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REVIEW ARTICLE

Pure Air, Perfect Medicine: A Review on How HVAC System Shape the Pharmaceutical Industry

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ABSTRACT
Heating, Ventilating, and Air Conditioning (HVAC) systems play a vital role in maintaining the environmental conditions necessary for pharmaceutical manufacturing and storage. These systems maintain critical parameters such as temperature, humidity, cleanliness, and airflow patterns. It uses various technologies to control the temperature, humidity, and purity of the air in an enclosed space. HVAC (Heating, Ventilating, and Air Conditioning) systems must be integrated with efficient control to maintain standard atmospheric parameters under any load conditions. This review highlights the types, importance, and role of HVAC systems in the pharmaceutical industry.
Keywords*: HVAC, GMP, Air Quality, Energy Efficiency, Risk Management, Pharmaceutical Industry, Sustainable Manufacturing, SDG 3 (Good Health and Well-Being), SDG 9 (Industry, Innovation and Infrastructure), SDG 12 (Responsible Consumption and Production), SDG 13 (Climate Action)*

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INTRODUCTION

In the pharmaceutical industry, the ventilation system is crucial. The quantity of microorganisms in the air and the temperature inside the enclosed space can change without a ventilation system, which could lead to a lower-quality medication. Enough clean air flowing through a ventilation system is essential for the pharmaceutical industry. The system must meet the clean room's standards for humidity and temperature [1]. The temperature, air humidity, dust, and microorganisms in the surrounding area are some variables that affect the air quality. In densely packed surroundings, where most people work, they are more susceptible to many infections. The pharmaceutical industry is an important sector that manufactures and distributes life-saving pharmaceuticals, treatments, and vaccines. Strict guidelines and rules are in place in this industry to guarantee the effectiveness and quality of the medications as well as the security of both patients and staff. Pharmaceutical facilities, including manufacturing, labs, and storage spaces, require an effective HVAC system to regulate temperature, humidity, and pressure. High-quality pharmaceutical products are essential for preserving health and avoiding disease. HVAC systems control temperature, humidity, air quality, air purity, and air movement to provide a comfortable and healthy living or working environment. Proper heating, ventilation, and air conditioning (HVAC) systems are critical to pharmaceutical cleanroom design. HVAC controls the pharmaceutical environmental conditions. This system may also provide fresh outdoor air to dilute interior airborne contaminants such as volatile Organic Compounds (VOCs) emitted from interior furnishings, and chemicals used for cleaning. A properly designed system will provide a comfortable pharmaceutical environment year-round and properly maintained. Ventilating or Ventilation systems is the process of circulating and exchanging indoor and outdoor air, removing pollutants, controlling moisture levels, and replenishing oxygen. HVAC systems are critical for ensuring maximum comfort, health, and productivity in pharmaceutical industrial settings. The system includes a wide range of equipment such as ductwork, fans, air conditioners, heat

pumps, boilers, furnaces, filters, and thermostats, all working together to achieve desired indoor conditions.

HISTORY AND APPLICATION OF HVAC

These early systems were originally designed using large fans and boilers that burned coal. The steam radiator was one of the first developments in heating systems, created in the 1820s [2]. The first air conditioning system was patented in 1851 by Florida physician and inventor John Gorrie as seen in Figure 1. A system of pipes and radiators allowed a central boiler to heat water and provide steam to every part of the pharmaceutical industry. This system made more even heat distribution possible compared to earlier stoves and fireplaces. Ventilation systems from the 19th century were usually made to supply fresh air.[3]. Openable windows and chimneys were the most common methods of ventilation at the time, although some buildings also used mechanical ventilation systems that used fans to circulate air. The forced-air furnace was another important invention of the 19th century. Alphonse Beau de Rochas in France invented this system and circulates hot air throughout a building with the help of a blower. The early HVAC systems were developed due to the growing demand for heating and cooling systems in factories and large buildings during the nineteenth-century industrial revolution. Overall, the 19th century was a time of great innovation in the field of HVAC systems. The invention of the steam radiator, forced-air furnace, and air conditioning system laid the foundations for the modern HVAC systems used today [3].

