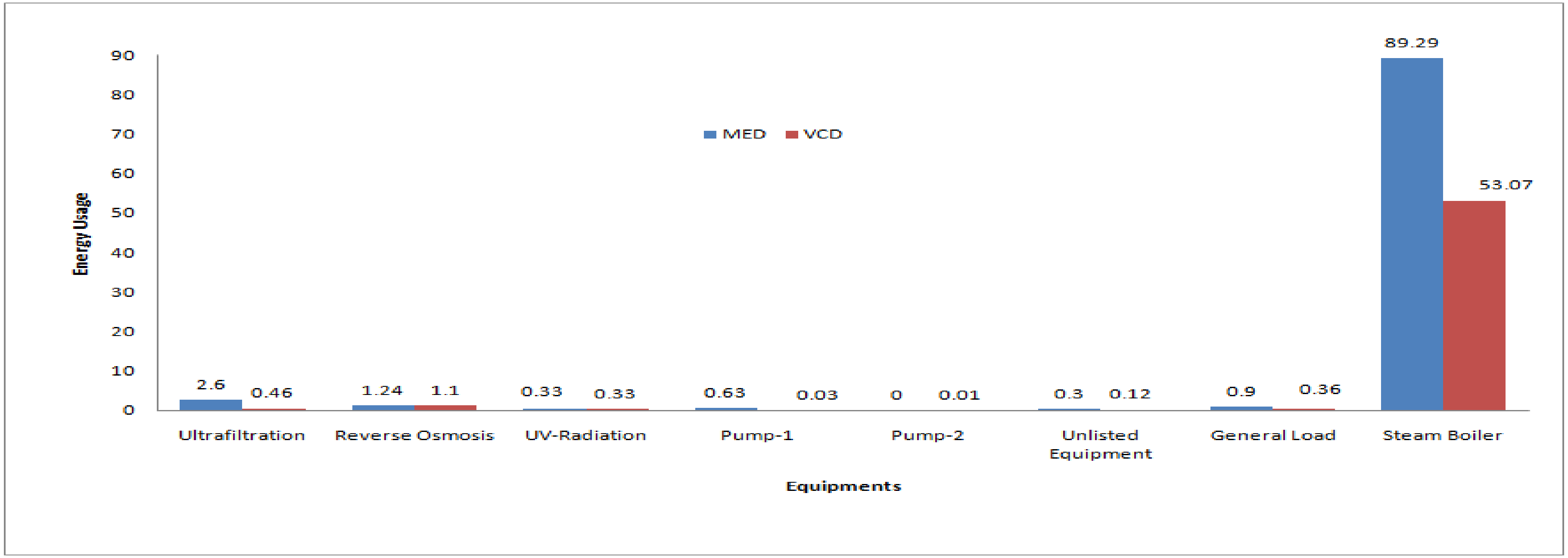


Figure 8: Comparison energy usage among equipments between MED and VCD method

Table 8: PEI for the energy consumption of 95.29 kWh

Energy consumption

Comp.	Emiss. factor (kg/kWh)	Normalized PEI								Specific PEI of comp
		HTPI	HTPE	ATP	TTP	GWP	PCOP	AP	ODP	
SOx	0.0005	0.020906364	0	0	0.020906364	0	0	0.019158845	0	0.11
NOx	0.0009	0.057894545	8.88162E-05	0.047763	0.057894545	0	0	0.061040079	0	0.40
CO2	0.53	0	84.05814314	0	0	28.1271	0	0	0	122.00
CO	0.0005	0	0.000255523	0	0	0	0	0	0	0.00
Total		**0.08**	**84.06**	**0.05**	**0.08**	**28.13**	**0.00**	**0.08**	**0.00**	

4.5 Energy usage in boiler

Boiler was used to generate the steam to supply in the MED process. Amount of heat transfer rate, Q can be calculated by multiply the steam consumption, m_s with specific enthalpy of heating steam, h_{fg}. Table 9 shows the amount of m_s in kg/h and h_{fg} in kJ/kg. More information in boiler system can be reviewed at the appendices.

Table 9: Amount of steam consumption and specific enthalpy

Heat transfer agent	**Consumption [kg/h]**	**specific enthalpy[kJ/kg]**
Steam	158.31	2030.5

Equation :

$$Q = m_s \times h_{fg}$$

$$= \frac{158.31\ \cancel{kg}}{\cancel{hr}} \left| \frac{2030.5\ kJ}{\cancel{kg}} \right| \frac{1\ hr}{3600\ s}$$

$$= 89.29\ kJ/s = 89.29kW$$

In the process of generate steam in boiler system; the process required 0.057 kg fuel to produce 85.31 kg/hr of heat steam and 89.29 kW heat transfer rate in the system.

