MASTERS THESIS

Design of a Heating, Ventilating and Air-conditioning system that utilizes multiple condensing units in the refrigeration circuit

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NOVEMBER 2019

DESIGN OF A HEATING, VENTILATING AND AIR-CONDITIONING SYSTEM THAT UTILIZES MULTIPLE CONDENSING UNITS IN THE REFRIGERATION CIRCUIT

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ABSTRACT

The heating, ventilating and air conditioning system performs a critical role in pharmaceutical products manufacturing by majorly providing thermal comfort and acceptable indoor air quality, conditions required for the production, efficacy and stability of the products. What motivated this study was downtime the HVAC system is likely to be subjected to. An HVAC system, just like any functional system is bound to be subjected to downtime, which is majorly because of the refrigeration loop. This downtime problem was approached by using the action research methodology, where after problem identification, steps were taken to design and model an HVAC system that not only eliminates the chilled water loop but also incorporates multiple condensing units of the same capacity in the refrigeration loop. This was done with the idea of providing backup for the major components of the refrigeration loop i.e the condensing units to minimize downtime. However, this is no mean feat owing to the fact that assembling refrigerant compressors in series is not an option since these compress a vapor into a liquid and, should a liquid be introduced into the compressor, one runs the obvious risk of damaging the compressor, which is expensive, and time consuming to replace. Despite a new design of the HVAC refrigeration loop being developed, care was taken to ensure that the modified system does not lose its characteristics that enable it to perform the other functions of an HVAC system. The physical model designed, constructed and installed answered the research question that multiple condensing units can be incorporated on a single refrigeration circuit. Validation of the installed system proved that the system is capable of attaining the thermal comfort requirements required for pharmaceutical products manufacturing. Lastly, a comparison with a conventionally designed HVAC system was made and in a four month time period, the conventional HVAC system had experienced down time totaling to 24 hours as a result of failure of components in the chilled water loop. This is dangerous to the products as it poses a risk of compromising production, efficacy and stability of the manufactured products. The new design gives HVAC design engineers an edge while designing HVAC systems for minimal downtime.

DECLARATION

I Brian Walugembe, declare that I solely composed this write-up and that it has not been submitted, in whole or in part, in any previous application for a degree. Except where stated otherwise by reference or acknowledgment, the work presented is entirely my own.

12-11-19

BRIAN WALUGEMBE

APPROVAL

DESIGN OF A HEATING, VENTILATING AND AIR-CONDITIONING SYSTEM THAT UTILIZES MULTIPLE CONDENSING UNITS IN THE REFRIGERATION CIRCUIT

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DEDICATION

For Beatrice Asaba - I cherished, you perished. The world has been empty without you.

ACKNOWLEDGEMENTS

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I would also like to extend my thanks to Mr. Robert Patrick Sombe and Mr. Gabriel Lukoda electrical engineers with whom we developed the control circuit of the system and to the management of CiplaQCIL for availing me with the necessary support to implement the project.

Finally, I wish to thank my parents Mr. Musanje James, Mr. Charles Wamara, Ms. Manyindo Annette and fiancé Ms. Patience Akankunda for their support and encouragement throughout my study.

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A/C	-	Air conditioning
ACPH	-	Air Changes per Hour
AHU	-	Air Handling Unit
BTU	-	British Thermal Units
C	-	Core
CFM	-	Cubic feet per minute
CFR	-	Code of Federal Regulations
CiplaQCIL	-	Cipla Quality chemical Industries Limited
Cu	-	Copper
DX	-	Direct expansion
EA	-	Exhaust air
ERB	-	Engineer's Registration Board
FAD	-	Free Air delivery
FCU	-	Fan Coil Unit
FPM	-	Feet per minute
G.I	-	Galvanized Iron
HEPA	-	High Efficiency Particulate Air
HVAC	-	Heating, Ventilation and Air Conditioning
MM	-	Millimeter
OA	-	Outdoor air
P&ID	-	Process and Instrumentation Diagram
PID controller	-	Proportional-Integral-Derivative controller
RA	-	Return air
RAD	-	Return Air Duct
RH	-	Relative humidity
RPM	-	Revolutions per minute
RTD	-	Resistance Temperature Detector
SA	-	Supply air
SAD	-	Supply Air Duct
SDGs	-	Sustainable Development Goals
Temp	-	Temperature
TR	-	Tons of Refrigeration
UIPE	-	Uganda Institution of Professional Engineers
UPS	-	Uninterrupted Power Supply
VAV	-	Variable air volume
WC	-	Water column

CHAPTER ONE: INTRODUCTION

This chapter introduces the concept of Heating Ventilation and Air conditioning and a justification for researching about the topic. It discusses the importance of the HVAC system to pharmaceutical products manufacturing and employs the create-a-research-space (CARS) model to demonstrate that the topic is interesting, problematic and worth researching about. The chapter highlights the objectives the study set out to attain and highlights the research questions it aims to answer.

1.1 Background of the Study

Heating, ventilation, and air conditioning (HVAC) is the technology of indoor and vehicular environmental comfort (Mull, 1998). The three major functions of HVAC systems: heating, ventilation, and air conditioning are interrelated, especially with the need to provide thermal comfort and acceptable indoor air quality within reasonable installation, operation, and maintenance costs (Dounis & Christos, 2009). HVAC systems have seen their application increasingly grow in the pharmaceutical industry where safe and healthy building conditions are a requirement with respect to temperature and humidity using fresh air from outdoors (Swenson & Don, 1995).

In the Pharmaceutical industry, HVAC system performs four basic functions: Control airborne particles, dust and micro-organisms; Maintain room pressure, Maintain space moisture (Relative Humidity), and Maintain space temperature (Bhatia, 2012). These clearly highlight the fact that control of the thermal environment is a key objective for virtually all occupied buildings especially in pharmaceutical products manufacturing.

The most common HVAC systems, commonly referred to as chilled water systems, employ chilled water flowing through the tubes of the cooling coil (Swenson & Don, 1995). Other systems have cold, liquid refrigerant flowing directly through the tubes of the cooling coil, and are referred to as direct-expansion, or DX, systems (TRANE, 2012). HVAC system design is a sub discipline of mechanical engineering, based on the principles of thermodynamics, fluid mechanics, and heat transfer (Jaluria, 2007). In designs where the chilled water system is used, a centralized chiller connected in parallel to a multitude of air-handling units is employed with chilled water pumped through piping to chilled water coils (Lillie, 2012).

The downside to this system is that once the centralized chiller requires maintenance, the whole system is down, as the system cannot attain the comfort requirements of temperature and humidity thence necessitating the acquisition of more than one centralized chiller of equal capacity, which is not only expensive, but also necessitates keeping one of the systems always idle. This downtime problem is also realized in DX systems that employ a single condensing unit where in the event of failure of the condensing unit, the system is worthless.

CiplaQCIL has over 50 air handling units spanning over two facilities. All these employ the chilled water loop and employ two centralized chillers of 200 TR each. Any malfunction of the chilled water system brings about a failure for all the 50 air-handling units. This leads to manufacturing downtime even when the firm employs a batch manufacturing strategy. Manufacturing downtime is also experienced in times of maintenance of equipment in the chilled water loop such as pumps, piping, valves, the chillers, etc.

The HVAC system, can be improved upon by designing a system that combines multiple condensing units in the refrigeration loop to a single DX coil. Thence eliminating the chilled water loop and its added capital and operating costs associated with this type of system but also at the same time, minimizing the adverse effects of having downtime on an HVAC system experienced in the pharmaceutical industry.

This, it is hoped, would be valuable to the industry practitioners as well as HVAC system design engineers in developing better HVAC system designs with an aim of minimizing downtime. The result is that engineers will be better positioned to keep indoor environments safe and productive while protecting and preserving the outdoors for generations to come.

1.2 Statement of the Problem

An HVAC system in pharmaceutical industry, is installed to provide thermal comfort and acceptable air quality; conditions required for the production, efficacy and stability of the products. However, designs that employ the chilled water loop require a centralized chiller connected in parallel to a multitude of air-handling units. This system is not only bulky, but is expensive, requires more energy to run the circulation pumps and should the centralized chiller require maintenance, the whole system will have to be down as the system cannot achieve the comfort requirements of temperature and humidity. This usually leads to sacrificing one activity of either manufacturing or maintenance for the other. In response to this problem, this study proposed to design a system that not only eliminates the chilled water loop but also incorporates multiple condensing units of the same capacity in the refrigeration circuit. These will act as a backup of the condensing units enabling for maintenance and maintaining indoor environmental conditions for longer.

1.3 Research Objectives

1.3.1 Main objective

The long-term goal of the research was to design, develop and test an HVAC system that combines multiple condensing units on a solitary refrigeration circuit.

1.3.2 Specific objectives

The study had the following specific objectives:

1) To test applicability of multiple condensing units on a refrigeration circuit having a single evaporator coil.
2) To establish the performance characteristics of multiple condensing units in a solitary refrigeration circuit.
3) To optimize the functionality of an HVAC system having multiple condensing units.

1.4 Research Questions

The research questions guiding this research include;-

1. How applicable are multiple condensing units on a refrigerant circuit having a single evaporator coil?
2. What are the performance characteristics of multiple condensing units if installed on a solitary refrigeration circuit?
3. How can the functionality of an HVAC system having multiple condensing units be optimized?

1.5 Justification of the Study

According to Vision 2040, Uganda aspires to see her citizens enjoying a high quality standard of living with focus on improving; the quality of its population, health and nutrition status, literacy and numeracy, housing, water and sanitation conditions and provision of social protection for the citizenry. (National Planning Authority, 2007). The vision objectives in alignment with goal three of the Sustainable Development Goals (SDGs) of Uganda, which aims to achieve universal health coverage including access to essential medicines and vaccines, will be possible if Uganda is in a position to manufacture its own medicines (United Nations Statistics division, 2016). This calls for Uganda to setup more pharmaceutical plants to attain the set goals.

However, with the stringent guidelines imposed on pharmaceutical products manufacturing combined with the ever-increasing demand for production in a pharmaceutical manufacturing facility like at CiplaQCIL where the HVAC system plays a crucial role in maintaining the right environmental conditions required for the manufacture of the products; maintaining thermal comfort and pressure cascades in the spaces. Downtime attributed to the HVAC system should be minimized as much as possible. This can be achieved by designing a robust system not susceptible to frequent failures because of any of the system components.

1.6 Theoretical Framework

Functionality and efficiency of the HVAC system is wholly dependent on the correct design / sizing of all components in the different loops of the system. Any loop failure will bring about a failure of the system (Jaluria, 2007). (Breuker & James, 1998) In their research, common faults and their impacts for rooftop air conditioners noted that HVAC systems that employ DX coils face 90% of their failures as attributed to failure of components in the refrigeration loop. In engineering, backup is widely used as a method to minimize effects of failure (Bala, Anju, & Inderveer , 2012) and by employing multiple condensing units; this can be seen as a backup of components in the refrigeration loop. Therefore, designing an HVAC system that employs multiple condensing units coupled to a single evaporator coil will give birth to a system that does not fail frequently but is also compact and efficient. However, running multiple condensing units in a single refrigeration circuit will birth a system that is working against itself as the compressors will be working against one another and consequently overloading the other compressor. When the recommended quantity of refrigerant is exceeded in a compressor, the compressor will be damaged because of pumping liquid refrigerant as opposed to vapor since it won't be capable of converting the excess refrigerant into a vapor (Stubblefield & John, 1989). However, by combining multiple condensing units on a single circuit leads to a possibility of such a scenario happening. Overloading of the compressor can also be as a result of having excess refrigerant gas in the circuit which can arise as a result of one compressor leaving excess refrigerant gas in the circuit at the time of change over (Harrison, 1996). In this study, it's intended to use the principle of refrigerant circuit pipeline blow down. Should the need to have multiple condensing units on a circuit arise, the operation should perform a blow down of the pipeline before changing over to the next condensing unit. This will eliminate chances of overloading a single compressor and eventually damaging it. Once this has been achieved, it can be stated that a successful back up of components in the refrigeration system has been achieved and thence reducing on chances of failure of the refrigeration loop. It should be noted that refrigeration compressors cannot be placed in series as they change the state of the refrigerant gas to liquid and yet they can only pump vapor for successful operation (Ndagijje, 2018).

1.7 Contribution of the Study

The result of this study will be valuable to the industry practitioners as well as HVAC system design engineers in developing better HVAC system designs with an aim to minimize downtime. The result is that engineers will be better positioned to keep indoor environments safe and productive while protecting and preserving the outdoors for generations to come. This study will also be useful to professional practice, as it has to be presented to Uganda Institution of Professional Engineers (UIPE) and Engineer's Registration Board (ERB) for the award of registered engineer to the researcher in Uganda.

1.8 Scope and Limitations of the Study

The study is limited to the design, installation, operation and performance of the refrigeration loop of an HVAC system that employs DX coils in attaining the environmental conditions required for pharmaceutical products manufacturing in Uganda. This study was conducted using CiplaQCIL's control sample room and stability chambers area location as a model plant for design. The test parameters for the study were limited to temperature and relative humidity of the model area. The study included all stages of design, installation and validation to test for operation and performance. Lastly, it is noteworthy to note that in this study, multiple was defined as two.

CHAPTER TWO: LITERATURE REVIEW

This chapter gives a reflection on the components that comprise of an HVAC system. It majorly employs a qualitative review approach. It is in this chapter that the concept of DX coil systems as those systems that do not incorporate the chilled water loop is introduced. This presents itself as an improvement as heat is transferred from the airside loop to the refrigeration loop directly. This chapter also highlights the advantages, disadvantages and application of the various HVAC systems there are.

2.1 Introduction

Heating, ventilation, and air conditioning (HVAC) is the technology of indoor and vehicular environmental comfort (Mull, 1998). The goal of the HVAC system is to create and maintain a comfortable environment within a building. Any building has an avalanche of comfort requirements, which include Temperature, Humidity, Air movement, Fresh air, clean air, Noise levels, lighting, furniture and work surfaces (TRANE, 2012). Comfort requirements that are typically impacted by the HVAC system include Dry-bulb temperature, Humidity, Air movement, Fresh air, Cleanliness of the air and Noise levels. Some HVAC systems address these comfort requirements better than others do (TRANE, 2012).

2.2 The HVAC Functions

Heating in HVAC relies heavily on heaters; appliances whose purpose is to generate heat (i.e. warmth) for the building (Godish, 2016). This can also be done via central heating. Such a system contains a boiler, furnace, or heat pump to heat water, steam, or air in a central location such as a furnace room in a home, or a mechanical room in a large building. The heat is transferred by any of the modes of heat transfer of convection or conduction (Cenegel, Klein, & Beckman, 1998).

Ventilation is the "V" in HVAC and is the process of changing or replacing air in any space to control temperature or remove any combination of moisture, odors, smoke, heat, dust, airborne bacteria, or carbon dioxide, and to replenish oxygen (Mishra, Shinde, & V. M. Athawale, 2019). Ventilation includes both the exchange of air with the outside as well as circulation of air within the building. It is one of the most important factors for maintaining acceptable indoor air quality in buildings. Methods for ventilating a building are categorized into mechanical / forced and natural types (American Society of Heating, Refrigerating and Air-Conditioning

Engineers, Inc, 2005). Mechanical or forced ventilation is provided by an air handler / air-handling unit (AHU) and is used to control indoor air quality. Excess humidity, odors, and contaminants are often controlled via dilution or replacement with outside air (American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc, 2005).

An air conditioning system, or a standalone air conditioner, provides cooling and humidity control for all or part of a building. Air-conditioned buildings often have sealed windows, because open windows would work against the system intended to maintain constant indoor air conditions (McDowall, 2007). Outside, fresh air is generally drawn into the system by a vent into the indoor heat exchanger section, creating positive air pressure. The percentage of return air made up of fresh air can usually be manipulated by adjusting the opening of this vent. Typical fresh air intake is about 10% (Mishra, Shinde, & V. M. Athawale, 2019). Air conditioning and refrigeration is provided through the removal of heat. Heat is removed through a combination of convection and conduction. Refrigeration conduction media such as water, air, ice, and chemicals referred to as refrigerants are generally applied in HVAC. A refrigerant is employed either in a heat pump system in which a compressor is used to drive thermodynamic refrigeration cycle, or in a free cooling system, which uses pumps to circulate a cool refrigerant (typically water or a glycol mix). Just like in Heating, a system that applies water as the cooling media employs centralized cooling. Such a system employs a centralized chiller, which could serve a multitude of air-handling units.

HVAC systems rely heavily on fundamental inventions and discoveries made by various scientists, namely: Nikolay Lvov, Michael Faraday, Willis Carrier, Edwin Ruud, Reuben Trane, James Joule, William Rankine, Sadi Carnot, and many others (Swenson & Don, 1995).

2.3 Background to HVAC

Multiple inventions preceded the beginnings of the first comfort air conditioning system designed for the New York Stock Exchange in 1902 by Alfred Wolff and in the same year, the one Willis Carrier equipped the Sacketts-Wilhems Printing Company (JC Heating & Cooling, Inc, 2018). Before the invention of HVAC, people used man-powered fans, rope fans to improve ambient conditions. Romans used a hypocaust (a central heating system with underground furnace and tile flues to distribute the heat) floor panel with radiant heating for rooms and baths for the rich. Below is a table depicting the chronological evolution of the HVAC system.

Table 1: History of the HVAC system

TIME PERIOD	EVOLUTION OF THE HVAC SYSTEM
In the 1400s	- Chimneys used to warm private rooms (Sugarman, 2005). - Leonardo da Vinci designs a water driven fan to ventilate a suite of rooms (Brown J. W., 1828)
In the 1500s	- Georguis Agricola publishes a treatise on ventilating machines for mines in De Re Metallica, describing and depicting various fans and fan blades used to direct fresh air into a shaft. (Sugarman, 2005)
In the 1600s	- Coal came into greater use as supplies of wood decrease. - Sir Christopher Wren uses a gravity exhaust ventilating system for the House of Parliament. - Stoves made of brick, earthenware, or tile were introduced.
In the 1800s	- Nicholas Carnot founds the science of thermodynamics. (Andrews & Nick, 2017) - James Joule discovers that a given amount of work always produces a given amount of heat, and that heat is a form of energy. (Joule, 2011) - Hot water heating systems are used for large public and commercial buildings. (Sugarman, 2005) - The first warm air furnace, similar to today's furnace, is manufactured in Massachusetts, USA, with no recirculation of indoor air and weighed a ton; and the House of Parliament was steam heated, humidified and cooled by a water spray system, using fans driven by steam engines to supply air and exhaust air. (Sugarman, 2005)
In the 1900s	- Furnace systems with centrifugal fans, high-pressure steam heating systems, massive fan systems, high-speed centrifugal fans and axial flow fans with small alternating current electric motors are introduced. (Boyce, 2003) (Sugarman, 2005) - A fan coil dehumidifying system, the world's first spray type air conditioning device (later known as the "Air Washer"), the first industrial process air conditioning system, were introduced (Sugarman, 2005)

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	- Sturtevant patents a system for railway car air conditioning. "The Cyclone Dust Collector" to remove particulate matter from air streams, the backward inclined blade centrifugal fan. (Sugarman, 2005) - Boilers with gas and oil burners and forced or induced draft fans with all operating and safety controls are widely used in the HVAC industry.
In 1906	- Willis Carrier gets a patent for his "Apparatus for Treating Air" (Washington, DC: U.S Patent No. 808,897, 1906)
In 1911	- Stuart H. Cramer coins the phrase "air conditioning" in a patent filed for a device that added water vapor to the air. (Simha & R) - Carrier presents his basic Rational Psychrometric Formulae that became the basis for fundamental calculations for the air conditioning industry. (Sauer Jr, H, & Xianghong, 2001) (Simha & R) - Forced air systems are developed by adding a fan. (Sugarman, 2005) - Willis Carrier patents the centrifugal refrigeration machine (Simha & R)
In 1913	- The centrifugal chiller is the first practical method for air conditioning large spaces with on personal comfort rather than industry. (Cooper, 2002) - The hydronic circulatory pumps that force water through the system with positive pressure and long - low - narrow radiators are introduced, allowing for inconspicuous heating. (Sugarman, 2005)
In 1928	- Carrier develops one of the first residential air conditioners for private home usage. (Simha & R) - Frigidaire manufactures the first individual room cooler using technology from the refrigerator (Sugarman, 2005) (Radermacher & K, 1996)

Generally, the invention of HVAC system - components went hand-in-hand with the industrial revolution, with new methods of modernization, higher efficiency, and system control constantly being introduced by companies and inventors worldwide.

2.4 Modern HVAC Systems

The most common HVAC systems employ chilled water flowing through the tubes of the cooling coil. These systems are referred to as chilled water systems. Other systems have cold, liquid refrigerant flowing directly through the tubes of the cooling coil. These are referred to as direct-expansion, or DX, systems (TRANE, 2012). The term "direct" refers to the position of the evaporator with respect to the airside loop. In a direct-expansion system, the finned-tube cooling coil of the airside loop is also the evaporator of the refrigeration loop. The evaporator is in direct contact with the airstream. The term "expansion" refers to the method used to introduce the refrigerant into the cooling coil. The liquid refrigerant passes through an expansion device also known as an expansion valve just before entering the cooling coil (evaporator) and reduces the pressure and temperature of the refrigerant to the point where it is colder than the air passing through the coil. The primary difference between a chilled-water system and a direct-expansion system is that the DX system does not include the chilled-water loop. Instead, heat is transferred from the airside loop directly to the refrigeration loop (Wang & Shan, 2000). In a chilled-water system, the chilled-water loop transports heat energy between the airside loop and the refrigeration loop.