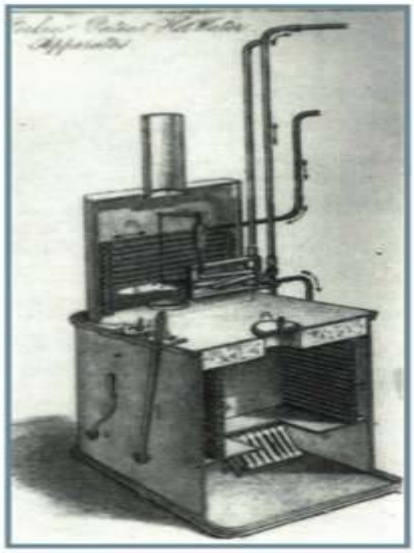

Figure 1: Steam HVAC System, Ref. [3].

HVAC systems saw major advancements in the 20th century because of the development of modern technologies and electricity use. With advancements in technology, HVAC systems have a variety of sensors that are used to detect the occupants within a controlled environment. Advancements in computer control systems and the use of smart technology have made HVAC systems even more sophisticated, allowing for approximate temperature control and energy management to cool the air and eliminate moisture. The simulation results showed that energy consumption was reduced by 15% and comfort level violation was reduced by 79%, and when compared with a rule-based HVAC control strategy, the comfort violation can be reduced by 98%. Carrier realized right away that there were other applications for his invention outside industrial dehumidification [4].

TYPES OF MODELING APPROACHES IN HVAC

Energy consumption and indoor environmental quality can only be studied and controlled through the modeling of heating, ventilation, and air conditioning systems. In HVAC systems, three different modeling approaches are utilized: data-driven, physics-based, and grey box models. Additionally, this modeling can be categorized as explicit, discrete, or continuous, linear, or nonlinear, static, or dynamic, inductive, or floating models. Data-driven methods (also known as inverse or black box) are the first. This system performance data is gathered through routine use, or an artificial neural network (ANN), and statistical

methods are used to find a relationship between the input and output variables, which is classified as an inductive model.[5]. The second method is physics-based, in which the system models are developed by applying the fundamental principles of physics and in-depth comprehension of the underlying mechanism. The deductive model applies to this method. Usually, this kind produces a deterministic, continuous model. The grey box approach is the third technique. Where in it created the fundamental framework of the model using techniques based on physics. Using parameter estimation on the system's measured data, the model's parameters are established. This model can be classified as both inductive and deductive, making it a hybrid model. The table lists the benefits and drawbacks of each type of HVAC system in Table 1.[13]

Table 1: Types of HVAC system

S.NO	TYPES OF HVAC	CRITERIA	ADVANTAGE	DISADVANTAGE
1.	Hybrid system or hybrid split systems	Contains both cooling and heating	It automatically switches at certain temperatures; it switches between the power supply.	The installation can be costly.
2.	Duct-free system	Control the temperature	For better temperature control, it consumes more energy than another HVAC system.	The installation will be costly and maintenance of this system is more.
3.	Hydronic heating	Liquid is used to control the temperature instead of air. Heating specific areas of the home.	In this system flow of heat will be separated into different rooms.	This type of system provides only heat and it is costly.
4.	Portable air pump	In warmer climates, these systems are not quite as powerful as other options.	It is safer than other systems, low cost, and easy to DIY.	It is only suitable in smaller places not in larger places, this type of system will be noisy.
5.	Portable air conditioner	Portable air conditioner. Temporary solution	This type of system installation is low-cost, it is portable and easy to DIY	The energy consumed is less in this system.
6.	Portable heat pump	Both heating and cooling. Heating small spaces.	This type of system is safer, this is more efficient, and easier to DIY	This type of system is not suitable for large places, this system is noisier
7.	Geothermal heat pump	Heating or cooling is pushed to the pipes underground and flows back into the pharmaceutical industry at a comfortable temperature.	The most energy efficient system, it will make savings for one year	This type of system installation will be more complex
8.	Split system	Cooling and heating	This type of system is low maintenance, each part of this system is customized as per the needs.	This system will be noisy, the installation part can be more complicated.

Split Systems

The split system for heating and cooling is the most widely used type of HVAC unit. As implied by the name, this type of system is made up of two parts: a heating unit and a cooling unit. There is a split cooling system inside the pharmaceutical industry. The heating unit of the system is located inside the pharmaceutical industry. The heated air is then dispersed throughout the pharmaceutical industry via an evaporator.