5 CONCLUSION AND RECOMMENDATION

5.1 Conclusion

The total energy demand is 95.29 kWh was calculated to produce 880 L/hr WFI in pharmaceutical industry. The energy produced from several equipment such as listed above. Result from the PEI value calculation suggested that the higher amount of component emission is 122 CO_2 contain. However, there is no any standard to verify the data. It can be compared with the results from other methods to produce WFI in pharmaceutical industry. The comparison suggested MED method used more energy compared with VCD because during process the heat was reuse to generate the new heat. While result related with the environment impact category suggest that human toxicity potential by inhalation (HTPE) contribute the higher impact to the environment for the WFI production in pharmaceutical industry followed by global warming potential (GWP). According with Cabezas et.al (1999), HTPE know as determined for chemical if it existed as a gas at those conditions. GWP is the extent to which a unit mass of a chemical absorbs infrared radiation over its atmospheric lifetime and the extent that CO2 absorbs infrared radiation over its respective lifetimes. Furthermore, from the PEI calculated can be obtained the amount of emission release to the environment. As CO_2 levels have higher, so have its responsible on air pollution to the environment.

5.2 Recommendation

In this study, MED methods were used to produce WFI. The energy values from the process were calculated to obtain the PEI. Result from the PEI value calculation suggested that the higher amount of component emission contain is 122 CO_2 for specific PEI of components. Furthermore, comparison with other method to determine energy usage would obtained the environmental impact was been suggested. There is because no any standard to verify the data to calculate the environmental impact. Besides that, to obtain the accurate calculation of greenhouse gas emission per kilowatt hour of electricity is difficult. It is can be compare with the result from other research such as greenhouse gas analysis. It calculated with different grid scale electricity generation system. One of the method can be use is inventory of the materials used the structural elements of the plant. Then the amounts are multiplied by greenhouse gas content. Other methods can used is carbon footprint which to measure of the environment impact from daily activities using electricity. There is most often expressed in pounds or metric tons of carbon dioxide.

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APPENDICES

A1: Energy Usage (Pump) Report from Super Pro Designer

for Mahirah New

1. EQUIPMENT SUMMARY (2010 prices)

Name	Type	Units	Standby/ Staggered	Size (Capacity)		Material of Construction	Purchase Cost ($/Unit)
GAC-101	GAC Column	4	0/0	26,252.19	L	CS	286,000
INX-101	INX Column	2	0/0	27,528.23	L	CS	291,000
UF-101	Ultrafilter	17	0/0	293.35	m2	SS316	41,000
INX-102	INX Column	1	0/0	0.00	L	CS	26,000
RO-101	Reverse Osmosis Filter	20	0/0	296.10	m2	SS316	44,000
MX-101	Mixer	1	0/0	524,934.38	kg/h	CS	0
UV-101	UV Radiator	42	0/0	11,279.84	L/h	SS316	0
PM-101	Centrifugal Pump	2	0/0	151.17	kW	SS316	133,000
MX-102	Mixer	1	0/0	526,246.48	kg/h	CS	0
EV-101	Evaporator	1	0/0	0.00	m2	SS316	95,000
EV-102	Evaporator	1	0/0	0.00	m2	SS316	95,000
EV-103	Evaporator	1	0/0	0.00	m2	SS316	95,000
EV-104	Evaporator	1	0/0	0.00	m2	SS316	95,000
HX-101	Heat Exchanger	1	0/0	0.00	m2	CS	27,000
HX-102	Heat Exchanger	1	0/0	0.00	m2	CS	27,000
HX-103	Heat Exchanger	1	0/0	0.00	m2	CS	27,000
HX-104	Heat Exchanger	1	0/0	0.00	m2	CS	27,000
MX-103	Mixer	1	0/0	0.00	kg/h	CS	0
MX-104	Mixer	1	0/0	0.00	kg/h	CS	0
HX-105	Heat Exchanger	1	0/0	0.00	m2	CS	27,000
FSP-101	Flow Splitter	1	0/0	526,246.48	kg/h	CS	0
HX-106	Heat Exchanger	44	0/0	99.34	m2	CS	106,000