HVAC system design is a sub discipline of mechanical engineering, based on the principles of thermodynamics, fluid mechanics, and heat transfer (Clarke, 2007). In designs where the chilled water system is used, a centralized chiller connected in parallel to a multitude of air-handling units is employed with chilled water pumped through piping to chilled water coils. The downside to this system is that once the centralized chiller requires maintenance, the whole system is down, as the system cannot attain the comfort requirements of temperature and humidity thence necessitating the acquisition of more than one centralized chiller of equal capacity, which is not only expensive, but also necessitates keeping one of the systems always idle. This downtime problem is also realized in DX systems that employ a single condensing unit where in the event of failure of the condensing unit, the system is worthless.

2.5 HVAC Subsystems

Any HVAC system can be dissected into five basic subsystems, which are also referred to as "loops". The five loops are the following: Airside loop, Chilled-water loop, Refrigeration loop, Heat-rejection loop and Controls loop. However, while these five loops can be used to describe virtually any HVAC system, not every system uses all the five loops (TRANE, 2012).

2.5.1 Airside loop

The first loop is the airside loop, and the first component of this loop is the *conditioned space* (TRANE, 2012). The first two comfort requirements here are the dry-bulb temperature and humidity. In order to maintain the dry-bulb temperature in the conditioned space, heat (referred to as sensible heat) must be added or removed at the same rate as it leaves or enters the space. In order to maintain the humidity level in the space, moisture (sometimes referred to as latent heat) must be added or removed at the same rate as it leaves or enters the space (Dincer & Thermal Energy Storage MA, 2002).

Most HVAC systems used today deliver conditioned (heated, cooled, humidified, or dehumidified) air to the conditioned space to add or remove sensible heat and moisture. This conditioned air is called supply air. The air that carries the heat and moisture out of the space is called return air (TRANE, 2012). The next component of the airside loop is a *supply fan* that delivers the supply air (SA) to the space. Air is supplied to the conditioned space to maintain a desired temperature in the space. This same supply fan is often used to also draw the return air out of the space (TRANE, 2012).

Another comfort requirement is to provide an adequate amount of fresh, outdoor air to the space. The required amount of outdoor air (OA) for ventilation is brought into the building and mixed with the recirculated portion of the return air (RA). The remaining return air, that which has been replaced by outdoor air, is exhausted as exhaust air (EA) from the building, often by an exhaust (or relief) fan (TRANE, 2012). The airside loop also needs to ensure that the air in the conditioned space is clean. Bringing in an adequate amount of fresh outdoor air, and exhausting some of the air from the space, can help meet this requirement. However, the air must also be filtered. In a typical HVAC system, the mixed air passes through a filter to remove many of the airborne contaminants (Bolashikov & Arsen, 2009). During the cooling mode, the supply air must be cold enough to absorb excess sensible heat from the space and dry enough to absorb excess moisture (latent heat). A heat exchanger, commonly known as a cooling coil, is often used to cool and dehumidify the supply air before it is delivered to the space (Dincer & Thermal Energy Storage MA, 2002).

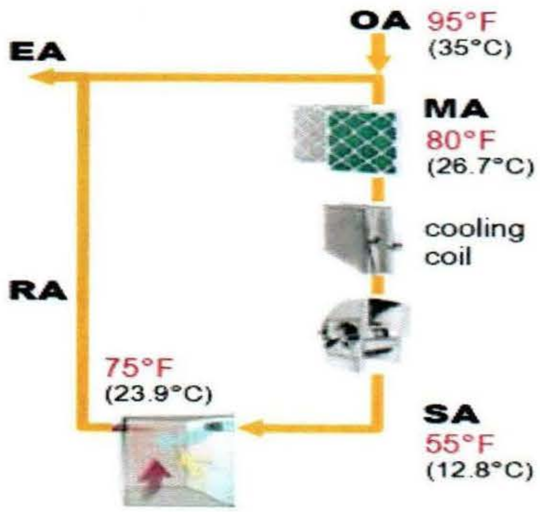

***Figure 1**: Schematic of the airside loop*

2.5.2 Chilled-water loop

In the airside loop, a cooling coil is employed to cool and dehumidify the supply air (American Society of Heating, Refrigerating and Air conditioning engineers, 2008). The cold fluid flowing through the tubes of the coil may be either water or liquid refrigerant (Arora, 2012). Systems that use water flowing through the cooling coil also contain a chilled-water loop. Heat energy flows from a higher-temperature substance to a lower-temperature substance (Cenegel, Klein, & Beckman, 1998). Therefore, in order for heat to be transferred from the air, the fluid flowing through the tubes of the cooling coil must be colder than the air passing over the tubes and fins. In this system, a heat exchanger is used to cool the water that returns from the coil back to the desired supply water temperature. This heat exchanger, called an evaporator, is one component of the refrigeration (cooling) equipment. The third component of the chilled-water loop is a pump that moves water around the loop. This pump needs to have enough power to move the water through the piping, the evaporator, the tubes of the coil, and any other accessories installed in the chilled-water loop. (TRANE, 2012)

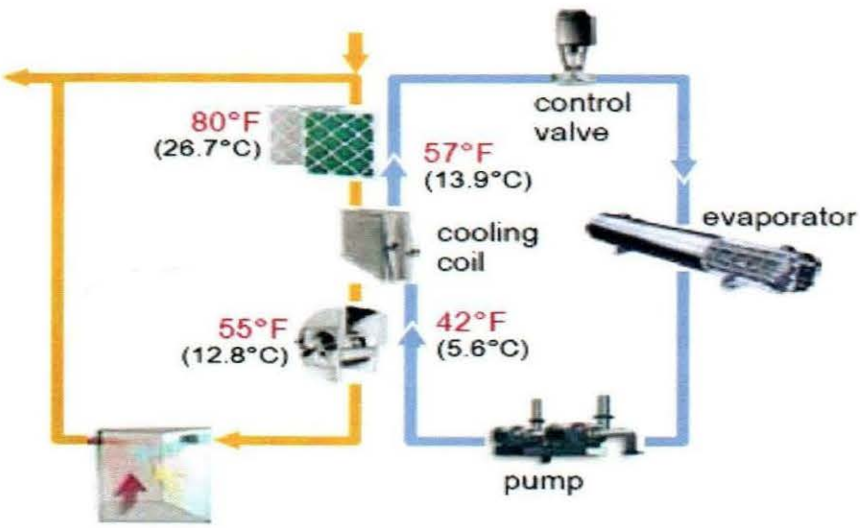

Figure 2: *Schematic of the chilled water loop*

2.5.3 Refrigeration loop

The third loop is the refrigeration loop. In the chilled-water loop, the evaporator allows heat to transfer from the water to cold liquid refrigerant. This loop employs the reverse Carnot cycle to eject heat from the water before it is pumped back to the chilled water coil. A variation of HVAC systems has cold liquid refrigerant flowing through the cooling coil instead of chilled water (Arora, 2012). In this case, the finned-tube cooling coil is also the evaporator of the refrigeration loop. As air passes through the coil, heat is transferred from the air to the refrigerant causing the refrigerant to boil and leave the evaporator as vapor (Arora, 2012). In this arrangement, the chilled-water loop does not exist. Heat is transferred from the airside loop directly to the refrigeration loop. (TRANE, 2012)

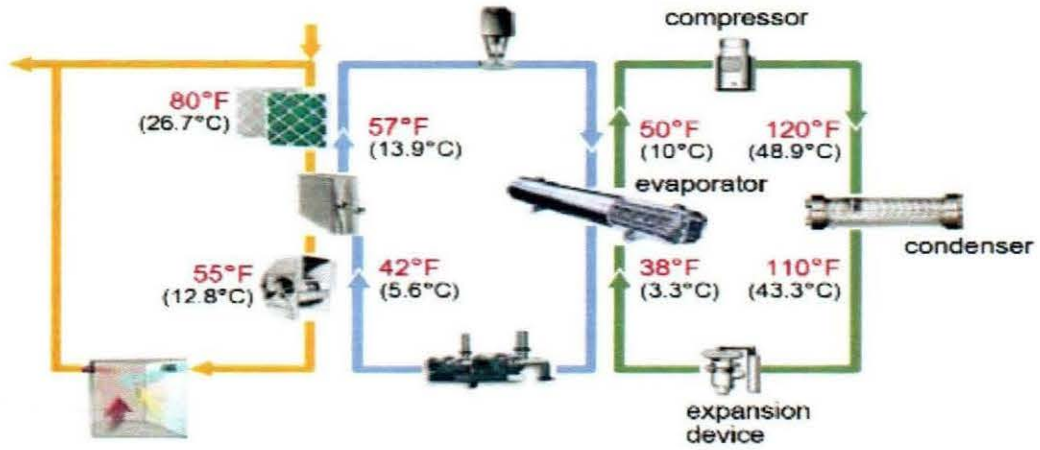

Figure 3: *Schematic of the refrigeration loop*

2.5.4 Heat-rejection loop

The fourth loop is the heat-rejection loop. In the refrigeration loop, the condenser transfers heat from the hot refrigerant to air, water, or some other fluid (Arora, 2012). Systems where heat from hot refrigerant is rejected to air are termed as air-cooled and those where the heat is rejected to water or any other fluid are termed as water-cooled and these employ a cooling tower (Kröger, 2004). In a cooling tower, the warm water returning from the condenser is sprayed over the fill inside the tower while a propeller fan draws outdoor air upward through the fill. (TRANE, 2012)

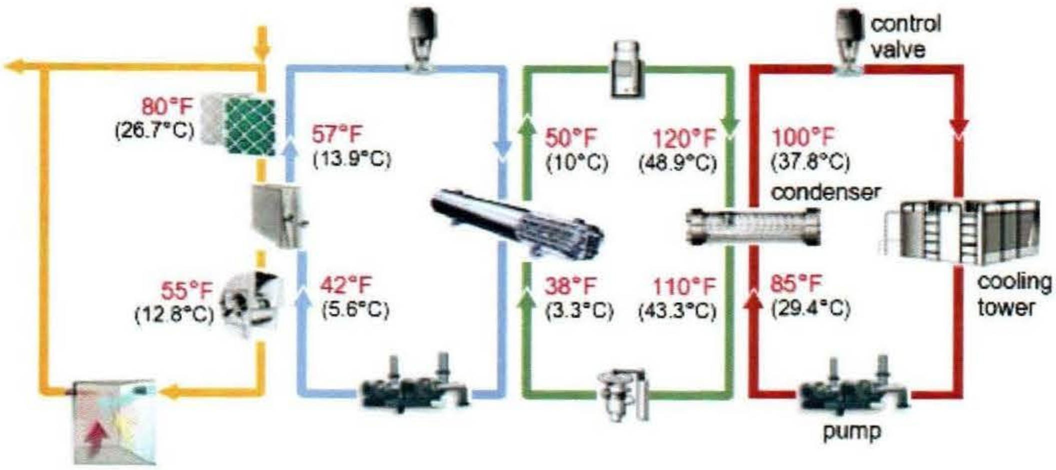

Figure 4*: Schematic of the heat rejection loop*

2.5.5 Controls loop

The fifth, and final, loop of the HVAC system is the controls loop. Each of the previous four loops contains several components and each component must be controlled in a particular way to ensure proper operation. Typically, each piece of equipment (which may be comprised of one or more components of a loop) is equipped with a unit-level, automatic controller. In order to provide intelligent, coordinated control so that the individual pieces of equipment operate together as an efficient system, these individual unit-level controllers are often connected to a central, system-level controller. (TRANE, 2012)

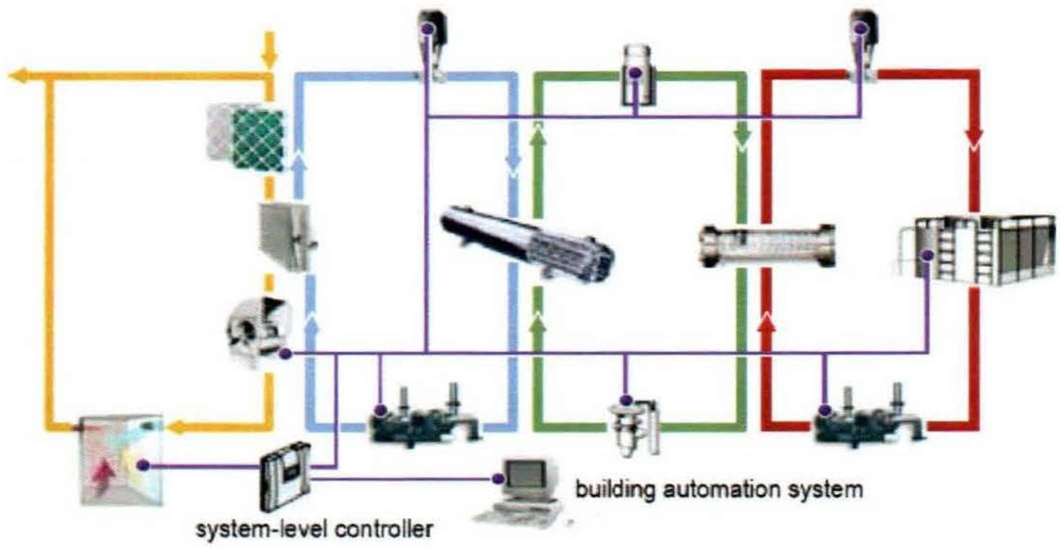

Figure 5: *Schematic of the controls loop*

2.6 Classification of HVAC Systems

Based on the working fluid used in the thermal distribution system, HVAC systems can be classified as: All Air system, All water system, Air-Water system, and Unitary Refrigerant based system (American Society of Heating, Refrigerating and Air conditioning engineers, 2008)

2.6.1 All air systems

As the name suggests, Air is used as the media in an all air system. Air transports thermal energy from the conditioned space to the HVAC plant (Chua, Chou, Yang, & Yan, 2013). In these systems air is processed in the A/C plant namely Air Handling Unit (AHU). AHU consists of Dampers, Mixing chambers, Filters, Cooling/ Heating coils, Humidifiers, Fans/ Blowers etc. in a packaged cabinet. This processed air is then supplied to the conditioned spaces through

Air Distribution system. Air Distribution system consists of Ducts, Dampers and Diffusers. This air extracts (or supplies in case of winter) the required amount of sensible and latent heat from the conditioned space. The duct that supplies the air to spaces is called Supply Air Duct (SAD). The return air from the conditioned space is conveyed back to the plant, where it again undergoes the required processing thus completing the cycle. The duct that returns the air from spaces to A/C plant is called Return Air Duct (RAD). Adequate Fresh air is always supplied by AHU to maintain Ventilation and Indoor Air Quality.

With All Air systems, effective Room air distribution and Ventilation is possible under widely varying load conditions, Stairwell Pressurization, kitchen ventilation etc. can be easily achieved. AHU which is a complete package can be remotely located, well away from conditioned spaces to reduce noise levels in occupied spaces, present great opportunities for Energy conservation such as heat recovery wheels. In addition, precise control is possible by use of high-class controls. According to McQuiston, Parker and Spitler (2014), close range of Temperature (± 0.15°C) and Humidity (± 0.5 %) can be achieved. Furthermore, simultaneous cooling and heating can be provided by dual duct system, and switching between summer and winter mode is quite easy in all air systems.

However, All Air systems are quite large, and require separate spaces like AHU Room. This reduces use of effective floor space. Particularly in high rise buildings, it is difficult to provide long runs of ducts, as AHUs are located either on roof or basement. They are also difficult to install in existing buildings, as large space is required in false ceiling to lay the ducts (McQuiston, Parker, & Spitler, 2014). Also, Testing, Adjusting, Balancing (TAB) may be very difficult task in case of VAV systems. All Air systems are used in Precision HVAC applications such as IT Data centers, Research Labs, Process industries, Clean rooms, Operation Theatres, Hospitals etc. where accurate and precise control of space environment is required (Carrier Air Conditioning Company, 2000), (American Society of Heating, Refrigerating and Air conditioning engineers, 2008). They are also used in Theatres, Auditorium, Functional halls, Retail stores etc. where loads are uniform with small external loads. As well as in large corporate buildings with varied requirements of heating and cooling which can be served by Dual duct systems with simultaneous cooling and heating. Multi zone All air systems are suitable for Offices, classrooms, hotels, ships etc. where individual control is required.

2.6.2 All water systems

In this system, water is used as working fluid that transports thermal energy between conditioned space and A/C plant (Chua, Chou, Yang, & Yan, 2013). Chilled water is circulated for cooling while Hot water is circulated through coils for space heating. As only water is supplied by HVAC plant to the space, Fresh air has to be supplied by another unit to maintain Indoor air quality and ventilation. These systems are also known as Chilled water systems for cooling application.

The All water system needs less space compared to the all air system for the same capacity. This is because water, which has higher specific heat capacity and density than air, is used as the transport media. Therefore, the pipe sizes are very small, and the system consumes very less space due to the absence of big duct works and fans (Pita, 2012). Thus, a less expensive Central Air Conditioning plant solution is offered by all water system (Pita, 2012). It is also more suitable for Individual room / zone control (Gheji, Kamble, Gavde, & Mane, 2016). Simultaneous cooling and heating is possible with 4-pipe system (McQuiston, Parker, & Spitler, 2014), and the system can be easily installed in old buildings without making much changes in the existing space setting (Gheji, Kamble, Gavde, & Mane, 2016).

However, a multiplicity of fan coil units in all water systems means a great deal of maintenance work and cost (Pita, 2012). Control of space humidity is limited, as only cooling and dehumidification occurs and FCUs do not have humidifiers or reheat coils (Carrier Air Conditioning Company, 2000). Also, separate ventilation system must be used to supply fresh air, which adds to cost. In addition, control of ventilation air is not precise, and the condensate may cause problems of dampness in ceiling or walls if condensate drain fails.

All water systems are suitable for use as low cost central HVAC systems in multi zone High Rise commercial applications (Pita, 2012). They offer the best solution to replace all air system in High Rise Tall buildings, as it is much easier to carry water through small sized pipes than air through very big sized ducts across farther heights (Carrier Air Conditioning Company, 2000). They are also very effective system in certain applications where space is extremely limited, such as narrow ceiling and shafts (Gheji, Kamble, Gavde, & Mane, 2016). All water systems are also more famous in case of Individual room control as required in hotels, multi storied apartments, offices etc. (Gheji, Kamble, Gavde, & Mane, 2016).

2.6.3 Air-water systems

Air water system employs best features of all air and all water systems. Combination air-water system distributes both chilled water and /or hot water and conditioned air from a central system to the individual spaces. Terminal units in each zone provide cooling or heating to that zone.

Simultaneous heating and cooling is possible in air-water system, and a lot of space is saved, as only ventilation air is supplied through ducts and chilled/ hot water is passed through pipes (McQuiston, Parker, & Spitler, 2014). Air-water systems also allow for economic control of individual zones using room thermostats, which can regulate either secondary air or secondary water in FCUs. 4. Since there is no latent load on cooling coil, troubles due to condensation do not occur. This prevents marshy or damp regions in the conditioned space. Servicing, Repair, Replacement, Maintenance works etc. are relatively easier than all water systems. And positive pressures can be maintained in conditioned spaces under all varying loads (American Society of Heating, Refrigerating and Air conditioning engineers, 2008)

Unfortunately, there are many complications in system operation and controls as both air and water have to be handled carefully. Consequently, most air- water systems find limited applications in perimeter zones (McQuiston, Parker, & Spitler, 2014). In these systems, constant supply of fresh air has to be supplied to all zones, no matter whether spaces are occupied or not. This is because control is only for cooling/ heating coil through room thermostat (Carrier Air Conditioning Company, 2000). In case of unusual high latent loads, excessive condensation may cause damp environment and discomfort in the zone. As systems are complicated with greater extent of controls, normally air-water systems are costlier than all water systems.

Air water systems are suitable for retrofitting of existing buildings, where there is space restriction. They provide a very good solution for perimeter zone buildings with large sensible loads (McQuiston, Parker, & Spitler, 2014), and can be used where close control of humidity in the space is not necessary. They serve well for large office buildings, hotels, lodges etc.

2.7 HVAC System Types

There are different types of HVAC systems, the most common types include: the standard split system, ductless split systems, packaged system, and geo-thermal systems (Homod, 2013). Due to the diversity in parts, sizes and types of the HVAC systems, no single type of HVAC system can be suitable for all applications.

The ***standard split system***, with one component outside referred to as the outdoor unit containing the condenser and compressor, and one inside referred to as the indoor unit containing the evaporator coil and blower, is the most popular residential HVAC system (Wang & Shan, 2000). ***Ductless split systems*** consist of an outside air conditioner for cooling only or a heat pump for cooling and heating; the indoor component has a fan for dispersing treated air and can be installed on the walls, ceiling or floor. Both systems face the downside of failing to provide ventilation as no fresh air is injected into the system but rather the same air is dispersed. The ***Geo-thermal systems*** use the stable temperatures of the earth to facilitate heating and cooling (HVAC system types, 2017). The ***packaged system*** is manufactured with all the major components in one large cabinet; all packaged systems contain a blower that forces treated air into the home and draws untreated air into the system. The method of treating the air varies with the type of packaged unit.