Hybrid Systems

The difference is that by switching between gas and electricity, a hybrid system can operate more efficiently. This could be advantageous for the environment as well as the electricity bill. By drawing air through a heat exchanger that is powered by the existing electricity, this system heats the air in the pharmaceutical industry. A blower forces the heated air in pharmaceutical industries through the ducts.

Packaged Heating and Air Systems

A packaged heating and air system is a less typical HVAC system. These systems are typically installed as high up in the pharmaceutical industry as is practical and work as a single, self-contained unit to provide both heating and cooling. These systems are significantly smaller than other HVAC systems for the pharmaceutical industry. They also work quite nicely. Though they have the disadvantage of the heating system not working as well as the cooling system, they are perfect for the pharmaceutical industry.

Duct-Free Systems

Unlike split systems, which have two large HVAC units in the pharmaceutical industry, duct-free systems have individual HVAC units in each room. The system is more costly than a standard split system because of this configuration, especially when it comes to installation fees. However, one advantage of them is that you can regulate the temperature in individual rooms more effectively. These kinds of systems are frequently found in establishments like the pharmaceutical industry where providing temperature control is essential. However, they are also utilized in the pharmaceutical industry, especially the building an addition and wish to have better temperature control in that particular space. Furthermore, these systems are more energy-efficient, which could result in long-term cost savings.

Hydronic Heating

The familiar with radiant floor heating and, by extension, hydronic heating ever enjoyed heated floors in the pharmaceutical industry. This HVAC system uses liquid rather than air to regulate temperature. The liquid (water or a glycol solution) that travels through the flexible pipes under the floors is heated by a boiler. Although it is most effective under concrete floors, hydronic heating can be used anywhere you want to feel warm under your feet. The pharmaceutical industry warms up in tandem with the floors.

Portable Air Conditioner

It is handy to have an air conditioning supply on wheels. It turns out that this is perfectly possible with a portable air conditioner. These portable gadgets act as fans by drawing in ambient air. The inner closed-loop coil of a portable air conditioner is cooled by the refrigerant, which also cools the outside air as it passes through the system, sending cool air blasting into the room. Because of its wheels, you can easily move this air conditioner from the pharmaceutical industry from one room to another room. This type of air conditioner is easy to install and reasonably priced upfront.

MODELING TYPES OF HVAC

The HVAC system modeling implies the modeling of the pharmaceutical industry exterior, interior, and air handling unit (AHU) equipment. Being all-inclusive in a single HVAC system model is usually difficult. Because of this, it is possible to divide the larger model into smaller models, which may be helpful in particular circumstances. Any successful indoor thermal analysis or representation depends on the accuracy of the model of the pharmaceutical industry indoor conditioned space and the AHU equipment. The cooling/heating load could be calculated manually using simple methods before the development of computer simulation programs for HVAC systems in the mid-1960s. In the first attempt at simulation, physical conditions were simulated by treating the variable time as independent.

MATHEMATICAL MODEL OR WHITE BOX MODEL

Mathematical models have been widely used for many different purposes, including prediction, control, fault diagnosis and inadequacies, simulation, and operator training. These applications have been seen in fields as diverse as engineering, economics, medicine, ecology, and agriculture, among many others. In the realm of HVAC system modeling, the building model is the most intricate model element. This is because components like the roof, walls, floor slab, windows, and external shading are not limited to those related to building construction and need to be modeled. Internal loads, such as the number of users, their activity level, and the heat gain from the lights, must also be modeled. The pharmaceutical industry model subdivision is rarely used, and the field of HVAC models is quite broad [9].

BLACK-BOX MODEL

The relationships between every parameter influencing the hygrothermal (temperature and humidity variation) system are thoroughly examined in the physical model. The application of physical modeling has become increasingly complex due to the large number of parameters involved and the complex nature of hydrothermal systems. Sometimes it is preferable to use the black-box model because it is easy to construct and does not require knowledge of the internal workings of the system. [10] used a variety of black-box model techniques, including Box-Jenkins (BJ), autoregressive with external inputs (ARX), autoregressive moving average exogenous (ARMAX) structure, and output error (OE) models, to identify the humidity and thermal behavior models of an office in a contemporary commercial building.