A2: Super Pro Data

Material Consumption			
Material	**kg/yr**	**kg/h**	**kg/kg MP**
FeedWater	7365600.00	930.00	N/A
NaOH (50% w/w)	1596.48	0.20	N/A
Water	238917.61	30.17	N/A
TOTAL	**7606114.09**	**960.37**	**N/A**

Overall Balance (kg/h)			
COMPONENT	**IN**	**OUT**	**OUT-IN**
Anion-Hardness	0.09	0.13	0.04
Anion-Other	0.01	0.01	0.00
Cation-Hardness	0.09	0.09	0.00
Cation-Other	0.01	0.01	0.00
Sodium Hydroxid	0.10	0.14	0.04
TOC	0.00	0.00	- 0.00
Water	960.06	911.16	- 48.89
TOTAL	**960.37**	**911.56**	**- 48.81**

Total Heat Transfer Agent Demand			
Heat Transfer Agent	**kg/yr**	**kg/h**	**kg/kg MP**
Steam	675661.70	85.31	N/A
Steam (High P)	0.00	0.00	N/A
Cooling Water	0.00	0.00	N/A
Chilled Water	0.00	0.00	N/A

Total Power Demand			
Power Type	**kW-h/yr**	**kW-h/h**	**kW-h/kg MP**
Std Power	47415.21	5.99	N/A
TOTAL	**47415.21**	**5.99**	**N/A**

Power Demand (Procedure Breakdown)			
Std Power	**kW-h/yr**	**kW-h/h**	**kW-h/kg MP**
	Main Section		
P-5	20600.43	2.60	N/A
P-6	9786.12	1.24	N/A
P-7	2574.00	0.33	N/A
P-9	4971.61	0.63	N/A
Unlisted Equipment	2370.76	0.30	N/A
General Load	7112.28	0.90	N/A
Section Total	**47415.21**	**5.99**	**N/A**
TOTAL	**47415.21**	**5.99**	**N/A**

Labor Demand (Procedure Breakdown)

Operator	labor-hrs/yr	labor-hrs/h	labor-hrs/kg MP
	Main Section		
P-1	1320.00	0.17	N/A
P-2	1320.00	0.17	N/A
P-4	1320.00	0.17	N/A
P-5	13200.00	1.67	N/A
P-6	13200.00	1.67	N/A
P-7	5657.14	0.71	N/A
P-8	11314.29	1.43	N/A
P-9	565.71	0.07	N/A
P-10	11314.29	1.43	N/A
P-12	11314.29	1.43	N/A
Section Total	**70525.71**	**8.90**	**N/A**
TOTAL	**70525.71**	**8.90**	**N/A**

A3: Information Data for Boiler System

1. Heating Steam: Dryness Fraction of Steam

If the water content of the steam is *5%* by mass, then the steam is said to be *95%* dry and has a dryness fraction of*0.95*. * Adapted from

2. Boiler: LHV Fuel & Efficiency

Energy Content and Combustion Efficiency of Fuels

Fuel Type	Combustion Efficiency (%)
Natural Gas (Therm)	81.7
Natural Gas (Cubic Foot)	81.7

Note: Combustion efficiency is based on boilers equipped with economizers and air pre-heaters and 3% oxygen in flue gas

The heat of reaction, hr, is the useful heat transferred from the combustion chamber during the combustion reaction. The heat of reaction depends on the phase of the water in the exhaust gasses. If water leaves as a vapor, it carries away the heat required to vaporize the water and less useful heat is available for the process. In this case, the heat of reaction equals the lower heating value (LHV) of the fuel. If water leaves as a liquid, more useful heat is available to the process and the heat of reaction equals the higher heating value (HHV) of the fuel. The heating values of natural gas are shown below:

Constant Data (for Natural Gas)

Lower Heating Value, LHV = 21,500 Btu/lb (Resham Gahla, 2013)

$$= \frac{21500\ \text{Btu}}{\text{lb}} \times \frac{\text{J}}{9.486 \times 10^{-4}\ \text{Btu}} \times \frac{2.20462\ \text{lb}}{1\text{kg}} \times \frac{\text{kJ}}{1000\ \text{J}}$$

$$= 49967.67\ \text{kJ/kg}$$

Lowest Heating Value (LHV) is the heating value that is obtained from combustion of 1 kg fuel without calculate the heat of steam condensation (water that produced from combustion in the form of gas / steam).