2.8 DX coil versus chilled water coil

The most common HVAC systems have chilled water flowing through the tubes of the cooling coil. These systems are referred to as chilled water systems. Other systems have cold, liquid refrigerant flowing directly through the tubes of the cooling coil. These are referred to as direct-expansion, or DX, systems (TRANE, 2012). The term "direct" refers to the position of the evaporator with respect to the airside loop. In a direct-expansion system, the finned-tube cooling coil of the airside loop is also the evaporator of the refrigeration loop. The evaporator is in direct contact with the airstream. The term "expansion" refers to the method used to introduce the refrigerant into the cooling coil. The liquid refrigerant passes through an expansion device also known as an expansion valve just before entering the cooling coil (evaporator) and reduces the pressure and temperature of the refrigerant to the point where it is colder than the air passing through the coil.

The primary difference between a chilled-water system and a DX system is that the DX system does not include the chilled-water loop. Instead, heat is transferred from the airside loop directly to the refrigeration loop. In a chilled-water system, the chilled-water loop transports heat energy between the airside loop and the refrigeration loop. Designs that employ the chilled water system require a centralized chiller connected in parallel to a multitude of air-handling units with chilled water pumped through piping to chilled water coils. This system has the advantage of low operating costs because of using chilled water as opposed to expensive refrigerant gas. It however has disadvantages of being bulky, expensive, requiring more energy to run the circulation pumps and once the centralized chiller requires maintenance, the whole system is down, as the system cannot attain the comfort requirements of temperature and humidity.

This for a manufacturing plant may necessitate the acquisition of more than one centralized chiller of equal capacity, which is not only expensive, but also necessitates keeping one of the systems always idle. This downtime problem is also realized in systems that employ a single condensing unit where in the event of failure of the condensing unit, the system is worthless.

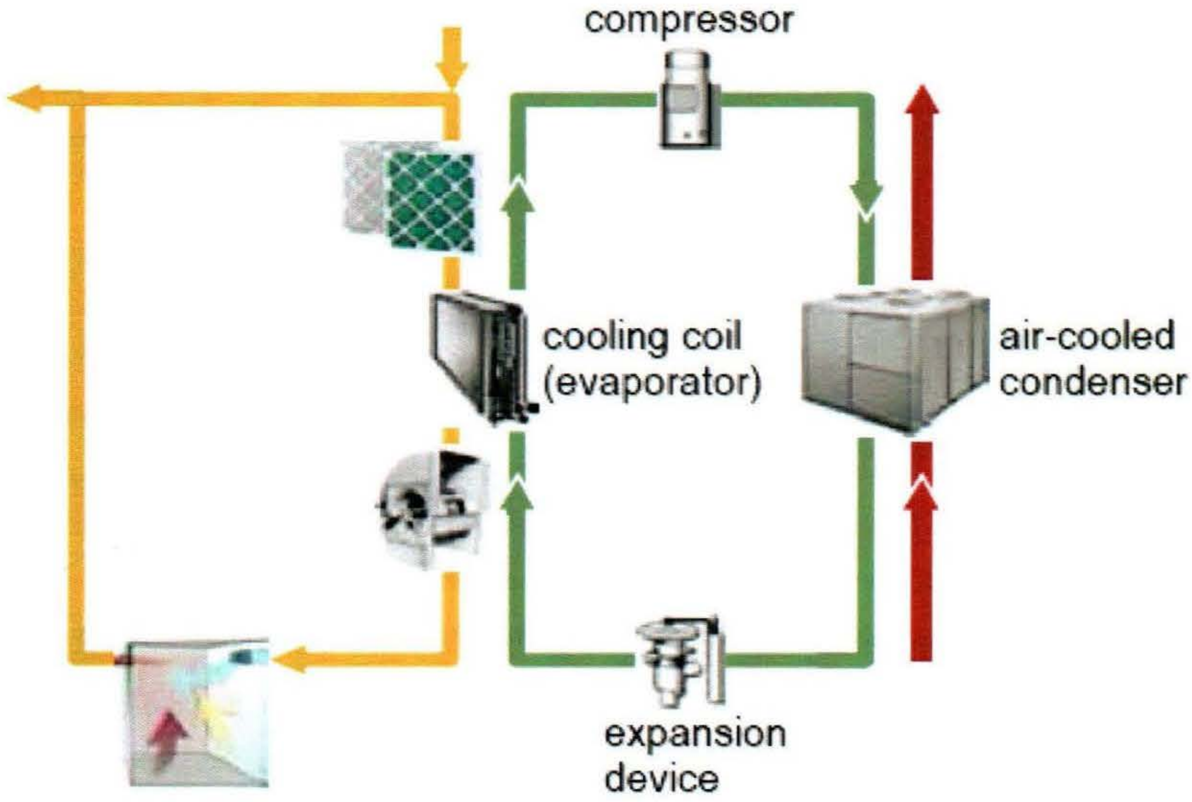

***Figure 6**: Schematic of a no chilled water loop (DX coil)*

CHAPTER THREE: METHODOLOGY

This chapter explains the concept of action research and a justification for using it as the most appropriate approach to achieving the research objectives. It discusses the methodology used in this study and a reflection on why it is appropriate for this research, the methods of collecting data and data analysis and their advantages and disadvantages. This study, perceived through the researcher's experience, reflections and activities designing and modifying an HVAC system that utilizes multiple condensing units in the refrigeration circuit at CiplaQCIL.

3.1 Action Research in Context

This study used the action research approach as the most appropriate approach to achieving the research objectives. Action research involves: a review of current practice, identification of an aspect that requires improvement, imagination of a way forward, trying out the innovation, and taking stock of what happens and making modifications until satisfactory results are achieved (McNiff J. , 2002). This involves four major phases namely: planning, acting, observing and reflecting' (Zuber-Skerritt, 1991). According to (Lindgren, Ola, & Ulrike, 2004), (Greenwood & Levin, 2006) and (Hines & Nick, 1997), action research is appropriate when firms recognize shortcomings in their operations, and wish to overcome them in an iterative fashion. As was the case with the HVAC system at Cipla Quality Chemical Industries Limited (CiplaQCIL); a state-of-the-art pharmaceutical plant based in Kampala, Uganda and focused on production of high quality WHO pre-qualified life-saving medicines for the Sub Saharan Africa region.

This research followed an action research design characteristic cycle involving: understanding the problem and developing plans for intervention, design validation, carrying out the intervention, collecting various forms of data during and after the intervention, making revisions where necessary in a cyclic process until an optimal solution to the problem was achieved (Plomp, 2013).

3.2 Understanding the Problem

The primary research method for understanding the problem was literature review on the different types of HVAC designs. Both quantitative and qualitative literature review methodologies were used. Quantitative literature review methodology, commonly called a meta-analysis, rigorously combines the outcomes of several works that study the same phenomena and use the same or comparable metrics (Smith, 2019).

Qualitative literature review methodology, also referred to as securities analysis is an analysis technique that uses subjective judgment based on unquantifiable information, such as HVAC design expertise, strength of research and development (Smith, 2019). This study first entailed gleaning information from various sources such as journals, articles, reference books, dictionaries, Internet, etc. with the aim of reviewing various types of HVAC system designs in the pharmaceutical industry, their characteristics and applications. This was reached after experiencing the challenges of HVAC systems that employ a centralized chilling plant. Discussions were held in the engineering department at CiplaQCIL to design a system that could mitigate on the downtime problem characteristic of the AHUs at the facility.

3.3 Developing Plans for Intervention

CIPLAQCIL has over 50 air handling units spanning over two facilities i.e., the main plant and the warehouse. A pilot design was purposed to serve in one of the areas. The role played by the concept design is fundamental to solution development. Design is a way of attending to problems of practice, encouraging the puzzlements during the process of attending to an experience to open new possibilities, then giving shape to those problems in order to discover new ways of both acknowledging one's responses as well as seeing and implementing solutions is the art of design (Schön, 1991). It is an important process of planning for new action. Designing enables the practitioner to examine changes, which occur during the moment of intense professional action (Brause and Mayher, 1991) and is a process of thinking about something while doing it (Schon, 1983). Decisions are taken on the spot by the practitioner to change the situation for the better and may be done impulsively and automatically, and may not be intellectual activities. It is internalized or intrinsic knowledge (McNiff & Whitehead, 2002).

Design practice enables the researcher to enhance the understanding of the process value, to move beyond improving the practice and become a producer of new systems (Elliot, 1991). By constructing a system that is applicable to the new system practice; the study is empowered to break free from established theories in order to research unique situations without knowing for sure the results that will ensue; thereby creating new knowledge (Kolb, 1984). The strength, rigour, the emergent and trial and error quality of design practice (Taylor A. , 1996), is therefore of paramount importance to this action research.

3.4 Selection of the Research Site

The selection of the research site was for convenience. The present research was carried out on the AHU that was installed to serve both the control sample room an area where samples of manufactured products are stored for future reference and the stability chambers room an area that houses the stability chambers; equipment where samples of manufactured products are kept to monitor their efficacy every predefined period of time. These areas are located on the ground floor of the CiplaQCIL facility and are expected to be maintained under environmental conditions where temperature is 17^0 C – 25^0 C and relative humidity of NMT 75% according to World Health Organization (2011). The layout of the areas is outlined in figure 1 below.

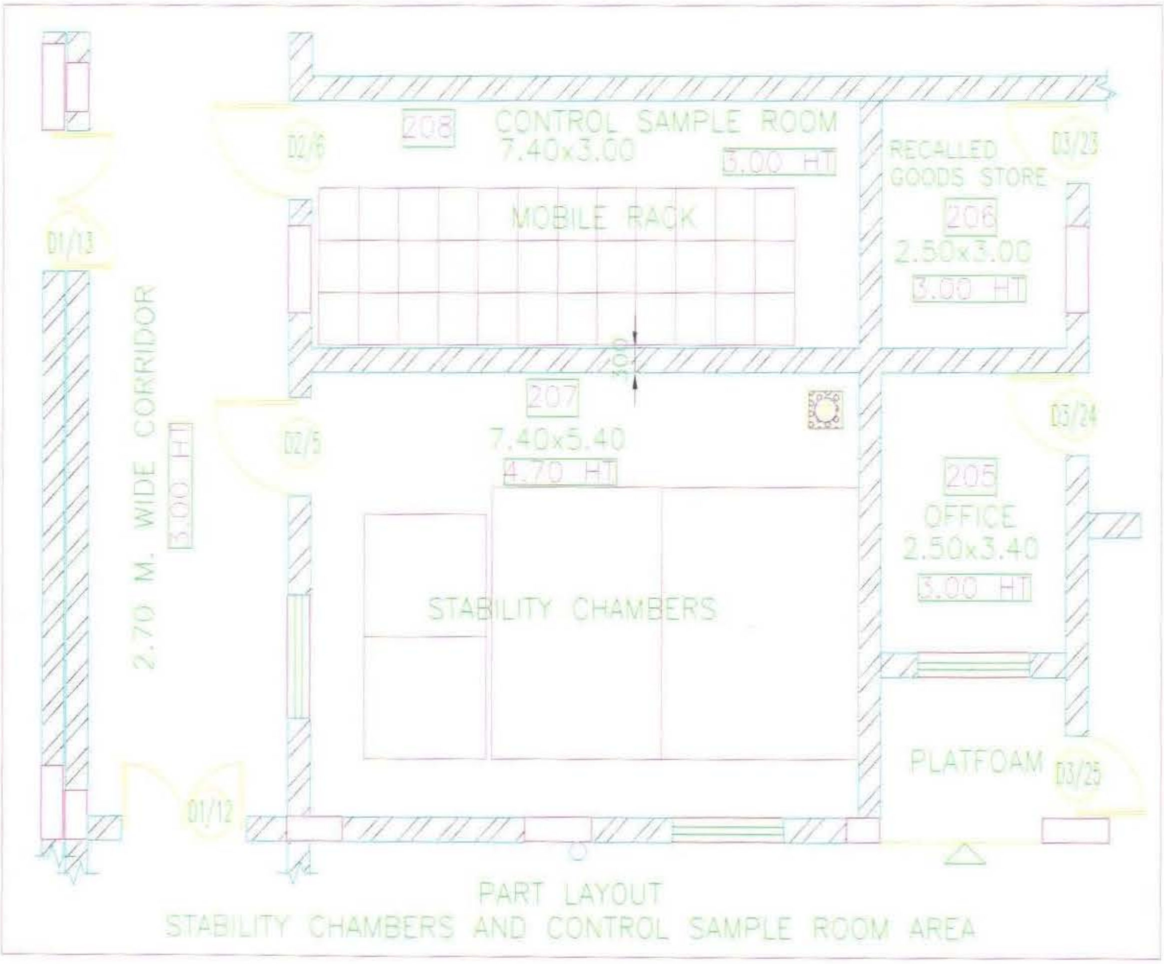

Figure 7: *Part layout of the stability chambers and control sample room area at CIPLAQCIL*

The design areas have the following dimensions. Control sample room: length of 7.4m, width of 3.0m height of 3.0 m and the stability chambers: length of 7.4m, width of 5.4m and height of 4.7m. The resultant AHU with dimensions of 3.15m length, width of 1.45m and height of 2.15m. This is summarized in table 2 below.

Table 2: Dimensions of designed for areas and resultant AHU size

AREA	LENGTH (m)	WIDTH (m)	HEIGHT (m)
Control sample room	7.40	3.00	3.00
Stability chambers area	7.40	5.40	4.70
AHU	3.15	1.45	2.15

3.5 Selection of the Control Parameters

Set points of temperature and relative humidity were established by use of Proportional-Integral-Derivative (PID) controllers (Model TC-533) connected to Resistance Temperature detectors (RTD) sensors located in the return duct of the HVAC unit, with temperature control in the range of 17 °C – 25 °C, and relative humidity control of NMT 75%. The designed air velocity control system consists of a blower (4300 CFM, backward curved plug type fan, 2434 RPM, 60 Hz frequency).

3.6 Carrying Out the Intervention

Conventional designs incorporate a single condensing unit in the refrigeration circuit or employ a chilled water loop with a centralized chiller. For this modification, it was intended to improve the refrigeration loop by connecting an additional condensing unit in parallel to the first one, which will be controlled by a set of timers.

This was intended to enable for the blowdown cycle and prevent the condensing units running concurrently. In the initial stages of the intervention, the condensing units were connected without timers and these ran concurrently. Unfortunately, as a result of the condensing units running concurrently, one of the condensing units got damaged. It is now that a decision was taken to incorporate a set of timers in the design.

The main timer that controls the switching over of the condensing units, achieved by closing a solenoid valve on the liquid line of the condensing unit that is operational and simultaneously opening the one of the non-operational condensing unit but maintaining the operational condensing unit in operational mode so as to perform a pipeline blow down. The blow down procedure was to ensure that refrigerant gas from one condensing unit does not mix with refrigerant gas of the parallel condensing unit, as this would overload the compressor and thence damaging it. After a preset time of 90 seconds, the intermittent timer then switches power to the parallel condensing unit, which does not start until the voltage regulator confirming that the condensing unit is receiving consistent and steady power for at least three minutes. After this confirmation, the parallel condensing unit starts running. This cycle is set to repeat every three hours as set on the main timer. In the event that a failure of one of the condensing units is observed, the knob on the main timer of the functioning condensing unit is set as high as possible and simultaneously, the knob of the malfunctioned condensing unit is set as low as possible to avoid the system being in off mode for a long period. This is left in this state until such a time that the malfunctioned condensing unit is fully repaired and functional.

3.6.1 Determining optimum time of the timers

The main timer, the timer dedicated for switching over between alternate condensing units was set at three hours. The background of the decision for the three hours was in order to prevent the system being in a non-operational state for a long period should the condensing unit fail prematurely and this failure is not realized / arrested. In the event that one of the compressors is malfunctioned, the damning effects of having the HVAC system being non-operational can be minimized by having a functional condensing unit operate and correct the environmental parameters of temperature and relative humidity until such a time that the malfunction is realized and corrected.

The intermittent timer, the timer dedicated to operate the solenoid valves on the liquid line of the compressors / condensing units to trigger a pipeline blowdown of the refrigeration circuit was set at 90 seconds. This was arrived at after conducting a manual blow down exercise of the compressors.

Blowdown in this study refers to the venting of refrigerant gas contained in the refrigeration circuit into a vessel i.e the compressor. The blowdown performed is referred to as pipeline blowdown and is conducted for the purpose of refrigerant gas recovery and consequently prevention of methane emissions into the atmosphere (Harrison, 1996). This procedure can also be conducted during maintenance where it is necessary to demount the refrigerant compressor from the circuit.

The blowdown activity was conducted manually by connecting a refrigerant gas manifold gauge on the suction line, thereafter, closing the two way valve on the liquid line and by observing from the gas manifold gauge until such a time that the line is fully vacuumed, thereafter closing the three way valve on the suction line of the compressor. This time was observed to take a total of 90 seconds.

3.7 Validating the Intervention

The modification was validated by first conducting an operational assessment by running individual components independently with the sole purpose of determining whether individual components and machine i.e. the entire system as a whole is functioning as specified.

Operational assessment was followed by conducting a performance assessment with the purpose of determining whether the system designed is capable to perform consistently as intended. Performance qualification was conducted by running the system at operational conditions for three consecutive days and recording results of temperature and humidity to confirm whether the system performance is consistent and meets predetermined limits under normal conditions.

3.8 Data Collection

To validate the system, a temperature and relative humidity study was carried out in the control sample room area shown in figure 7. This was carried out with the objective of ensuring that the temperature and relative humidity in the area is uniformly distributed, within specified range and determining the most fluctuating location, hottest and coldest location of the area.

1) The area was first divided into grids i.e $NL = \sqrt{A}$ (where; NL = number of grid, A= Area of room in square meter). For this case, $NL = \sqrt{(7.4 \times 3.0)} = 4.71 \approx 5$ Grids.
2) Calibrated data loggers were then placed in each grid. The data loggers of Testo make, used in the study, has the following specifications: measuring range -20 to 70 0C with an accuracy of ± 0.5 0C and 0 to 100% RH with an accuracy of ± 3% RH.
3) The data loggers were placed at working height but since the area contains mobile racks for storage, additional 5 data loggers were placed one in each grid in the intermittent space between the storage racks.
4) The data loggers were programmed to start recording with one value being recorded every 15 minutes for the next 72 hours.
5) This data was then downloaded and results reviewed.
6) The most fluctuating point was then determined as that point with the maximum

difference between the minimum and maximum temperature.

7) The hottest point was determined as that point with the highest temperature(s) recorded over the study period but with the highest temperature(s) remaining within specified range.

8) The coldest point was determined as that point with the lowest temperature(s) over the study period but with these temperature(s) remaining within specified range. (World Health Organization, 2011)

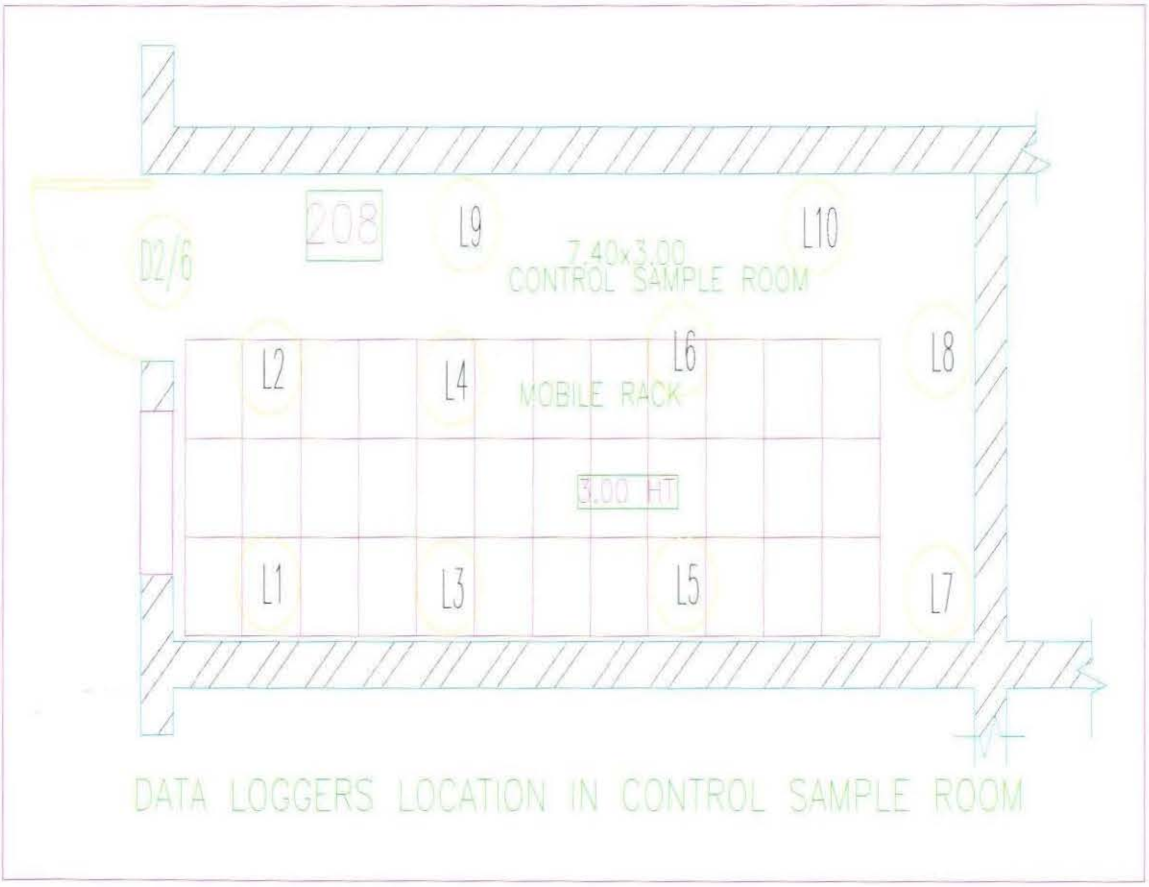

Figure 8: *Data loggers' location in control sample room*

3.9 Equipment / Instruments / Tools

All instruments used in the assessment of the system were equipped with 21 Code of Federal Regulations (CFR) part 11 compliant software which means the data generated should be tamper proof and should have audit trails to record all the login and changes done during the study and can be printed (Vadepalli, 2019).