GRAY BOX MODEL

The goal of the Gray-box model, sometimes referred to as the semi-physical or hybrid model, is to combine the best features of the physical and empirical models to compensate for their respective shortcomings. In some gray-box modeling, the model structures themselves are mathematically derived from physical or thermodynamic principles, while the parameters of the model structures are found in the commissioning, operating, or catalog data.[11] after they introduced the idea of air saturation-specific heat [12]. Using catalog data at a single operating condition, the number of transfer units is determined.

IMPORTANCE OF HVAC

The pharmaceutical industry is one of the world's more crucial and dynamic sectors. The industry manufactures and distributes life-saving drugs, medications, and vaccines. To ensure employees' safety, quality, and efficiency of the drugs, the industry must maintain and adhere to strict working and storage standards and regulations. HVAC systems regulate temperature, humidity, air filtration, ventilation, and pressure to establish positive or negative pressure zones as needed. The HVAC also functions the climate control systems in pharmaceutical facilities, where they can heat or cool the air to maintain specific temperature ranges, humidify or dehumidify to control moisture levels, filter out dust, microbes, and other contaminants, and ventilate to ensure proper air exchange and prevent stagnation. The HVAC systems control pressure to establish positive or negative pressure zones in different areas and monitor and control pharmaceutical industry environmental parameters. The significance of HVAC control is particularly evident in manufacturing and storage roles. In the drug manufacturing industry, maintaining a for instance, producing a vaccine requires a precise temperature; if it's too high, the reaction might proceed too quickly and damage the vaccine, while too low a temperature can slow the reaction, rendering the vaccine ineffective [13]. HVAC systems are the main strength of a controlled and contamination-free environment essential for the pharmaceutical industry.

HVAC-BASED GMP GUIDELINES

According to the Good Manufacturing Practice (GMP) guidelines, HVAC (Heating, Ventilation, and Air Conditioning) systems play a crucial role in ensuring the quality and safety of pharmaceuticals and other products that are manufactured in controlled environments. These guidelines mandate strict standards for air quality, temperature, humidity, and cleanliness in manufacturing facilities to prevent contamination, maintain product integrity, and comply with regulatory requirements. HVAC systems are vital for achieving and sustaining these controlled environments. First and foremost, HVAC systems in GMP-regulated facilities are intended to maintain precise temperature and humidity control throughout the manufacturing process. This control is critical for maintaining the stability and efficacy of sensitive pharmaceutical products while avoiding deviations that could jeopardize their quality. HVAC systems play an important role in regulating air circulation and filtration to minimize the presence of particulate matter, microorganisms, and other contaminants in manufacturing environments. To maintain specific air cleanliness levels (such as ISO classes), cleanrooms and controlled areas in facilities use filtration systems, air change rates, and strict protocols for personnel gowning and behavior. Furthermore, HVAC systems are critical in maintaining positive or negative pressure differentials between different zones within the facility to prevent cross-contamination and contain hazardous materials such as potent drugs or biological agents. Regular monitoring, validation, and maintenance of HVAC systems are essential components of GMP compliance. This includes calibration of sensors, periodic testing of air quality and flow rates, validation of critical parameters, and documentation of maintenance activities to demonstrate compliance with regulatory standards. Pharmaceutical businesses face increasing difficulties in following GMP requirements and running a successful business due to the rising costs of plant construction and modifications.

WORKING AND COMPONENTS OF HVAC

The secret to making quality pharmaceutical items produced by an industry of high quality is heating, ventilation, and air conditioning (HVAC). It ensures that all favourable conditions exist for successful manufacturing. The following explains the fundamental principles that drive an HVAC system: First, fresh air from outside the plant is collected by the system and purified with a filter. Here, the cooling coil expels surplus humidity, which is then removed via the drainage system. After passing via the supply duct, the filtered air passes through the air handling unit for additional filtering. The filtered air is subsequently supplied by the air handling unit to various rooms in the manufacturing facility. The air supplied to each room is determined by the temperature and humidity that is required in the room. In addition to the Air handling unit, air is additionally filtered through the High-Efficiency Particulate Air (HEPA) systems which guarantee up to 99.995% efficiency. To raise the interior temperature, air is driven through that heat and re-distributed throughout the structure. Warm air is driven across the refrigerant coil of the

cooling system when cooling is required. The refrigerant absorbs heat naturally, releasing cool air in its wake. As shown in Figure 2, the pharmaceutical industry rooms are subsequently filled with this chilly air again. When trying to keep an acceptable interior temperature, humidity can be a serious issue. The moisture in the air will evaporate as heat is delivered to the refrigerant inside the cooling system's coil. This is the process of eliminating humidity.