3.9.1 Temperature data loggers

A temperature data logger, also called temperature monitor, is a portable measurement instrument that is capable of autonomously recording temperature over a defined period of time (Taylor J. , 2001). The digital data can be retrieved, viewed and evaluated after it has been recorded. A data logger is commonly used to monitor environmental conditions in a space.

3.9.2 Aerosol particle counter

Aerosol particle counters are used to determine the air quality by counting and sizing the number of particles in the air (Tuch, Brand, Wichmann, & Heyder, 1997). This information is useful in determining the quantity of particles inside a building or in the ambient air. It also is useful in understanding the cleanliness level in a controlled environment (Chen, 2009).

3.9.3 Magnehelic gauge

A magnehelic gauge displays pressure differences in cylinders in terms of inches or mm in a water column (Lobnan, 2005). It is a device commonly used in the analysis of air filter restrictions in air handling units (Franconi & James, 2000). A reading of 0, shows no difference in pressures of cylinders. The gauge has two ports with one port connected to the low-pressure side and the other to the high-pressure side (Franconi & James, 2000).

Figure 9: *A magnehelic gauge*

3.9.4 Refrigerant gas manifold gauge

A manifold gauge is a chamber device that is used to control the flows of pressure or gases (U.S Patent No. 13/674,399, 2013). The manifold gauge set gives a reading of the refrigerant gas pressures to the operator that they can interpret of the air-conditioning system as it operates (Washington, DC: U.S Patent No. 4,285,206, 1981).

These pressures tell the technician if the system is operating correctly or if there is a problem with the system. The gauge is also used to release moisture and sludge (Washington, DC: U.S Patent No. 3,699,781, 1972). The manifold valve is used in air conditioning or HVAC systems.

***Figure 10**: Refrigerant gas manifold gauge set*

A manifold gauge set consists of a manifold block, two hand valves, three refrigerant hoses, and two pressure gauges. The hose on the left is blue and is connected to the low pressure/suction side of the air conditioning system (Daly, 2011). Because the gauge reads in two different ranges of pressure, it is usually called a compound gauge. The high-pressure side is red coloured (Daly, 2011).

3.10 Data Analysis

Once the 72 hours elapsed, the data loggers were demounted and the data off them downloaded one at a time. This data was analyzed using Excel software where a trend of the respective environmental conditions and for each data logger was taken. The observed results were first compared with the conditions set out to be attained. The hottest, coldest and most fluctuating spot(s) were determined basing on temperature and RH trends.

Additionally, at the completion of the validation, performance of the newly designed system was compared to conventional designed systems with the aim of proving that the newly designed system is less susceptible to failure because of the refrigeration loop. Temperature – relative humidity excursion results because of the chilled water loop for AHU 18; an AHU that was installed to maintain environmental requirements of temperature and relative humidity in blend and bulk store at CiplaQCIL, were used.

3.11 Ethical Issues in Data Collection

From the inception of this research, the researcher was determined to conduct an ethical inquiry, pondering seriously on all ethical issues associated with this study. As an employee, my primary responsibility was to my employer and workmates. Whatever was done during this study falls within the everyday decision-making of a maintenance engineer at CiplaQCIL and is in-line with good engineering practice. This study never, at any one time, put the employer or any employee at any psychological or physical risk. On the onset, this research was discussed with the management and affected employees whose approval was sought and granted before commencement of the study. Indeed, this research operated under a nondisclosure agreement with CiplaQCIL.

CHAPTER FOUR: RESULTS AND DISCUSSION

This chapter discusses the findings obtained from the study and an interpretation of the obtained findings. The findings were both qualitative and quantitative. From the perceived problem, right to the methods employed to overcome the same, this chapter discusses what was observed in lieu with the objectives of why the study was conducted in the first place.

4.1 Developing Plans for Intervention

In the study, concept models were designed with the first model designed by incorporating multiple DX coils equal to the number of condensing units to be installed. This however presented a challenge where the blower size had to be increased so as to be able to overcome the extra resistance posed by the extra DX coils. The concept of incorporating two condensing units in parallel to a single DX coil was developed and tested as one of the ways to have the blower size minimized. The challenge to overcome with this concept was on how to prevent liquid refrigerant being introduced into a compressor. A realization that this concept could take advantage of the compressor blow down cycle was made. This unfortunately is a manual activity, which couldn't be implemented as it necessitated employing a full time employee to cater for that particular activity. A control circuit as shown in figure 12 below was therefore designed that could control the system.

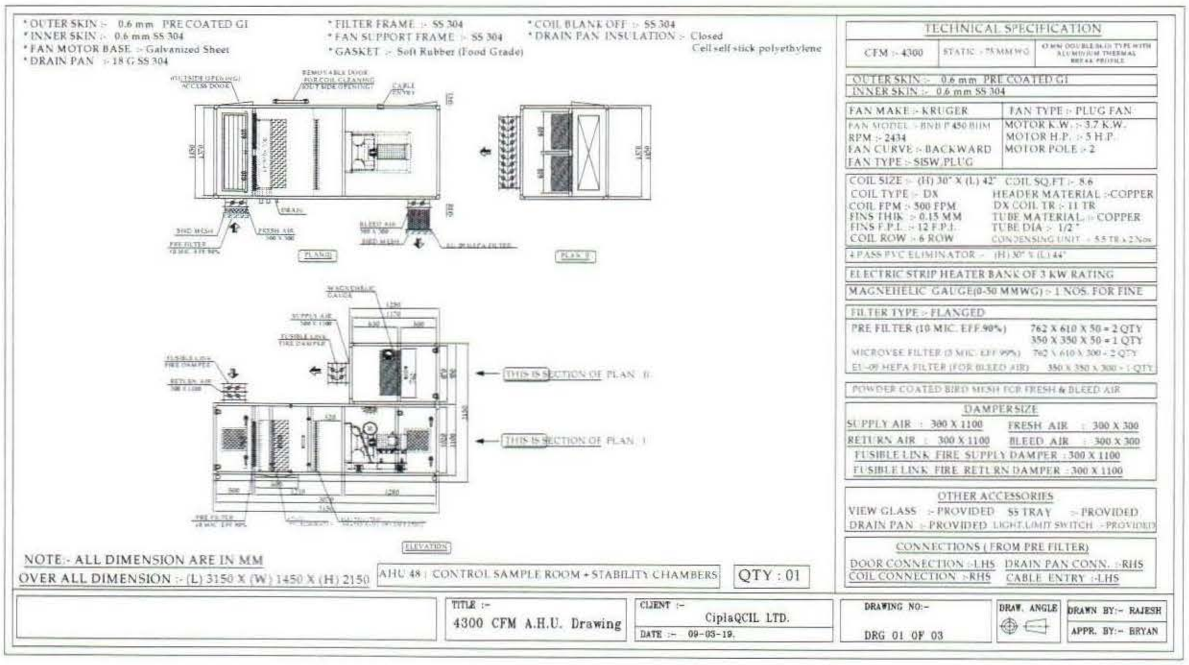

Figure 11: *General arrangement diagram of the AHU installed with technical specifications*

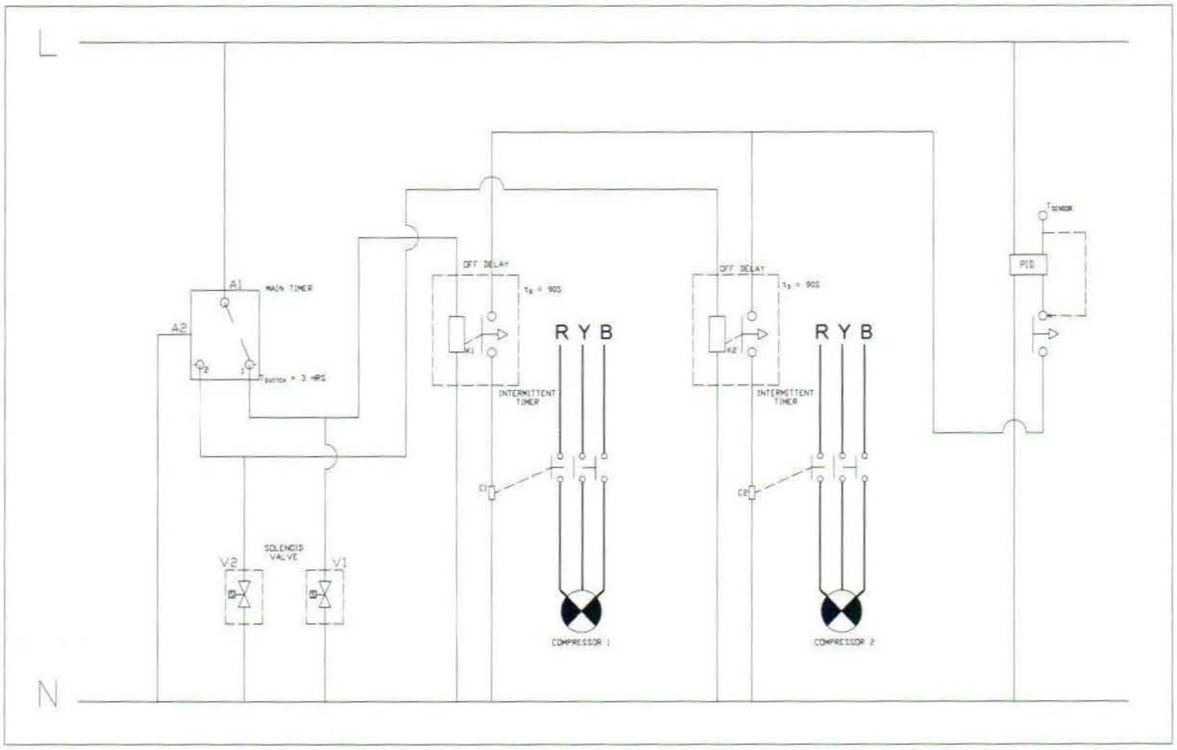

Figure 12: *The designed control circuit*

In the new design, as shown in figure 12 above, the main timer is closed for condensing unit one and so is the corresponding intermittent timer thus compressor one is operational. After the preset time of three hours on the main timer, the main timer switches power to the contactor of condensing unit two. The solenoid valve on the discharge of compressor one will instantaneously shut and simultaneously opening the solenoid valve on the discharge line of compressor two. However, condensing unit two does not start immediately as the presence of an off delay intermittent timer preset at ninety seconds will delay closing the contactor of compressor two. During this time, the intermittent timer is still sending power to the contactor of compressor one thence keeping it operational so as to perform a blow down of compressor one. After the elapse of the ninety seconds, the intermittent timer on compressor one circuit is fully open and the one on the compressor two is closed thence completing the circuit to enable compressor two to run. However, the power supplied to the compressors goes through a phase monitor that samples the power quality so as to ensure that a steady supply of power / current is being supplied to the compressor. Once the sampling is done and passed, compressor number two will start running for the next three hours and at the elapse of this time, the sequence is repeated again this time with the changeover being from compressor two to compressor one.

4.2 Reflecting On the Intervention

In this phase of the research, observations and discussions about the modified system were made in relation to the set out objectives. The main intervention of the research was to develop and test an HVAC system that combines multiple condensing units on a solitary refrigeration circuit. This objective was to be considered attained after the results from the specific objectives of testing applicability of duo condensing units on a single evaporator coil, establishment of performance characteristics of an HVAC system with multiple condensing units in the refrigeration circuit and optimization of the functionality of an HVAC system having multiple condensing units. Assessments were made in regards to achievement of the three specific objectives.

4.2.1 Installation of duo condensing units on a single evaporator coil

This was done by connecting components matching the Carnot cycle. An intersecting point was then selected on both the liquid and suction lines of the first condensing unit where the second condensing unit was connected thereafter. This process was done putting into consideration the right positioning of control components such as solenoid valves and manual shutoff valves. Solenoid valves were installed on only the liquid line as the compressor is constructed with a non-return valve at the inlet into the compressor to prevent a backflow of refrigerant gas. The intervention is illustrated in figure 13 below.

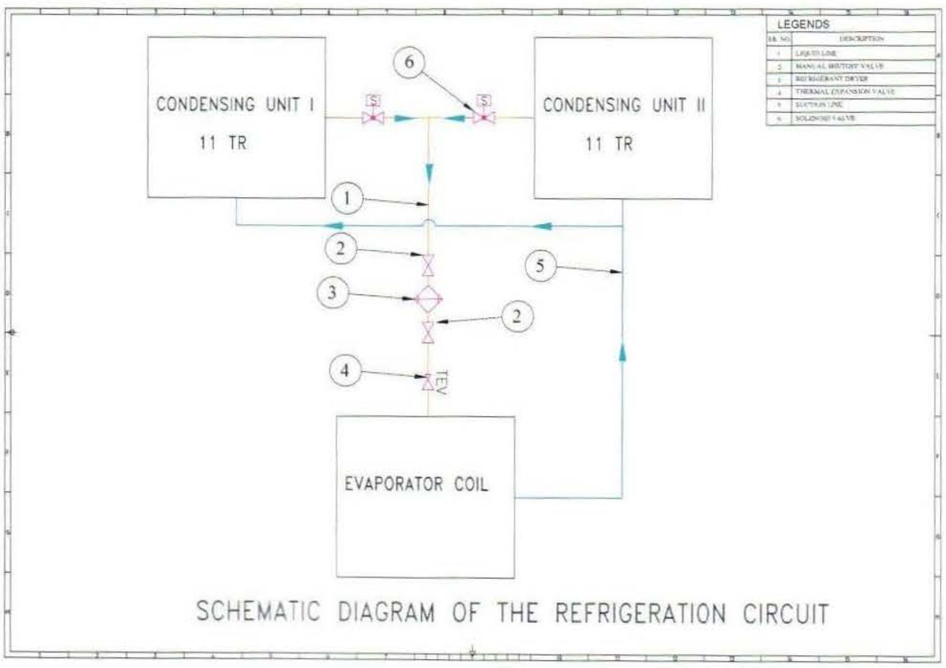

Figure 13: *Schematic of the refrigeration circuit*

4.2.2 Testing applicability of multiple condensing units on a single evaporator coil

In line with the first specific objective of testing applicability of multiple condensing units on a single evaporator coil, this was achieved and a proof of concept attained. The consideration made in this case is that the condensing units should be connected in parallel and at no time should both operate concurrently. This is as a result of the principles of the reverse Carnot cycle; the principle of heat movement (Sugarman, 2005). Refrigerant gas as a vapor from the evaporator is compressed into a high-pressure vapor in the refrigerant compressor. It is then discharged into the condenser coil from where heat gained from the evaporator is dissipated into the atmosphere for air-cooled condensers and liquid for water-cooled condensers and condenses into a liquid before it flows back to the evaporator via an expansion valve (U.S Patent No. 5,174,130, 1992). In the event that liquid refrigerant gas is introduced into the compressor, the compressor is bound to be severely damaged, as the liquid refrigerant is incompressible (Brown, 1997). The theory of not running both condensing units concurrently confirmed as highlighted in section 3.6 above as when the condensing units were observed to be operational at the same time, the result was a failure of one of the condensing units. Close investigation conducted on the malfunctioned condensing unit revealed damaged seals and the piston proof that the liquid refrigerant is incompressible.

4.2.3 Performance characteristics of an HVAC system with multiple condensing units.

In the second specific objective, the study set out to establish the performance characteristics of an HVAC system with multiple condensing units in the refrigeration circuit. This was done by determining the effectiveness of the multiple condensing unit system in fulfilling the major functions of an HVAC system when an operational assessment as highlighted in section 3.7: validating the system. As shown in figures 14 and 15 below, the designed system was capable of attaining and maintaining the major HVAC function of maintaining thermal comfort.

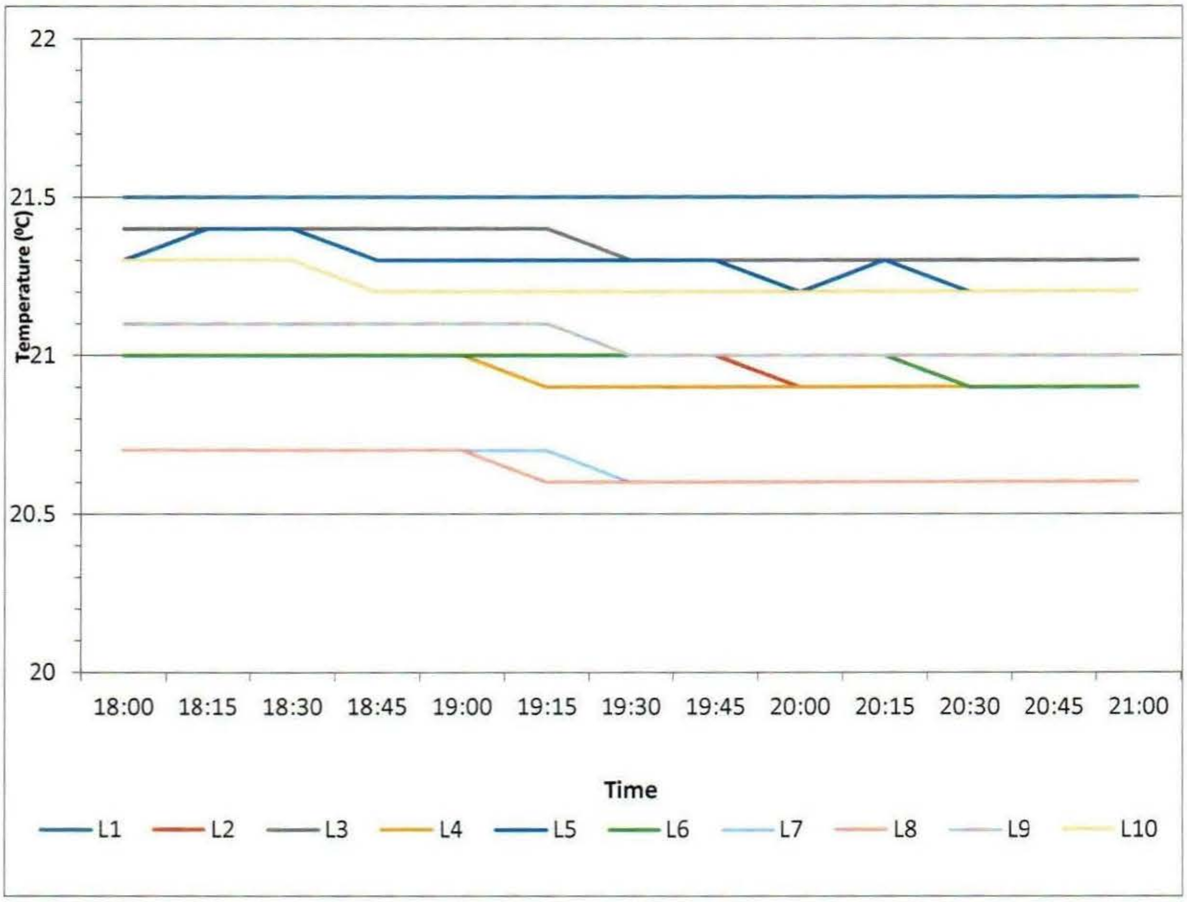

***Figure 14**: Temperature mapping trends over three hours*

Temperature mapping trends over the 72 hours are attached in appendix 8. During the validation of the modified system, a temperature of 22.8^0 C was used as the set value with a system bias of $\pm 3^0$ C. The results indicated temperature process values ranging between 20.5^0 C to 21.5^0 C. This variation in values can be attributed to the fact that the system is a control system, which cannot be maintained at a single value thence always oscillating between the low and high limit set values. Difference in the attained mean value and set value can be attributed to accuracy of the controller.

Process variability matches the preset specifications. All the output values of temperature fall within the preset specifications of 17^0 C – 25^0 C. This means that the system is capable of maintaining the temperature of the area within the preset specifications.

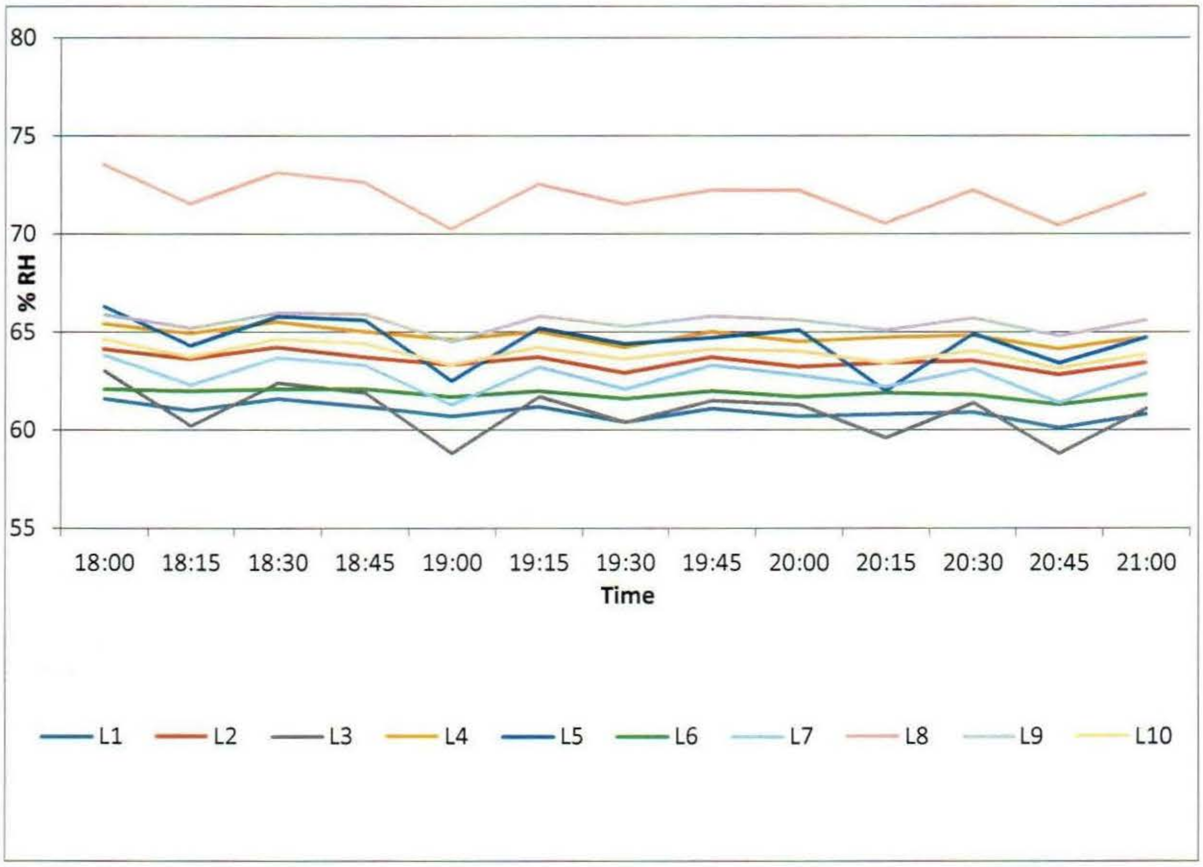

Figure 15: *RH mapping trends over three hours*

RH mapping trends over 72 hours are attached in appendix 8. The same is observed to have happened to the relative humidity parameter as a set value of 60% was input in the controller with a ± 15% system bias. The result was a system that maintains relative humidity between 55 % to 75 %. The attained results demonstrate that the system is capable of achieving and maintaining the required environmental conditions.

Process variability closely matches the preset specifications. Almost all the output values of Relative humidity fall within the preset specifications. The only values out of preset specifications were for a single location i.e L8 and this was for only 45 minutes out of the 72 hours. This variability can be considered as a type-1 error. This means that the system is capable of maintaining the relative humidity of the area within the preset specifications of NMT 75% RH. Location L8 was observed to have the highest RH and the lowest temperature satisfying the relationship of Temperature and relative humidity being inversely proportional. The same can be said of location L3 that had the lowest RH and highest temperature throughout the temperature mapping exercise.

Table 3: Temperature and RH summary

Location No's		Maximum	Minimum	Average	Difference (max-min)
L1	%RH	62.8	57.5	60.2	0.3
	°C	21.5	21.2	21.4	
L2	%RH	65.5	60.9	62.9	0.3
	°C	21.1	20.8	20.9	
L3	%RH	65.2	56.4	60.5	0.4
	°C	21.5	21.1	21.3	
L4	%RH	66.8	62.2	64.2	0.4
	°C	21.2	20.8	21	
L5	%RH	68.3	59.1	63.7	0.4
	°C	21.5	21.1	21.3	
L6	%RH	62.2	59.4	61.1	0.3
	°C	21.1	20.8	20.9	
L7	%RH	66	59.5	62.3	0.4
	°C	20.9	20.5	20.7	
L8	%RH	76	67.5	71.1	0.4
	°C	20.9	20.5	20.7	
L9	%RH	68.1	62.6	65.2	0.5
	°C	21.3	20.8	21	
L10	%RH	66.4	61	63.5	0.2
	°C	21.3	21.1	21.2	

4.2.4 Determination of the hot, cold and fluctuating locations

Table 4: The hottest, coldest and most fluctuating locations

	HOT SPOT	LOCATIONS	COLD SPOT	LOCATIONS
Temperature	**21.5**	**L1,L3,L5**	**20.5**	**L7,L8**
% RH	**76.0**	**L8**	**56.4**	**L3**
	HIGHEST POINT	**LOCATION**	**LOWEST POINT**	**LOCATION**
Fluctuating point	**0.5**	**L9**	**0.2**	**L10**

The hottest spot was deemed as being either of locations L1, L3 or L5 with a temperature of 21.5 ^{0}C. This can be attributed to the fact that locations L1, L3 and L5 were located in the mobile rack where airflow could have been limited. The coldest spots with a temperature of 20.5 ^{0}C being observed at locations L7 and L8. This can be attributed to their close proximity relative to the supply air grills of the AHU. This implies that locations L7 and L8 had sufficient airflow. The temperature mapping study satisfies the relationship of temperature and relative humidity being inversely proportional. This is because as the air temperature increases, air can hold more water molecules, and its relative humidity decreases. When temperatures drop, relative humidity increases. High relative humidity of the air occurs when the air temperature approaches the dew point value.

4.2.5 Optimization of the functionality of an HVAC system having multiple condensing units

In the third specific objective of optimization of the functionality of an HVAC system having multiple condensing units, the benefits of such a system were established. The benefits include among others economic benefits as only a single evaporator coil is installed as much as multiple condensing units are installed. In the same line is that the blower CFM need not be over designed from conventional HVAC systems to overcome the resistance posed by the corresponding multiple evaporators. In HVAC design, any obstacle such as evaporator coil or filter is designed at 50 FPM face velocity consideration and the airflow requirement increases with increased cross section area (Korad, 2017). The pressure drop increases with increased breadth of the installed obstacles. By incorporating a single evaporator coil with multiple condensing units, the pressure drop was significantly reduced thence, the CFM requirement of the blower greatly reduced.

The HVAC design developed has extrinsic benefits, which include the complete elimination of the chilled water loop, which poses a requirement of extra energy required in operating the pumps and chilling plant, insulation to lag the chilled water pipes and maintenance requirement of components of the chilled water loop.

The system was designed with an aim to minimize downtime in mind. A comparison with the conventional design using AHU 18 was consequently made over a four-month period beginning July 2019 to October 2019. Temperature and relative humidity excursions; deviation from the preset parameters for AHU 18 as attributed to failure of components in the chilled water loop recorded. The results from reports in appendix 9 are summarized in table 5 below.

Table 5: Excursions recorded over a four-month period for both the new design and conventional design

DATE	NEWLY DESIGNED SYSTEM	CONVENTIONAL DESIGN
07.06.2019	0	2
17.06.2019	0	2
18.06.2019	0	2
02.07.2019	0	2
24.07.2019	0	1
16.08.2019	0	1
27.08.2019	0	3
02.09.2019	0	1
16.09.2019	0	3
17.09.2019	0	2
16.10.2019	0	2
21.10.2019	0	3
Total	**0**	**24**

The results as exhibited in appendix 9 and table 5 show that AHU 18 experienced 24 excursions over a four-month period beginning July 2019 to October 2019. This translates to 24 hours of downtime in which the conventional design couldn't achieve the comfort requirements of temperature and relative humidity. In contrast, zero excursions were recorded for the new design in the same time. This is dangerous and places the production, efficacy and stability of the manufactured products at risk. This implies that the new system will be less susceptible to downtime because of the refrigeration loop since a backup option is availed in the event that one condensing unit fails. This gives ample time to the maintenance technician to maintain the parallel condensing unit without tampering with operations of the whole system.

4.3 Summary of Findings

Incorporating multiple condensing units on a single refrigeration circuit is possible. This was the main objective of the study. Accomplishment of the objective was a proof of concept that this is plausible.

An HVAC system that incorporates multiple condensing units on a single refrigeration circuit functions as good as a conventional HVAC system. The advantage the modified system holds over conventional system designs is that it would require the system to experience failure in the refrigeration circuit equal to the number of condensing units installed before a total failure can be registered.

An HVAC system that employs a single evaporator coil / DX coil in the refrigeration circuit will have lower CFM requirements as opposed to a system with multiple evaporator coils as a higher CFM of the blower will be necessary to overcome the resistance offered because of each DX coil.

HVAC systems that employ DX coils have lower energy requirements as the chilled water loop is eliminated altogether. Energy requirements to run the circulation pumps and overcome evaporation effects by employing a top-up pump are eliminated in this setup. Additionally, Chilled water piping, insulation and accessories are eliminated as a result of not incorporating the same.

HVAC systems that adopt the multiple condensing units in the refrigeration circuit are not susceptible to downtime as a result of failure of components in the refrigeration loop unlike conventional designs that are likely to be affected by failure of components in the chilled water loop.

Temperature and relative humidity are inversely proportional. This can be observed from the results obtained in figures 14, 15, 21 & 22 and tables 3 & 4. This collaborates with work of (Greenspan, 1977).

CHAPTER FIVE: CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

This research aimed at testing the plausibility of incorporating multiple condensing units on a solitary refrigeration circuit. This was achieved as an HVAC system that employs two condensing units was designed and installed to maintain the thermal comfort requirements of the control sample room and stability chambers area at CIPLAQCIL. Based on the validation of the system, it can be concluded that such a system is effective and has the benefit of experiencing minimal downtime being caused because of the failure of the refrigeration loop. This system was observed to be less susceptible to failure because of failure of components in the refrigeration loop unlike conventional HVAC designs. HVAC design engineers are thence encouraged to adopt this design while designing for minimal downtime.

The benefit of having multiple condensing units on a single evaporator coil is that reduced costs are incurred in designing and constructing of the system. This is because;-

I. No additional refrigeration circuit components such as DX coils, cooper pipes, expansion valves and insulation material, which would drive costs up, have to be included.
II. The blower designed for the system will have a lower CFM requirement since the CFM required to overcome each DX coil is eliminated as its only one coil.

5.2 Recommendations

The designed HVAC unit is recommended for use in pharmaceutical products manufacturing. The refrigeration loop designed is particularly recommended to be adopted for HVAC system design that aims at minimizing equipment downtime.

HVAC systems being instrumental in creating and maintaining conditioned environmental parameters required for pharmaceuticals products manufacturing, further work is recommended in designing a control system where the temperature and relative humidity of the HVAC system can be controlled independently to enable for specific environmental conditions being attained for different manufactured products.

Further work is particularly recommended in evaluating the impact of the designed system when installed in ISO 8 and / or cleaner areas such as ISO 7, ISO 6,etc

Further work is recommended in evaluating the need and effectiveness of having a dedicated refrigerant filter dryer for each condensing unit with a view to lengthen on service life of the refrigerant filter dryer.

Further work is also recommended in designing an HVAC system whose operation of the condensing unit is dependent on operation of the air mover in the airside loop as failure of the air mover will lead to no heat exchange at the evaporator coil and consequently failure of the condensing unit.

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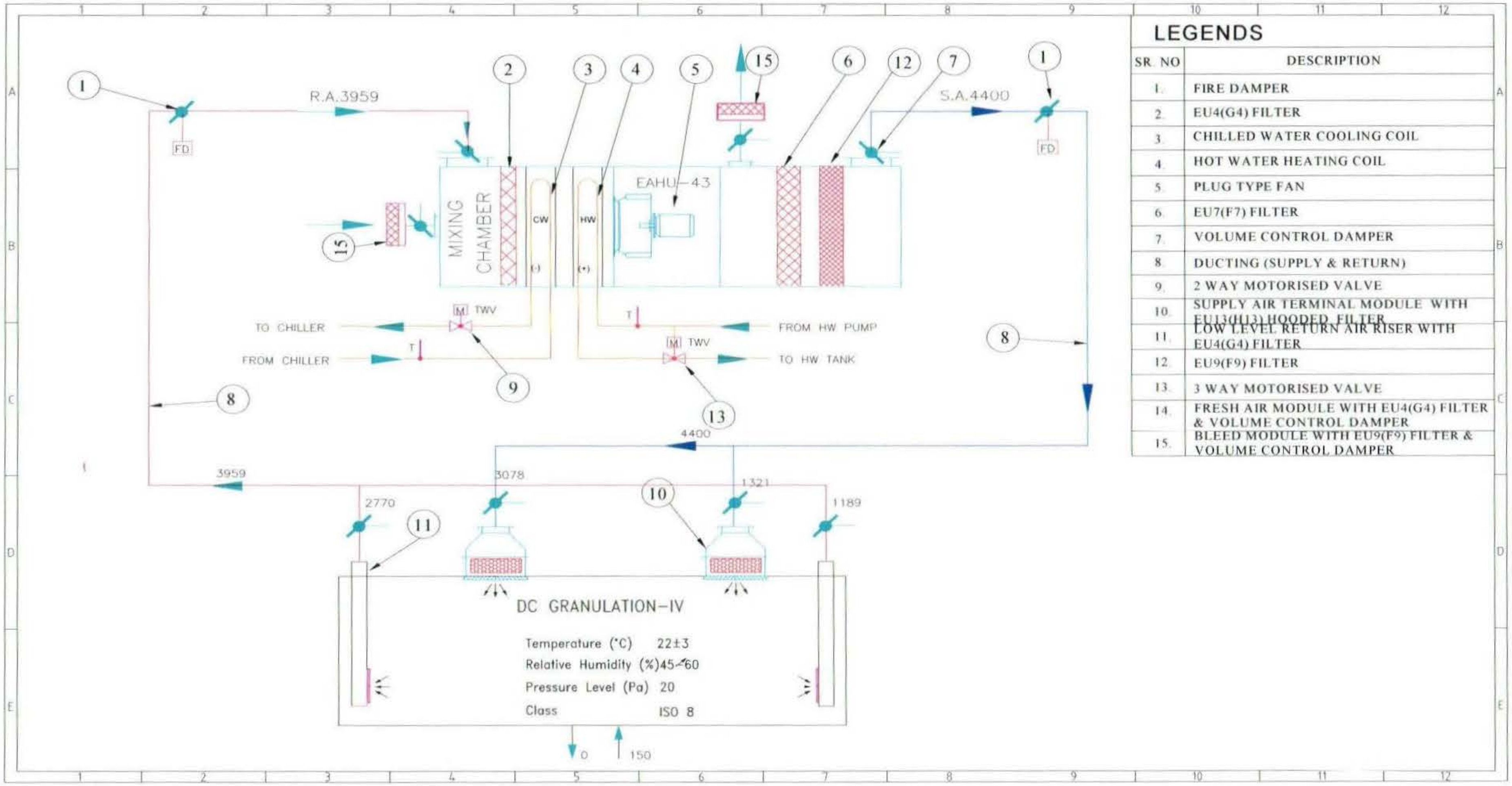
APPENDICES

Appendix 1: Schematic of an air handler unit



LEGENDS

SR. NO	DESCRIPTION
1.	FIRE DAMPER
2.	EU4(G4) FILTER
3.	CHILLED WATER COOLING COIL
4.	HOT WATER HEATING COIL
5.	PLUG TYPE FAN
6.	EU7(F7) FILTER
7.	VOLUME CONTROL DAMPER
8.	DUCTING (SUPPLY & RETURN)
9.	2 WAY MOTORISED VALVE
10.	SUPPLY AIR TERMINAL MODULE WITH EU13(H13) HOODED FILTER
11.	LOW LEVEL RETURN AIR RISER WITH EU4(G4) FILTER
12.	EU9(F9) FILTER
13.	3 WAY MOTORISED VALVE
14.	FRESH AIR MODULE WITH EU4(G4) FILTER & VOLUME CONTROL DAMPER
15.	BLEED MODULE WITH EU9(F9) FILTER & VOLUME CONTROL DAMPER

Appendix 2: Cleanroom Classification and Air Changes per Hour

Table 6: Number of airborne particles in a clean room

ROOM CLASSIFICATION	NUMBER OF AIR BORNE PARTICLES
ISO 3	1
ISO 4	10
ISO 5	100
ISO 6	1000
ISO 7	10000
ISO 8	100000

Air cleanliness is achieved by passing the air through HEPA filters. The more often the air passes through the HEPA filters, the fewer particles are left in the room air. The volume of air filtered in one hour divided by the volume of the room gives the number of air changes per hour.

Table 7: Average air changes per hour in a clean room

ISO Class	Average number of air changes per hour (ACPH)
ISO 5	240–360 (unidirectional airflow)
ISO 6	90–180
ISO 7	30–60
ISO 8	10–25
Conventional building	*2–4*

The above-suggested air changes per hour are only a design rule of thumb. They should be computed by an HVAC cleanroom expert, as many aspects must be taken into consideration, such as the size of the room, the number of people in the room, the equipment in the room, the processes involved, the heat gain, etc

Appendix 3: Calculation of Required CFM for A Clean Room

$$Required\ CFM = \frac{VOLUME\ OF\ THE\ ROOM\ \ x\ ACPH}{60\ minutes}$$

Equation 1: *Calculation of required CFM in a clean room*

(Falke, 2016)

Appendix 4: Design Data

Table 8: The design data of the AHU

SR.	SYSTEM	NAME OF AREA	AREA DIMENSIONS					AREA LOAD			FRESH AIR ESTIMATE			DESIRED CONDITIONS				SYSTEMS PARAMETERS						
NO	NO		Length	Width	Area	Ht.	Volume	Equip	Light	Occupancy	Door	Door	Exhaust	Temp.	Humidity	Press.	Min. ACH	Min. Air Flow	A/C Load	Dehum. Air	Supply	Bleed	Return	Resultant
			M	M	M^2	M	M^3	KW	W/ Sq.ft.		In	Out		°C	NMT	Pa. Room		CFM	TR	CFM	CFM	CFM	CFM	ACPH
1	AHU-45	Control sample room	7.50	3.00	22.5	3.0	67.5	-	2.0	1	200	0		21 ± 4	75.0	20.0	15.0	600	11.0	-	1720		1880	43
2		Stability chambers area	7.40	5.40	40.0	4.7	187.8	142.0	2.0	5	200	0		21 ± 4	75.0	20.0	15.0	1660		-	2580		2820	23