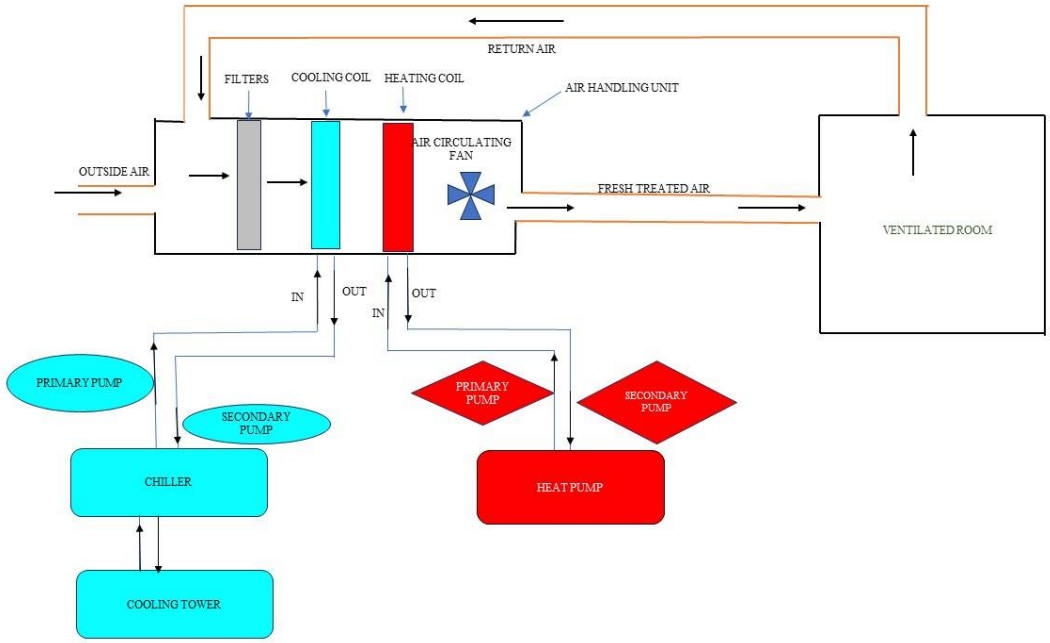

Figure 2: The schematic working representation of the HVAC system

COMPONENTS OF HVAC

- Air return setup
- Air filters
- Damper
- Compressors
- Blowers
- Coil

DAMPER

HVAC dampers

HVAC dampers regulate or control the airflow in your heating, ventilation, and air conditioning (HVAC) system. They can be automatic or manual, and they are usually installed in the system's ductwork. While automatic dampers are managed by a thermostat or other system controls, manual dampers must be adjusted by hand.

Although dampers vary in size and form, they all share the same fundamental parts. They comprise a frame that is put inside the ducting and has movable blades or vanes to regulate the airflow. Air can move freely through the ductwork when the blades are open. The airflow is restrained when they are closed.

COIL

The key component of the HVAC system is the coils which are essential for providing indoor air temperatures. There are two types of coils used in the HVAC. Heating and cooling coils are used in the system to maintain the temperature of the room in the pharmaceutical industry.

Heating coil

Working of heating coil in HVAC system

The indoor evaporator coil is responsible for releasing heat into the room. When turning on the furnace adjust the thermostat to a specific setting. After passing through the coil, the heat will finally enter the room through vents. For the coils to produce and transport heat, there must be adequate airflow. If not, the thermostat might not reach the desired temperature, which would result in higher energy usage. The heat from the interior of the room is captured by the refrigerant by the indoor coil and transferred to the outdoor condenser coil. The heat energy is then compressed into condensation by the condenser and released outside the room. While the air conditioner runs, this process is repeated.[12]

Cooling coil

Working of cooling coil in HVAC system

In the process of cooling the air, the cooling unit is turned on. Air is circulated via a coil, a component of a heat exchanger, in the cooling unit. There are two types of heat exchangers available: cross-flow coil and shell and tube. The refrigerant in the exchanger unit removes heat from the suction air so that only cooled air is introduced into the space. The refrigerant is liquefied using a compressor that is built within the cooling units [14].