Appendix 5: The Installed HVAC Unit

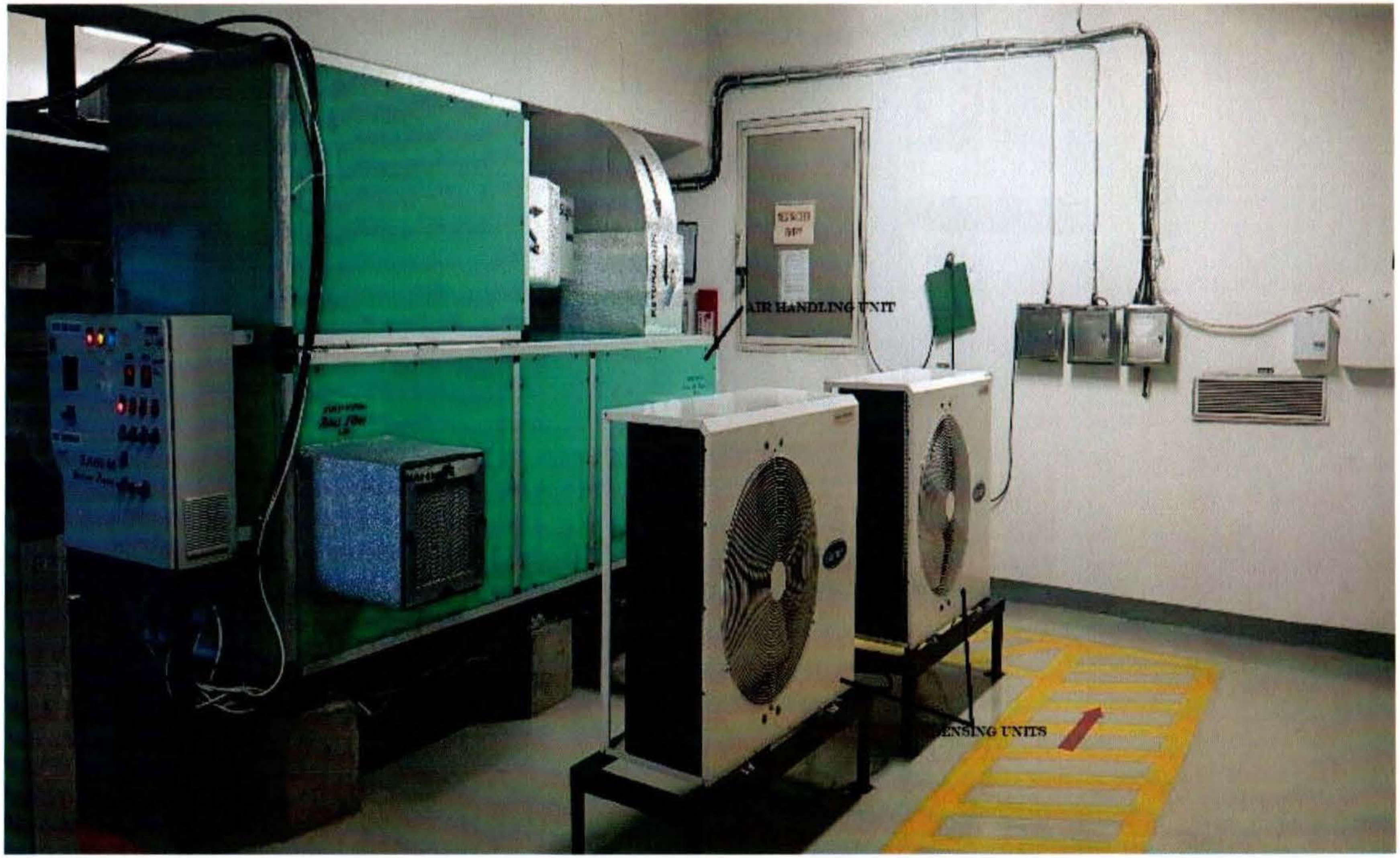


Figure 17: *AHU with the two condensing units*

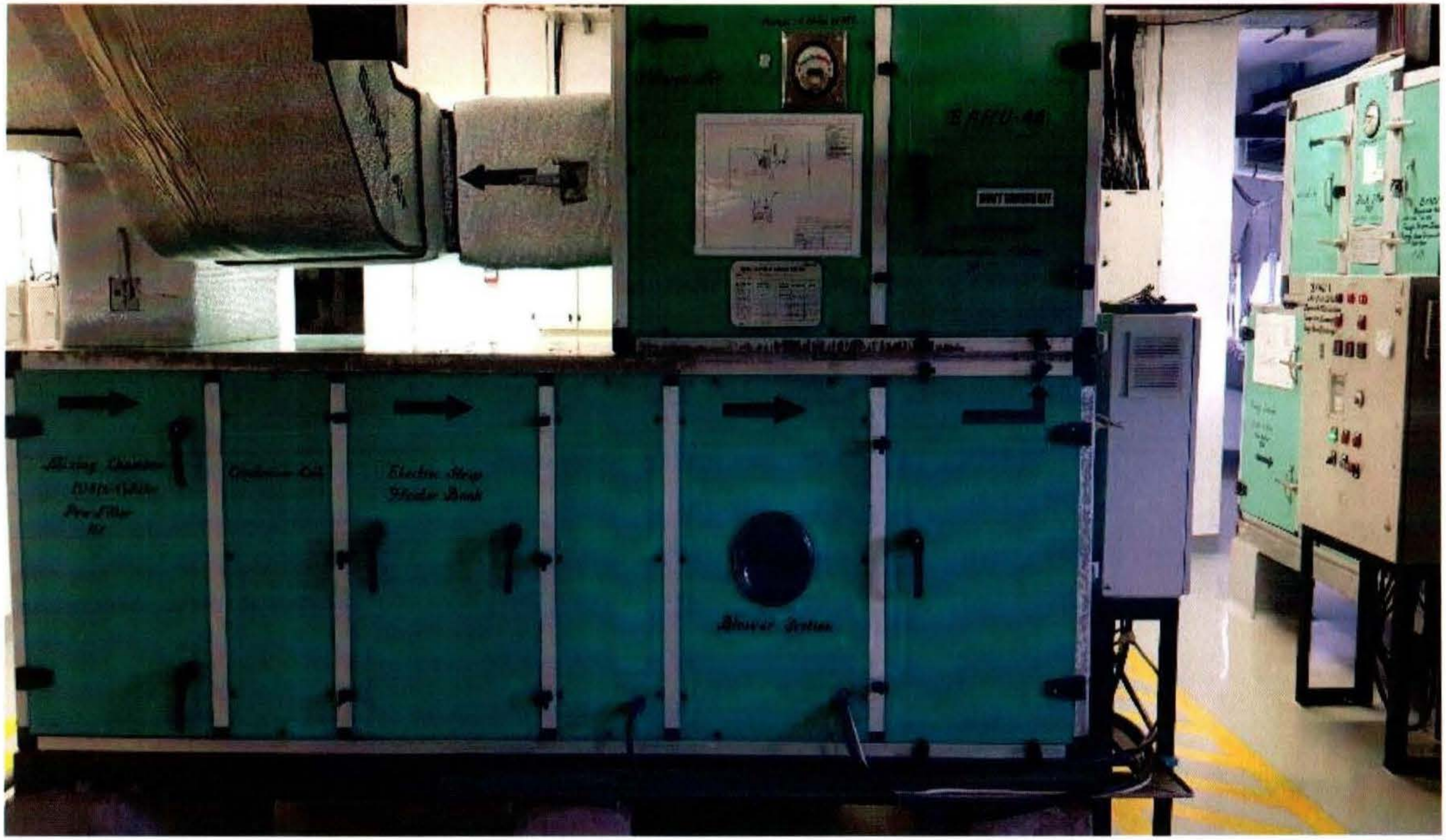


***Figure 19**: Front view of the installed AHU*

Appendix 6: Heat Load Calculations

The heat gain of a room or building depends on:

- The size of the area being cooled
- The size and position of windows, and whether they have shading
- The number of occupants
- Heat generated by equipment and machinery
- Heat generated by lighting

By calculating the heat gain from each individual item and adding them together, an accurate heat load figure can be determined.

Step One

Calculate the area in square feet of the space to be cooled, and multiply by 31.25

Area BTU = length (ft.) x width (ft.) x 31.25

***Equation 2**: Calculating BTU of an area*

Step Two

Calculate the heat gain through the windows. If the windows don't have shading multiply the result by 1.4

North window BTU = Area of North facing windows (m. sq.) x 164

***Equation 3:** Heat gain calculation through North facing window*

If no shading, **North window BTU = North window BTU x 1.4**

***Equation 4:** Heat gain calculation through North facing window with no shading*

South window BTU = Area of South facing windows (m. sq.) x 868

***Equation 5:** Heat gain calculation through South facing window*

If no shading, **South window BTU = South window BTU x 1.4**

***Equation 6:** Heat gain calculation through South facing window with no shading*

Add the results together.

Total window BTU = North window + South window

Step Three

Calculate the heat generated by occupants, allow 600 BTU per person.

Occupant BTU = number of people x 600

Equation 7*: Heat generated by occupants*

Step Four

Calculate the heat generated by each item of machinery - copiers, computers, ovens etc. Find the power in watts for each item, add them together and multiply by 3.4

Equipment BTU = total equipment watts x 3.4

Equation 8: *Heat generated by equipment*

Step Five

Calculate the heat generated by lighting. Find the total wattage for all lighting and multiply by 4.25

Lighting BTU = total lighting watts x 4.25

Equation 9: *Heat generated by lighting*

Step Six

Add the above together to find the total heat load.

Total heat load BTU = Area BTU + Total Window BTU + Occupant BTU + Equipment BTU + Lighting BTU

(W. Tombling LTD, 2002)

Appendix 7: The State Of Refrigerant Gas at Every Stage of the Refrigeration Cycle

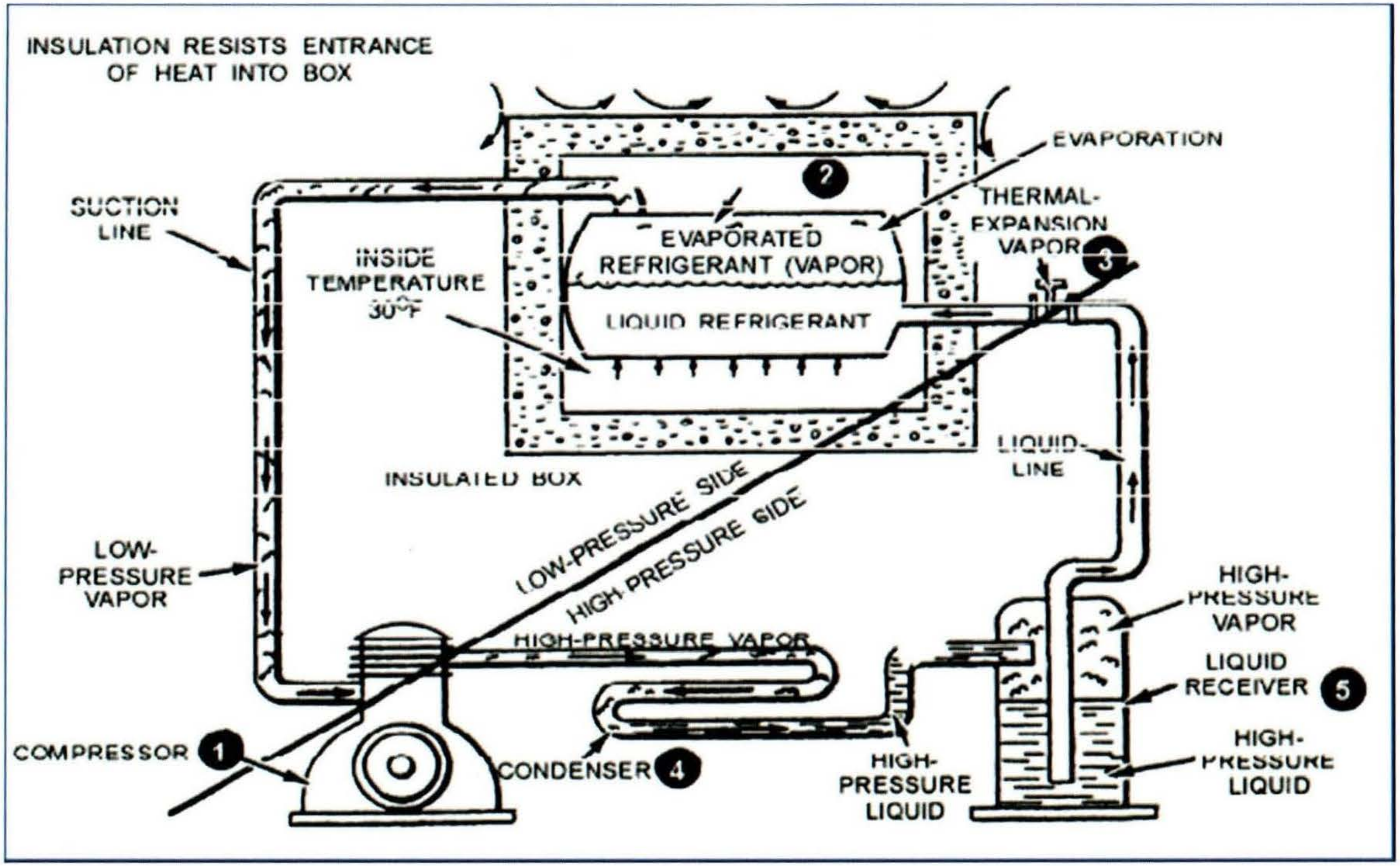


Figure 20: *The state of refrigerant gas at every stage of the refrigeration cycle*

Appendix 8: Temperature – RH Mapping Trends Over 72 Hours

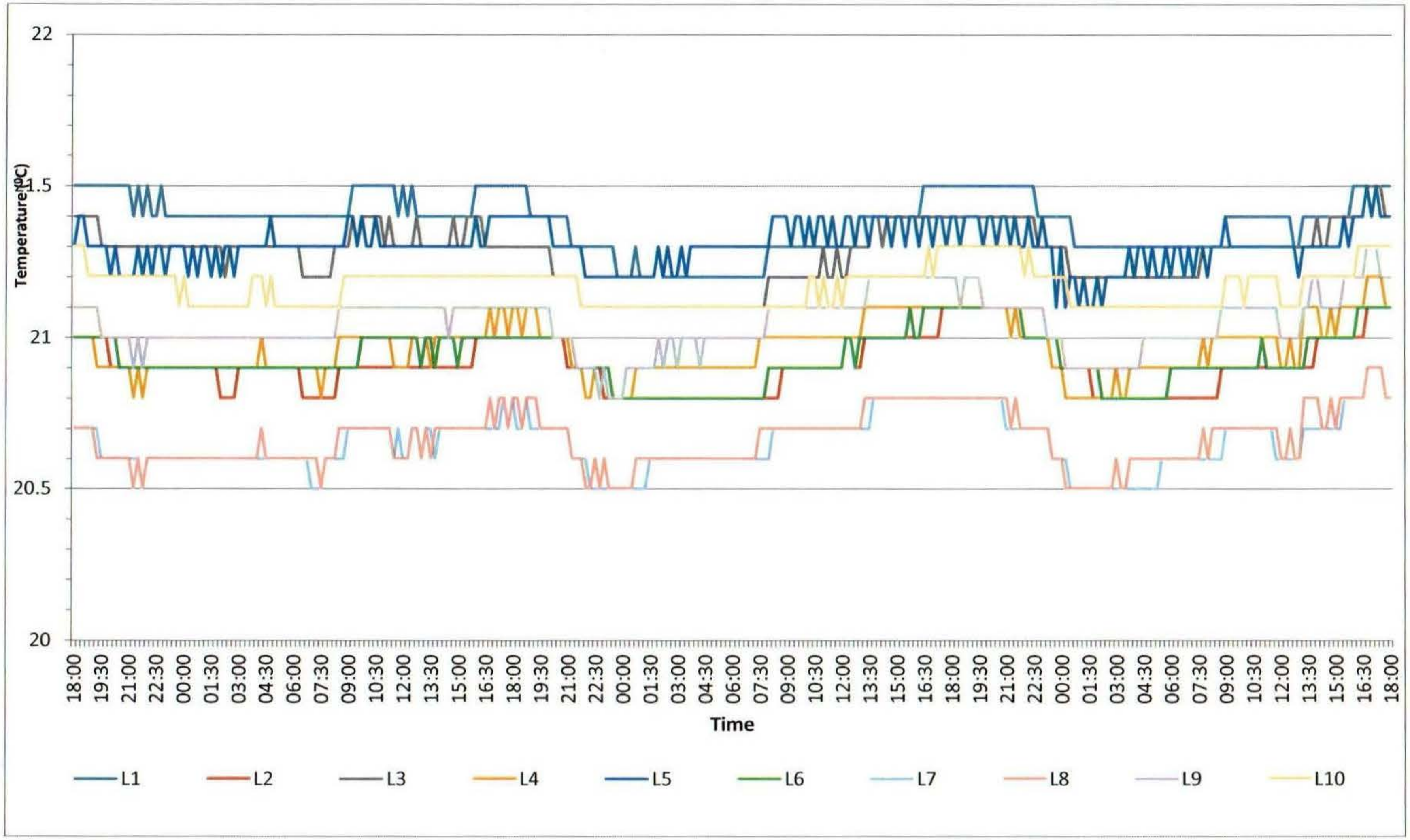


Figure 21: *Temperature mapping trends over 72 hours*

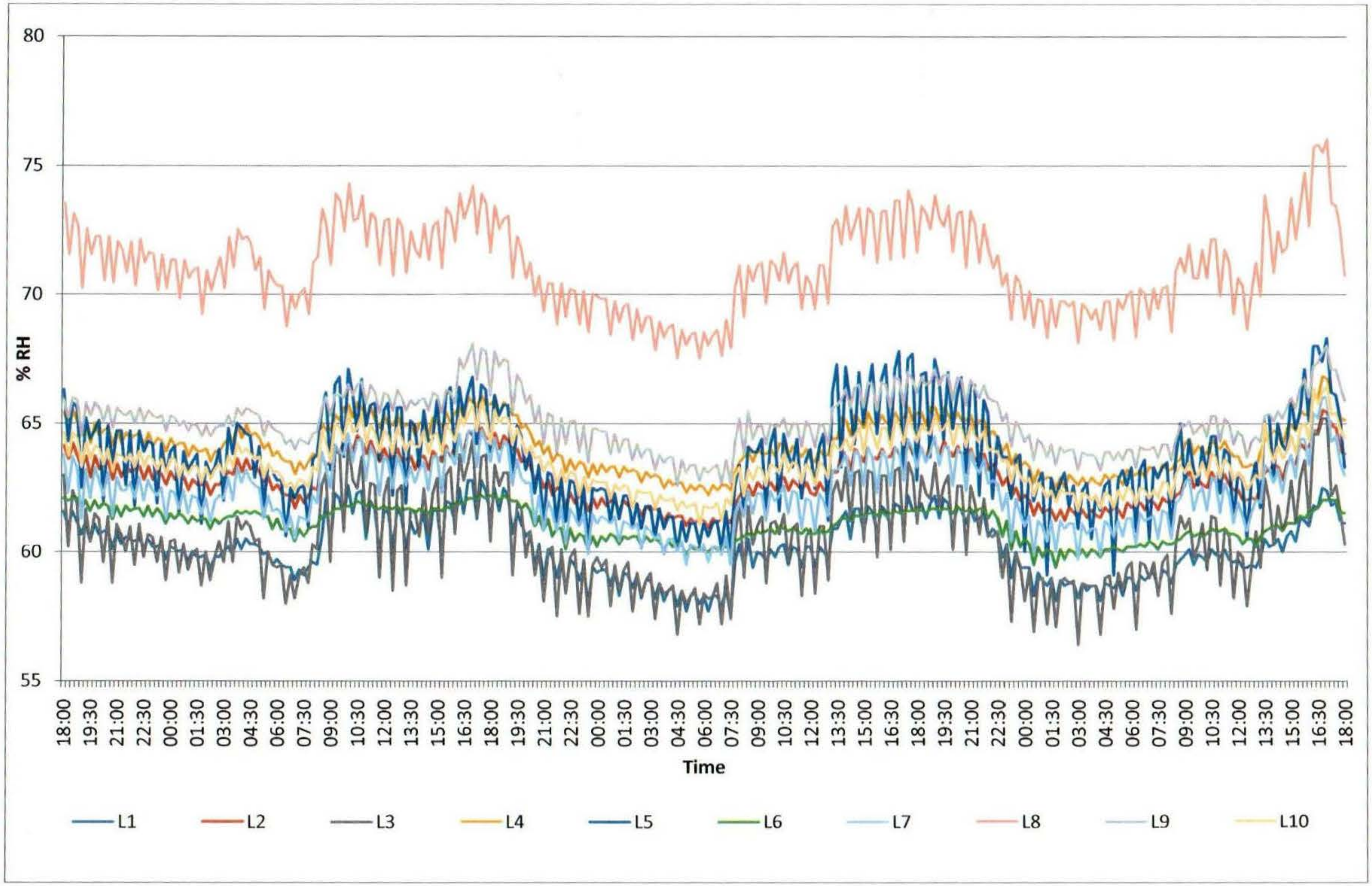


Figure 22: *RH mapping trends over 72 hours*

Appendix 9: Temperature – RH excursion reports as a result of the chilled water loop on AHU 18

CiplaQCi

TEMPERATURE / RH DAILY RECORD
PRODUCTION BLEND STORE, DATALOGGER CODE NO. MTRH 01.
TEMP. LIMIT 19 °C TO 25 °C / RH LIMIT 45 % TO 60 %
From 21-Oct-2019 08:00:00 TO 22-Oct-2019 08:00:00

DATE	TIME	MTRH01 T	MTRH01 RH
21.10.2019	08:00	21.1	55.5
21.10.2019	09:00	21.1	55.8
21.10.2019	10:00	21.1	56.1
21.10.2019	11:00	21.2	58.1
21.10.2019	12:00	21.6	55.7
21.10.2019	13:00	21.6	55.1
21.10.2019	14:00	21.6	54.3
21.10.2019	15:00	21.6	53.6
21.10.2019	16:00	21.7	55.0
21.10.2019	17:00	21.7	53.8
21.10.2019	18:00	22.5	* 65.3
21.10.2019	19:00	22.2	* 73.1
21.10.2019	20:00	22.6	* 64.5
21.10.2019	21:00	22.6	52.2
21.10.2019	22:00	22.2	51.8
21.10.2019	23:00	21.9	51.1
22.10.2019	00:00	21.9	50.7
22.10.2019	01:00	21.8	50.7
22.10.2019	02:00	21.8	50.8
22.10.2019	03:00	21.8	50.8
22.10.2019	04:00	21.5	51.3
22.10.2019	05:00	21.3	51.8
22.10.2019	06:00	21.3	51.8
22.10.2019	07:00	21.7	52.8
22.10.2019	08:00	21.6	54.6
	Min.	21.1	50.7
	Max.	22.6	73.1

Results :- Within limit / Out of limit.

°C : Degrees Celsius, * : Reading out of limit

Remark :

Reviewed By :
Date : 22.10.2019

Checked By :
Date : 25.10.19

ANNEXURE MT-03/A7

Approved By: [signature] Sign & Date: 27-05-19	Implementation Date: 11-06-2019 Sign & Date: [signature] 11-06-19	Issued By: [signature] 22-10-19 Sign & Date

CiplaQCIL

Investigation Report of Temperature / Relative Humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Section I : Reporting of Temperature / Relative Humidity Excursion, Alarms and Data loss

Temperature / Relative humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Equipment Name: Temperature / RH indicator.   Equipment Number: MTRH01, MTRH02, MTRH03.

Make: Anatech.   Set Condition: 19-25°C / 45-60%.

Details of Excursion / Alarms / Data loss :
- Relative humidity is observed to be above the set upper limit, (60.2%, 60.5%, 61.4%, 60.8%, 99.9%, 70.6%, 68.6%) and Temperature above the limit 99.9°C - Bulk store. 65.3%, 73.1%, 64.5% - Blend store and 66.7%, 71.2%, 63.2 - In process store.

Alarm Activation Date (DD.MM.YYYY): 21.10.2019   Time (HH:MM): 08:00, 09:00, 10:00, 11:00, 17:00, 18:00, 19:00, 20:00

[signature] 22.10.2019
Stores/Production Officer / Date

[signature] 22.10.19
Dept. / Date

Section – II : Assessment of Incidence by Production/ Stores / Quality Assurance/ Engineering/ IT

Investigation review started on (DD.MM.YYYY): 22.10.2019   at (HH:MM): 14:00

Details Of Investigation :

Power surge had led to the chiller being in off mode.

[signature] 22.10.19
Stores/ Production/ Engineering/ IT/ Date

[signature] 23.10.19
Dept. Head / Date

[signature] 25.10.19
QA / Date

Section – III: Impact Evaluation, Conclusion, Corrective and Preventive Action

Impact Evaluation :
- All materials and products are stored in double polybags which are kept inside well closed material IPCs.
- Weight re-verification is done on bulk-finished products before being transferred to packing.

O

CiplaQCi

TEMPERATURE / RH DAILY RECORD
PRODUCTION BLEND STORE, DATALOGGER CODE NO. MTRH 01.
TEMP. LIMIT 19 °C TO 25 °C / RH LIMIT 45 % TO 60 %
From 16-Oct-2019 08:00:00 TO 17-Oct-2019 08:00:00

DATE	TIME	MTRH01 T	MTRH01 RH
16.10.2019	08:00	22.0	51.6
16.10.2019	09:00	22.0	52.3
16.10.2019	10:00	22.0	52.4
16.10.2019	11:00	22.3	52.0
16.10.2019	12:00	22.3	52.0
16.10.2019	13:00	22.3	52.0
16.10.2019	14:00	22.3	51.2
16.10.2019	15:00	22.2	51.9
16.10.2019	16:00	22.4	51.5
16.10.2019	17:00	22.7	* 62.4
16.10.2019	18:00	23.0	* 70.8
16.10.2019	19:00	23.1	55.8
16.10.2019	20:00	22.6	51.5
16.10.2019	21:00	22.6	50.2
16.10.2019	22:00	22.3	50.4
16.10.2019	23:00	22.0	50.1
17.10.2019	00:00	22.0	50.0
17.10.2019	01:00	22.0	50.3
17.10.2019	02:00	22.0	49.8
17.10.2019	03:00	22.0	49.7
17.10.2019	04:00	22.0	49.6
17.10.2019	05:00	22.0	49.6
17.10.2019	06:00	21.8	49.9
17.10.2019	07:00	22.0	50.1
17.10.2019	08:00	22.0	50.5
	Min.	21.8	49.6
	Max.	23.1	70.8

Results :- Within limit / Out of limit.

°C : Degrees Celsius, * : Reading out of limit

Remark : RH above the set limit.

Reviewed By :
Date : 17-10.2019

Checked By :
Date : 18-10-19 18-10-19

ANNEXURE MT-03/A7

Approved By: Sign & Date 27.05.19	Implementation Date: 11.06.2019 Sign & Date	Issued By: 17.10.19 Sign & Date

CiplaQCIL

Investigation Report of Temperature / Relative Humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Section I : Reporting of Temperature / Relative Humidity Excursion, Alarms and Data loss

Temperature / Relative humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Equipment Name: Temperature / RH indicator. Equipment Number : MTRH01 MTRH02 MTRH03.

Make: Anatech. Set Condition : 19-25°C / 45-60%.

Details of Excursion / Alarms / Data loss : Relative humidity is above the set limit, (62.4%, 70.8% - Blend store, 63.0%, 71.8% - In-process store and 66.5%, 74.3%, 60.4% - Bulk store).

Alarm Activation Date (DD.MM.YYYY) : 16.10.2019 Time (HH:MM) : 17:00, 18:00 and 19:00

17.10.2019 — Stores/Production Officer / Date

17.10.19 — Dept. / Date

Section – II : Assessment of Incidence by Production/ Stores / Quality Assurance/ Engineering/ IT

Investigation review started on (DD.MM.YYYY) : 17.10.2019 at (HH:MM) : 09:30.

Details Of Investigation :

Power surge lead to dry

Chiller being in off mode.

17.10.2019 — Stores/ Production/ Engineering/ IT/ Date

18.10.19 — Dept. Head / Date

18.10.19 — QA / Date

Section – III: Impact Evaluation, Conclusion, Corrective and Preventive Action

Impact Evaluation :

- All materials and products are stored in well double polybags and placed in well closed material IPCs.
- Analysis is done by GC on bulk finished products as per respective specification.

Q

CiplaQCi

TEMPERATURE / RH DAILY RECORD
PRODUCTION BLEND STORE, DATALOGGER CODE NO. MTRH 01.
TEMP. LIMIT 19 °C TO 25 °C / RH LIMIT 45 % TO 60 %
From 17-Sep-2019 08:00:00 TO 18-Sep-2019 08:00:00

DATE	TIME	MTRH01 T	MTRH01 RH
17.9.2019	08:00	22.5	54.9
17.9.2019	09:00	22.9	51.4
17.9.2019	10:00	23.1	51.2
17.9.2019	11:00	23.3	49.6
17.9.2019	12:00	23.1	53.6
17.9.2019	13:00	23.6	* 60.3
17.9.2019	14:00	23.8	58.1
17.9.2019	15:00	23.9	53.1
17.9.2019	16:00	23.9	51.4
17.9.2019	17:00	24.0	49.4
17.9.2019	18:00	24.0	48.5
17.9.2019	19:00	24.0	55.5
17.9.2019	20:00	24.0	59.9
17.9.2019	21:00	24.5	* 60.1
17.9.2019	22:00	24.7	53.3
17.9.2019	23:00	24.6	47.6
18.9.2019	00:00	24.3	47.9
18.9.2019	01:00	24.3	47.6
18.9.2019	02:00	24.2	47.8
18.9.2019	03:00	24.2	47.4
18.9.2019	04:00	24.2	47.3
18.9.2019	05:00	24.0	47.4
18.9.2019	06:00	23.8	47.8
18.9.2019	07:00	23.8	48.1
18.9.2019	08:00	23.8	48.5
	Min.	22.5	47.3
	Max.	24.7	60.3

Results :- Within limit / Out of limit.

°C : Degrees Celsius, * : Reading out of limit

Remark : RH excursion to be explained in the investigation report.

Reviewed By :
Date : 18.09.2019

Checked By :
Date : 18.09.19

ANNEXURE MT-03/A7

Approved By:	Implementation Date: 11-06-2019	Issued By:
Sign & Date 27-05-19	Sign & Date 11-06-19	Sign & Date 18-09-2019

CiplaQCIL

Investigation Report of Temperature / Relative Humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Section I : Reporting of Temperature / Relative Humidity Excursion, Alarms and Data loss

Temperature / Relative humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Equipment Name: Temperature / RH indicator.

Equipment Number : MTRH01, MTRH02, MTRH03.

Make: Anatech.

Set Condition : 19 - 25°C / 45 - 60%

Details of Excursion / Alarms / Data loss :
Relative humidity observed to be above the set upper limit, (62.9%, 60.3%, 61.5% - bulk store, 60.3%, 60.1% - blend store, 60.1 - inprocess store.

Alarm Activation Date (DD.MM.YYYY) : 17 . 09 . 2019 Time (HH:MM) : 13:00, 14:00, 20:00 and 21:00

18.09.2019 — Stores/Production Officer / Date

18-09-19 — Dept. / Date

Section – II : Assessment of Incidence by Production/ Stores / Quality Assurance/ Engineering/ IT

Investigation review started on (DD.MM.YYYY) : 18 . 09 . 2019. at (HH:MM) : 10:00

Details Of Investigation :

Chiller trip leading to chiller running at half capacity

18.09.2019 — Stores/ Production/ Engineering/ IT/ Date

18.09.19 — Dept. Head / Date

18.09.19 — QA / Date

Section – III: Impact Evaluation, Conclusion, Corrective and Preventive Action

Impact Evaluation :
- All materials and products are stored in double polybags which are placed inside well enclosed material IPCs thus limiting interaction with the external environment.
- Tablets are inspected during the packing activity by the tablet inspection systems placed on packing lines.

* — over writing
18.09.19

(MT-03/F9/1)

S

CiplaQCi

TEMPERATURE / RH DAILY RECORD
PRODUCTION BLEND STORE, DATALOGGER CODE NO. MTRH 01.
TEMP. LIMIT 19 °C TO 25 °C / RH LIMIT 45 % TO 60 %

From 16-Sep-2019 08:00:00 TO 17-Sep-2019 08:00:00

DATE	TIME	MTRH01 T	MTRH01 RH
16.9.2019	08:00	21.1	52.5
16.9.2019	09:00	21.2	52.8
16.9.2019	10:00	21.5	53.7
16.9.2019	11:00	21.7	52.1
16.9.2019	12:00	22.0	52.7
16.9.2019	13:00	22.4	53.5
16.9.2019	14:00	22.6	53.1
16.9.2019	15:00	22.8	53.6
16.9.2019	16:00	23.0	53.4
16.9.2019	17:00	23.0	51.9
16.9.2019	18:00	23.0	56.7
16.9.2019	19:00	23.2	* 60.1
16.9.2019	20:00	23.6	* 60.2
16.9.2019	21:00	23.6	* 60.3
16.9.2019	22:00	23.1	54.1
16.9.2019	23:00	22.8	53.0
17.9.2019	00:00	22.8	52.1
17.9.2019	01:00	22.6	52.3
17.9.2019	02:00	22.5	52.2
17.9.2019	03:00	22.4	52.1
17.9.2019	04:00	22.4	52.9
17.9.2019	05:00	22.4	52.5
17.9.2019	06:00	22.4	52.5
17.9.2019	07:00	22.4	51.6
17.9.2019	08:00	22.5	54.9
	Min.	21.1	51.6
	Max.	23.6	60.3

Results :- Within limit / Out of limit.

°C : Degrees Celsius, * : Reading out of limit

Remark : Investigation logged on to explain the RH excursion.

Reviewed By :
Date : 17.09.2019

Checked By : LB
Date : 17.09.19

T

ANNEXURE MT-03/A7

Approved By: Sign & Date 27.05.19	Implementation Date: 11-06-2019 Sign & Date 11-06-19	Issued By: Sign & Date 17-09-2019

CiplaQCIL

Investigation Report of Temperature / Relative Humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Section I : Reporting of Temperature / Relative Humidity Excursion, Alarms and Data loss

Temperature / Relative humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Equipment Name: Temperature / RH indicator.

Equipment Number : ~~MTRH 04~~, MTRH02, MTRH03, MTRH01

Make: Anatech

Set Condition : 17-25°C / 45-60%.

Details of Excursion / Alarms / Data loss :
Relative humidity observed to be above the set limit, (60.4%, 61.1% - in process store, 60.5%, 64.2%, 64.7%, 65.3 - Bulk store, 60.1%, 60.2% and 60.3% - Blend store).

Alarm Activation Date (DD.MM.YYYY) : 16.09.2019. Time (HH:MM) : 18:00, 19:00, 20:00 and 21:00.

17-09-2019.

Stores/Production Officer / Date

17.09.19

Dept. / Date

Section – II : Assessment of Incidence by Production/ Stores / Quality Assurance/ Engineering/ IT

Investigation review started on (DD.MM.YYYY) : 17.09.2019 at (HH:MM) : 10:00.

Details Of Investigation :
Power outage had led to the Aircon being in off mode

17.09.19.

Stores/ Production/ Engineering/ IT/ Date

17.09.19

Dept. Head / Date

17.09.19

QA / Date

Section – III: Impact Evaluation, Conclusion, Corrective and Preventive Action

Impact Evaluation :
- All materials and products are kept in double polybags which are placed inside well enclosed material IPCs thus limiting interaction with the external environment.
- In process checks are performed by both QA and production personnel during the compression activity thus being able to detect any defects on the materials and products

*Overwriting
17.07.2019.

(MT-03/F9/1)

U

CiplaQCi

TEMPERATURE / RH DAILY RECORD
PRODUCTION BULK STORE, DATALOGGER CODE NO. MTRH 03.
TEMP. LIMIT 19 °C TO 25 °C / RH LIMIT 45 % TO 60 %
From 02-Sep-2019 08:00:00 TO 03-Sep-2019 08:00:00

DATE	TIME	MTRH03 T	MTRH03 RH
2.9.2019	08:00	20.7	55.2
2.9.2019	09:00	20.8	55.1
2.9.2019	10:00	20.9	55.3
2.9.2019	11:00	20.9	56.4
2.9.2019	12:00	21.0	56.8
2.9.2019	13:00	21.0	59.6
2.9.2019	14:00	21.6	* 61.5
2.9.2019	15:00	21.5	56.7
2.9.2019	16:00	21.4	51.4
2.9.2019	17:00	21.3	51.3
2.9.2019	18:00	21.3	52.0
2.9.2019	19:00	21.3	51.7
2.9.2019	20:00	21.3	51.6
2.9.2019	21:00	21.5	51.4
2.9.2019	22:00	21.7	50.7
2.9.2019	23:00	21.7	50.7
3.9.2019	00:00	21.8	50.3
3.9.2019	01:00	22.1	50.7
3.9.2019	02:00	22.1	50.9
3.9.2019	03:00	22.0	49.8
3.9.2019	04:00	22.0	49.8
3.9.2019	05:00	22.0	49.5
3.9.2019	06:00	22.1	49.2
3.9.2019	07:00	22.0	49.4
3.9.2019	08:00	21.9	50.8
	Min.	20.7	49.2
	Max.	22.1	61.5

Results :- Within limit / Out of limit.

°C : Degrees Celsius, * : Reading out of limit

Remark : RH excursion to be explained.

Reviewed By :
Date : 03.09.2019.

Checked By : LB
Date : 03.09.19

ANNEXURE MT-03/A7

Approved By: [signature] Sign & Date 27.05.19	Implementation Date: 11.06.2019 Sign & Date [signature] 11.06.19	Issued By: [signature] 03.09.2019 Sign & Date

CiplaQCIL

Investigation Report of Temperature / Relative Humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Section I : Reporting of Temperature / Relative Humidity Excursion, Alarms and Data loss

Temperature / Relative humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Equipment Name: Temperature / RH indicator.

Equipment Number : MTR H02, MTR H03

Make: Anatech.

Set Condition : 19-25°C / 45-60%.

Details of Excursion / Alarms / Data loss : Relative humidity above the limit. (61.5% and 60.2%)

Alarm Activation Date (DD.MM.YYYY) : 02.09.2019 Time (HH:MM) : 14:00.

[signature] 03.09.2019 — Stores/Production Officer / Date

[signature] 03.09.19 — Dept. / Date

Section – II : Assessment of Incidence by Production/ Stores / Quality Assurance/ Engineering/ IT

Investigation review started on (DD.MM.YYYY) : 03.09.2019. at (HH:MM) : 09:40

Details Of Investigation :

[illegible] of [illegible] [illegible] tripped.

[signature] 03.09.19 — Stores/ Production/ Engineering/ IT/ Date

[signature] 03.09.19 — Dept. Head / Date

[signature] 03.09.19 — QA / Date

Section – III: Impact Evaluation, Conclusion, Corrective and Preventive Action

Impact Evaluation :

* ~~Stor~~ All materials and products are kept in double polybags which are placed in well closed material IPCs.

- Tablets are inspected during the packing activity by the tablet inspection machines placed on the packing lines.

* Wrong entry. [signature]

CiplaQCi

TEMPERATURE / RH DAILY RECORD
PRODUCTION BLEND STORE, DATALOGGER CODE NO. MTRH 01.
TEMP. LIMIT 19 °C TO 25 °C / RH LIMIT 45 % TO 60 %
From 27-Aug-2019 08:00:00 TO 28-Aug-2019 08:00:00

DATE	TIME	MTRH01 T	MTRH01 RH
27.8.2019	08:00	22.4	53.6
27.8.2019	09:00	22.5	53.8
27.8.2019	10:00	22.5	53.7
27.8.2019	11:00	22.9	54.5
27.8.2019	12:00	23.0	52.8
27.8.2019	13:00	22.9	52.2
27.8.2019	14:00	22.9	51.6
27.8.2019	15:00	22.9	51.8
27.8.2019	16:00	23.0	51.7
27.8.2019	17:00	23.0	53.1
27.8.2019	18:00	23.0	53.8
27.8.2019	19:00	23.2	* 60.3
27.8.2019	20:00	23.3	* 62.1
27.8.2019	21:00	23.6	* 60.1
27.8.2019	22:00	23.4	52.0
27.8.2019	23:00	23.0	51.6
28.8.2019	00:00	23.1	50.7
28.8.2019	01:00	23.0	50.8
28.8.2019	02:00	23.0	51.0
28.8.2019	03:00	22.8	51.3
28.8.2019	04:00	22.7	51.1
28.8.2019	05:00	22.6	51.5
28.8.2019	06:00	22.6	51.4
28.8.2019	07:00	22.6	52.1
28.8.2019	08:00	22.7	52.5
	Min.	22.4	50.7
	Max.	23.6	62.1

Results :- Within limit / Out of limit.

°C : Degrees Celsius, * : Reading out of limit

Remark : RH out of limit on 27.8.2019 from 19:00 to 21:00

Reviewed By : [signature]
Date : 28.8.2019.

Checked By : [signature]
Date : 29.08.19

ANNEXURE MT-03/A7

Approved By: Sign & Date 27.08.19	Implementation Date: 11.06.2019 Sign & Date 11.06.19	Issued By: Sign & Date 29.08.2019

CiplaQCIL

Investigation Report of Temperature / Relative Humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Section I : Reporting of Temperature / Relative Humidity Excursion, Alarms and Data loss

Temperature / Relative humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Equipment Name: Temperature / RH indicator.　　Equipment Number : MTRH01 MTRH02 MTRH03.

Make: Anatech.　　Set Condition : 19 - 25°C / 45 - 60%.

Details of Excursion / Alarms / Data loss : Relative humidity observed to be above the set limit (60.3%, 62.1%, 60.1%, 60.5%, 61.5% and 60.2%).

Alarm Activation Date (DD.MM.YYYY) : 27 . 08 . 2019　Time (HH:MM) : 19:00, 20:00 and 21:00.

~~28~~ 29 . 07 . 2019　　29.08.19

Stores/Production Officer / Date　　Dept. / Date

Section – II : Assessment of Incidence by Production/ Stores / Quality Assurance/ Engineering/ IT

Investigation review started on (DD.MM.YYYY) : 29 . 08 . 2019　at (HH:MM) : 09 : 30.

Details Of Investigation :

Power surge that led to the chiller being in off mode. This wasn't detected though

29.08.19　　29.08.19　　29.08.19

Stores/ Production/ Engineering/ IT/ Date　　Dept. Head / Date　　QA / Date

Section – III: Impact Evaluation, Conclusion, Corrective and Preventive Action

Impact Evaluation :
- All materials and products are kept in double polybags and placed in well closed material IPCs.
- Tablets are inspected by the tablet inspection machines during the packing activity thus being to detect any defects on the tablets.

wrong entry. 28.8.2019

(MT-03/F9/1)

Y

CiplaQCi

TEMPERATURE / RH DAILY RECORD
PRODUCTION BLEND STORE, DATALOGGER CODE NO. MTRH 01.
TEMP. LIMIT 19 °C TO 25 °C / RH LIMIT 45 % TO 60 %
From 15-Aug-2019 08:00:00 TO 16-Aug-2019 08:00:00

DATE	TIME	MTRH01 T	MTRH01 RH
15.8.2019	08:00	23.1	52.1
15.8.2019	09:00	23.1	54.0
15.8.2019	10:00	23.1	56.6
15.8.2019	11:00	23.4	54.7
15.8.2019	12:00	23.4	54.2
15.8.2019	13:00	23.4	53.1
15.8.2019	14:00	23.4	52.5
15.8.2019	15:00	23.3	51.9
15.8.2019	16:00	23.4	51.8
15.8.2019	17:00	23.6	51.6
15.8.2019	18:00	23.2	51.9
15.8.2019	19:00	23.1	51.8
15.8.2019	20:00	23.3	52.0
15.8.2019	21:00	23.2	52.0
15.8.2019	22:00	23.1	52.3
15.8.2019	23:00	23.1	52.3
16.8.2019	00:00	23.1	52.3
16.8.2019	01:00	23.0	51.2
16.8.2019	02:00	22.9	51.7
16.8.2019	03:00	22.9	52.1
16.8.2019	04:00	23.0	52.3
16.8.2019	05:00	23.0	52.1
16.8.2019	06:00	23.0	52.0
16.8.2019	07:00	23.1	52.2
16.8.2019	08:00	23.7	* 63.1
	Min.	22.9	51.2
	Max.	23.7	63.1

Results :- Within limit / Out of limit.

°C : Degrees Celsius, * : Reading out of limit

Remark : RH excursion to be explained.

Reviewed By : [signature]
Date : 16.08.2019.

Checked By :
Date :

ANNEXURE MT-03/A7

Approved By: [signature] Sign & Date 27.08.19	Implementation Date: 11.06.2019 Sign & Date [signature] 11.06.19	Issued By: [signature] Sign & Date 16.08.2019

CiplaQCIL

Investigation Report of Temperature / Relative Humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Section I : Reporting of Temperature / Relative Humidity Excursion, Alarms and Data loss

Temperature / Relative humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Equipment Name: Temperature / RH indicator.

Equipment Number : MTRH01, MTRH03

Make: Anatech.

Set Condition : 19-25°C / 45-60%

Details of Excursion / Alarms / Data loss : Relative humidity above the limit, (63.1% - Blend store and 61.6% - Bulk store).

Alarm Activation Date (DD.MM.YYYY) : 16.08.2019. Time (HH:MM) : 08:00.

[signature] 16.08.2019 — Stores/Production Officer / Date

[signature] 16.08.19 — Dept. / Date

Section – II : Assessment of Incidence by Production/ Stores / Quality Assurance/ Engineering/ IT

Investigation review started on (DD.MM.YYYY) : 16.08.2019 at (HH:MM) : 15:00

Details Of Investigation :

Lower voltage leading to two Chillers being in off mode.

[signature] 16.08.19 — Stores/ Production/ Engineering/ IT/ Date

[signature] 19.08.19 — Dept. Head / Date

[signature] 19.08.19 — QA / Date

Section – III: Impact Evaluation, Conclusion, Corrective and Preventive Action

Impact Evaluation :
- Blend is stored in well closed IPCs thus limiting interaction with the external environment.
- Bulk finished tablets are inspected during the packing activity by the tablet inspection systems placed on the packing lines.

CiplaQCi

TEMPERATURE / RH DAILY RECORD
PRODUCTION BLEND STORE, DATALOGGER CODE NO. MTRH 01.
TEMP. LIMIT 19 °C TO 25 °C / RH LIMIT 45 % TO 60 %
From 24-Jul-2019 08:00:00 TO 25-Jul-2019 08:00:00

DATE	TIME	MTRH01 T	MTRH01 RH
24.7.2019	08:00	22.8	49.7
24.7.2019	09:00	22.8	50.3
24.7.2019	10:00	22.8	50.4
24.7.2019	11:00	22.9	50.3
24.7.2019	12:00	23.4	* 66.3
24.7.2019	13:00	23.5	55.0
24.7.2019	14:00	23.3	52.0
24.7.2019	15:00	23.3	51.8
24.7.2019	16:00	23.2	51.2
24.7.2019	17:00	23.1	51.2
24.7.2019	18:00	22.8	51.3
24.7.2019	19:00	22.8	50.9
24.7.2019	20:00	22.7	52.6
24.7.2019	21:00	22.9	50.0
24.7.2019	22:00	22.9	50.0
24.7.2019	23:00	22.7	50.7
25.7.2019	00:00	22.8	50.2
25.7.2019	01:00	23.0	49.4
25.7.2019	02:00	23.0	49.1
25.7.2019	03:00	23.0	48.7
25.7.2019	04:00	22.9	48.7
25.7.2019	05:00	22.9	49.0
25.7.2019	06:00	22.8	49.2
25.7.2019	07:00	22.9	50.0
25.7.2019	08:00	22.8	51.7
	Min.	22.7	48.7
	Max.	23.5	66.3

Results :- Within limit / Out of limit.

°C : Degrees Celsius, * : Reading out of limit

Remark : RH out of limit at 12:00.

Reviewed By [signature]
Date : 25.07.2019.

Checked By : [signature] LB
Date : 25.07.19

ANNEXURE MT-03/A7

Approved By:	Implementation Date:	Issued By:
Sign & Date 27.05.19	11.06.2019 Sign & Date 11.06.19	25.07.2019 Sign & Date

CiplaQCIL

Investigation Report of Temperature / Relative Humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Section I : Reporting of Temperature / Relative Humidity Excursion, Alarms and Data loss

Temperature / Relative humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Equipment Name: Temperature / RH Indicator

Equipment Number : MTRH-01, MTRH-02, MTRH-03.

Make: Anatech.

Set Condition : 19-25°C / 45-60%

Details of Excursion / Alarms / Data loss : RH observed to be above the set limit in Blend store, Inprocess store and Bulk store on 24.07.2019 at 12:00. RH recorded as (66.3, 68.2 and 65.8% respectively).

Alarm Activation Date (DD.MM.YYYY) : 24.07.2019 Time (HH:MM) : 12:00

25.07.2019. — Stores/Production Officer / Date

25.07.19 — Dept. / Date

Section – II : Assessment of Incidence by Production/ Stores / Quality Assurance/ Engineering/ IT

Investigation review started on (DD.MM.YYYY) : 25.07.2019. at (HH:MM) : 10:30

Details Of Investigation :

Chiller momentarily switched off to close and a leaking chilled water pipe.

25.07.19 — Stores/ Production/ Engineering/ IT/ Date

25.07.19 — Dept. Head / Date

25.07.19 — QA / Date

Section – III: Impact Evaluation, Conclusion, Corrective and Preventive Action

Impact Evaluation :
- Blend is stored in well closed IPCs thus limiting interaction with the external environment.
- Tablets are stored in double polybags which are kept in well closed IPCs thus limiting interaction with the external environment.
- Weight reverification is done before batches being transferred to packing.

CC

CiplaQCi

TEMPERATURE / RH DAILY RECORD
PRODUCTION BLEND STORE, DATALOGGER CODE NO. MTRH 01.
TEMP. LIMIT 19 °C TO 25 °C / RH LIMIT 45 % TO 60 %
From 02-Jul-2019 08:00:00 TO 03-Jul-2019 08:00:00

DATE	TIME	MTRH01 T	MTRH01 RH
2.7.2019	08:00	23.3	52.5
2.7.2019	09:00	23.6	53.0
2.7.2019	10:00	24.0	52.3
2.7.2019	11:00	23.9	52.2
2.7.2019	12:00	24.0	51.5
2.7.2019	13:00	24.0	51.6
2.7.2019	14:00	23.6	46.9
2.7.2019	15:00	23.4	49.7
2.7.2019	16:00	23.3	49.9
2.7.2019	17:00	23.0	49.8
2.7.2019	18:00	23.7	* 67.6
2.7.2019	19:00	24.5	57.4
2.7.2019	20:00	24.5	* 62.4
2.7.2019	21:00	24.0	48.6
2.7.2019	22:00	23.8	48.0
2.7.2019	23:00	23.5	47.8
3.7.2019	00:00	23.3	48.3
3.7.2019	01:00	23.2	48.2
3.7.2019	02:00	23.0	48.5
3.7.2019	03:00	23.0	48.7
3.7.2019	04:00	23.0	48.5
3.7.2019	05:00	23.0	48.5
3.7.2019	06:00	22.9	49.1
3.7.2019	07:00	22.9	49.5
3.7.2019	08:00	22.8	50.1
	Min.	22.8	46.9
	Max.	24.5	67.6

Results :- Within limit / Out of limit.

°C : Degrees Celsius, * : Reading out of limit

Remark : RH above the set limit.

Reviewed By :
Date : 03.07.2019

Checked By :
Date : 05.07.2019

ANNEXURE MT-03/A7

Approved By: [signature] Sign & Date 27.05.19	Implementation Date: 11.06.2019 Sign & Date [signature] 11.06.19	Issued By: [signature] 03.07.19 Sign & Date

CiplaQCIL

Investigation Report of Temperature / Relative Humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Section I : Reporting of Temperature / Relative Humidity Excursion, Alarms and Data loss

Temperature / Relative humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Equipment Name: Temperature /RH indicator. Equipment Number : MTRH01, MTRH02, MTRH03

Make: Anatech. Set Condition : 19-25°C /45-60%.

Details of Excursion / Alarms / Data loss : Relative humidity observed to be above the set limits, (66.1%, 61.2% bulk store, 67.6%, 62.4 blend store and 65.5%, 68.6% inprocess store.

Alarm Activation Date (DD.MM.YYYY) : 02.07.2019 Time (HH:MM) : 18:00 and 20:00.

[signature] 03.07.2019 — Stores/Production Officer / Date

[signature] 03.07.2019 — Dept. / Date

Section – II : Assessment of Incidence by Production/ Stores / Quality Assurance/ Engineering/ IT

Investigation review started on (DD.MM.YYYY) : 03.07.2019 at (HH:MM) : 12:30.

Details Of Investigation :

[illegible handwriting]

[illegible handwriting] made

[signature] 03.07.19 — Stores/ Production/ Engineering/ IT/ Date

[signature] 05.07.19 — Dept. Head / Date

[signature] 05.07.19 — QA / Date

Section – III: Impact Evaluation, Conclusion, Corrective and Preventive Action

Impact Evaluation :
- blend is stored in well closed IPCs thus limiting ~~no~~ interaction between blend and the external environment.
- All batches are analysed by QC at bulk finished stage and thus any effect of excursions on the product will be identified.

[signature] 05.07.19

(MT-03/F9/1)

EE

CiplaQCi

TEMPERATURE / RH DAILY RECORD
PRODUCTION INPROCESS STORE, DATALOGGER CODE NO. MTRH 02.
TEMP. LIMIT 19 °C TO 25 °C / RH LIMIT 45 % TO 60 %
From 18-Jun-2019 08:00:00 TO 19-Jun-2019 08:00:00

DATE	TIME	MTRH02 T	MTRH02 RH
18.6.2019	08:00	22.1	57.4
18.6.2019	09:00	22.1	59.3
18.6.2019	10:00	22.0	59.5
18.6.2019	11:00	22.2	59.4
18.6.2019	12:00	21.8	60.0
18.6.2019	13:00	21.9	* 60.4
18.6.2019	14:00	22.6	* 60.1
18.6.2019	15:00	22.7	58.2
18.6.2019	16:00	22.7	58.4
18.6.2019	17:00	22.8	58.9
18.6.2019	18:00	22.8	57.1
18.6.2019	19:00	22.9	56.3
18.6.2019	20:00	22.9	56.6
18.6.2019	21:00	22.8	57.5
18.6.2019	22:00	22.8	58.2
18.6.2019	23:00	23.0	58.0
19.6.2019	00:00	22.9	57.9
19.6.2019	01:00	23.0	57.9
19.6.2019	02:00	22.9	57.9
19.6.2019	03:00	22.9	57.8
19.6.2019	04:00	22.9	57.5
19.6.2019	05:00	22.9	57.4
19.6.2019	06:00	22.8	57.2
19.6.2019	07:00	22.8	55.6
	Min.	21.8	55.6
	Max.	23.0	60.4

Results :- Within limit / Out of limit.

°C : Degrees Celsius, * : Reading out of limit

Remark : Investigation to be done.

Reviewed By : [signature]
Date : 19.06.2019

Checked By : [signature]
Date : 20.06.2019

ANNEXURE MT-03/A7

Approved By:	Implementation Date: 11-06-2019	Issued By:
Sign & Date 27-05-19	Sign & Date 11-06-19	Sign & Date 19-06-2019

CiplaQCIL

Investigation Report of Temperature / Relative Humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Section I : Reporting of Temperature / Relative Humidity Excursion, Alarms and Data loss

Temperature / Relative humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Equipment Name: Temperature /RH indicator.

Equipment Number : MTRH02.

Make: Anatech.

Set Condition : 19-25°C /45-60%.

Details of Excursion / Alarms / Data loss :

Relative humidity observed to be above the set parameters. (60.4% and 60.1%).

Alarm Activation Date (DD.MM.YYYY) : 18.06.2019. Time (HH:MM) : 13:00 and 14:00.

19.06.2019 — Stores/Production Officer / Date

19.06.19 — Dept. / Date

Section – II : Assessment of Incidence by Production/ Stores / Quality Assurance/ Engineering/ IT

Investigation review started on (DD.MM.YYYY) : 19.06.2019 at (HH:MM) : 12:30.

Details Of Investigation :

Chiller momentarily switched off as a leaking chilled water pipe was being fixed

20.06.19 — Stores/ Production/ Engineering/ IT/ Date

20.06.19 — Dept. Head / Date

20.06.19 — QA / Date

Section – III: Impact Evaluation, Conclusion, Corrective and Preventive Action

Impact Evaluation :

- All materials and products in inprocess store are stored in well closed material IPCs thus no interaction with the external environment.
- Inprocess checks are done by both production and quality assurance according to MT-06 version 07.

GG

CiplaQCi

TEMPERATURE / RH DAILY RECORD
PRODUCTION BLEND STORE, DATALOGGER CODE NO. MTRH 01.
TEMP. LIMIT 19 °C TO 25 °C / RH LIMIT 45 % TO 60 %
From 17-Jun-2019 08:00:00 TO 18-Jun-2019 08:00:00

DATE	TIME	MTRH01 T	MTRH01 RH
17.6.2019	08:00	21.1	53.8
17.6.2019	09:00	21.3	53.1
17.6.2019	10:00	21.5	52.1
17.6.2019	11:00	21.6	52.1
17.6.2019	12:00	22.3	* 60.1
17.6.2019	13:00	22.1	52.5
17.6.2019	14:00	23.3	* 62.1
17.6.2019	15:00	23.0	54.4
17.6.2019	16:00	22.8	53.3
17.6.2019	17:00	22.9	52.4
17.6.2019	18:00	22.8	51.2
17.6.2019	19:00	22.6	50.9
17.6.2019	20:00	22.8	49.7
17.6.2019	21:00	22.7	49.1
17.6.2019	22:00	22.5	49.3
17.6.2019	23:00	22.3	49.8
18.6.2019	00:00	22.3	49.7
18.6.2019	01:00	22.3	49.9
18.6.2019	02:00	22.3	49.8
18.6.2019	03:00	22.1	50.3
18.6.2019	04:00	22.0	50.4
18.6.2019	05:00	22.0	50.2
18.6.2019	06:00	21.9	49.2
18.6.2019	07:00	21.8	51.3
	Min.	21.1	49.1
	Max.	23.3	62.1

Results :- Within limit / Out of limit.

°C : Degrees Celsius, * : Reading out of limit

Remark : Investigation to be done.

Reviewed By :
Date : 17.06.2019

Checked By :
Date : 18.06.19

ANNEXURE MT-03/A7

Approved By: [signature] Sign & Date 27.05.19	Implementation Date: 11.06.2019 Sign & Date [signature] 11.06.19	Issued By: [signature] Sign & Date 18.06.2019

CiplaQCIL

Investigation Report of Temperature / Relative Humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Section I : Reporting of Temperature / Relative Humidity Excursion, Alarms and Data loss

Temperature / Relative humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Equipment Name: Temperature / RH indicator.   Equipment Number : NTRH01, NTRH02, NTRH03.

Make: Anatech.   Set Condition : 19-25°C / 45-60%

Details of Excursion / Alarms / Data loss :
Relative humidity observed to be above the set limit, (60.1%, 62.1% blend store, 60.1%, 63.1% in process store and 60.4%, 68.7% bulk store).

Alarm Activation Date (DD.MM.YYYY) : 17.06.2019   Time (HH:MM) : 12:00, 13:00 and 14:00.

[signature] 17.06.2019   [signature] 18.06.2019

Stores/Production Officer / Date   Dept. / Date

Section – II : Assessment of Incidence by Production/ Stores / Quality Assurance/ Engineering/ IT

Investigation review started on (DD.MM.YYYY) : 18.06.2019   at (HH:MM) : 11:00.

Details Of Investigation :
- Chiller switched off at around 1200 hrs so as to close out a leaking of chilled water on the macro purifier
- At around 1400 hrs, operator failed to top up water in the chilled water loop, hence leading to low water pressure in the loop.

[signature] 18.06.19   [signature] 18.06.2019   [signature] 18.06.19

Stores/ Production/ Engineering/ IT/ Date   Dept. Head / Date   QA / Date

Section – III: Impact Evaluation, Conclusion, Corrective and Preventive Action

Impact Evaluation :
- All products and materials are stored in well fastened double polybags and kept inside well enclosed IPCs which limits interaction with the external environment.
- Analysis is done bulk finished tablets.

CiplaQCi

TEMPERATURE / RH DAILY RECORD
PRODUCTION BLEND STORE, DATALOGGER CODE NO. MTRH 01.
TEMP. LIMIT 19 °C TO 25 °C / RH LIMIT 45 % TO 60 %
From 07-Jun-2019 08:00:00 TO 10-Jun-2019 08:00:00

DATE	TIME	MTRH01 T	MTRH01 RH
7.6.2019	08:00	23.2	51.8
7.6.2019	09:00	23.2	52.6
7.6.2019	10:00	23.3	51.9
7.6.2019	11:00	23.3	54.2
7.6.2019	12:00	23.3	51.6
7.6.2019	13:00	23.5	56.2
7.6.2019	14:00	24.2	* 64.2
7.6.2019	15:00	24.3	* 71.2
7.6.2019	16:00	24.4	56.5
7.6.2019	17:00	24.1	52.0
7.6.2019	18:00	24.0	50.7
7.6.2019	19:00	23.7	49.0
7.6.2019	20:00	23.7	48.5
7.6.2019	21:00	23.5	48.4
7.6.2019	22:00	23.3	47.0
7.6.2019	23:00	23.3	47.4
8.6.2019	00:00	22.9	48.1
8.6.2019	01:00	23.4	48.3
8.6.2019	02:00	23.4	47.9
8.6.2019	03:00	23.3	47.6
8.6.2019	04:00	23.2	48.1
8.6.2019	05:00	23.1	47.3
8.6.2019	06:00	23.0	47.3
8.6.2019	07:00	23.0	47.1
8.6.2019	08:00	23.0	48.4
8.6.2019	09:00	23.2	50.0
8.6.2019	10:00	23.0	52.3
8.6.2019	11:00	23.1	52.6
8.6.2019	12:00	23.5	52.2
8.6.2019	13:00	23.7	53.4
8.6.2019	14:00	23.6	53.3
8.6.2019	15:00	23.7	52.6
8.6.2019	16:00	23.6	51.2
8.6.2019	17:00	23.6	51.6
8.6.2019	18:00	23.6	51.3
8.6.2019	19:00	23.4	49.8
8.6.2019	20:00	23.3	50.1
8.6.2019	21:00	23.5	50.0
8.6.2019	22:00	23.4	49.5
8.6.2019	23:00	23.2	49.3
9.6.2019	00:00	23.0	50.0
9.6.2019	01:00	23.3	50.8
9.6.2019	02:00	23.4	50.5
9.6.2019	03:00	23.2	51.6
9.6.2019	04:00	23.0	51.2
9.6.2019	05:00	23.1	50.4
9.6.2019	06:00	23.1	49.8
9.6.2019	07:00	23.0	51.3
9.6.2019	08:00	23.0	50.5
9.6.2019	09:00	23.0	51.1
9.6.2019	10:00	23.1	52.1
9.6.2019	11:00	23.3	51.8
9.6.2019	12:00	23.3	52.2
9.6.2019	13:00	23.4	51.4
9.6.2019	14:00	23.3	51.1
9.6.2019	15:00	23.3	51.1
9.6.2019	16:00	23.5	55.6

ANNEXURE MT-03/A7

Approved By: 28.09.18 Sign & Date	Implementation Date: 05.10.2018 Sign & Date 05-10-2018	Issued By: Sign & Date 10.06.2019

CiplaQCIL

Investigation Report of Temperature / Relative Humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Section I : Reporting of Temperature / Relative Humidity Excursion, Alarms and Data loss

Temperature / Relative humidity Excursion, Alarms and Data loss of Anatech Online Temperature and RH Monitoring System

Equipment Name: Temperature / RH indicator.

Equipment Number : MTRH01, MTRH02, MTRH03.

Make: Anatech.

Set Condition : 19-25°C / 45-60%.

Details of Excursion / Alarms / Data loss :

Temperature above the set limit, (25.4°C and 25.3°C) in process store.

Relative humidity above the set limit, (63.6%, 68.9%, 64.2%, 71.2%, 70.4% and 75.4%)

Alarm Activation Date (DD.MM.YYYY) : 07.06.2019. Time (HH:MM) : 14:00, 15:00 and 20:00.

10.06.2019 — Stores/Production Officer / Date

10.06.19 — Dept. / Date

Section – II : Assessment of Incidence by Production/ Stores / Quality Assurance/ Engineering/ IT

Investigation review started on (DD.MM.YYYY) : 10.06.2019. at (HH:MM) : 11:40.

Details Of Investigation :

Power outage which eventually led into tripping of the chillers as a result of drawing high current

10.06.19 — Stores/ Production/ Engineering/ IT/ Date

Dept. Head / Date 10.06.19

10.06.19 — QA / Date

Section – III: Impact Evaluation, Conclusion, Corrective and Preventive Action

Impact Evaluation :

- Tablets are inspected during the packing activity by the tablet inspection systems placed on the packing lines.
- All products and material are kept inside double polybags and stored inside well enclosed IPCs which limits interaction with the external environment.
- Weight reverification is done on bulk-fabricated tablets before transferred to packing.

KK