AIR RETURN SETUP

Supply air is heated or cooled air from the furnace or air conditioner that is pumped through supply ductwork into individual rooms around the pharmaceutical industry. The return air from the rooms is taken out and directed through return ductwork to the indoor air handler where it is filtered before being heated or cooled by the air conditioner or furnace once more. Then, to preserve the ideal thermostat setting and the highest level of comfort in every room in the pharmaceutical industry, conditioned air cycles back into the supply ducting [20].

AIR FILTERS

An essential component of every HVAC system is the air filter. They act as the first line of protection against airborne particles that could endanger the building's inhabitants as well as the system. The way air filters function is by collecting and retaining different kinds of pollutants and particulates that enter your HVAC system. Typical pollutants like dust, pollen, mold spores, and other allergens are among them. Air filters do this by collecting these particles and keeping them from recirculating into industry interior air or getting inside HVAC system's delicate parts, where they could damage or reduce efficiency[15].

Types of air filters

There are many different kinds of air filters, each made to fit particular requirements and situations. The efficiency of your HVAC system, the standard of the air inside the pharmaceutical industry and the well-being of the building's occupants can all be greatly impacted by the type of air filter you select.

Mechanical air filters

HVAC systems frequently use mechanical air filters as a type of air filter. They function by trapping dust, debris, and tiny particles in their synthetic fibers while air flows through them. Usually, the material of the filter is folded or pleated to maximize its surface area and filtering ability. The Minimum Efficiency Reporting Value (MERV), which goes from 1 to 16, is used to rate mechanical air filters. The smaller the particles the filter can capture, the higher the MERV rating. Higher MERV ratings, however, also indicate that the filter will impede airflow more, which could strain your HVAC system if it's not built to handle it.

Pleated air filters

An improvement over conventional mechanical air filters is pleated air filtration. They are constructed with folds of cotton or polyester that expand the filter's surface area and enable it to capture more airborne particles and pollutants. The filter's pleats produce more pockets for capturing particles, increasing their efficiency compared to non-pleated filters.

Electrostatic air filters

The principle of operation of electrostatic air filters differs from that of mechanical or pleated filters. Particles are drawn to and retained by them via electrostatic charges. A static charge is produced as air flows through the filter, drawing dust, pollen, and other particles and trapping them inside the filter.

HEPA filters

High-efficiency particulate Air is referred to as HEPA. With a 99.97% retention rate for particles 0.3 microns and larger, HEPA filters are among the most effective filters on the market. They function by pushing air through a fine mesh that collects noxious particles like tobacco smoke, dust mites, pet dander, and pollen[16].

COMPRESSOR

Refrigerant is pumped through the air conditioning system by an air conditioning compressor. It is essential to an air conditioning system because it makes the heat pump function. Compressing refrigerant vapor is the function of the compressor, which is located inside the condenser unit. The HVAC system's compressor is its central component. It moves heat from the condenser the part that removes heat from the air to the refrigerant, the liquid that cools the air. Refrigerant is compressed by the compressor into a smaller volume, increasing its temperature and pressure and, as a result, its energy efficiency. When cooling has occurred, this process also reverses itself and increases the temperature.[17]

Types of compressors in HVAC

Reciprocating:

This kind of compressor was the first and most widely used. As technology advances, so does the design. This operates under Boyle's law, which states that in a closed system, " In an ideal gas, the volume and

temperature remain constant, and the absolute pressure released by a given quantity of the gas is inversely proportional to the volume". utilized in pharmaceutical industrial air conditioning applications.

Rotary:

The next compressor type is mostly found in air conditioners and heat pump types. This type is portable and quiet. This type is also known as a "helical screw compressor". The two helical screws are in opposite directions to compress the refrigerant. It can be used in appliances [17].

Scroll compressor

This type is also called a scroll vacuum pump. This type is a positive displacement type that only produces intermittent air. This type is preferred scroll compressor is a simple design structure, that has two interleaving spiral-shaped parts. This type is a low-noise compressor.[18].

WORKING AND COMPONENTS OF HVAC

The secret to making quality pharmaceutical items produced by an industry of high quality is HVAC. It ensures that all favourable conditions exist for successful manufacturing. The following explains the fundamental principles that drive an HVAC system: First, fresh air from outside the plant is collected by the system and purified with a filter. Here, the cooling coil expels surplus humidity, which is then removed via the drainage system. After passing via the supply duct, the filtered air passes through the air handling unit for additional filtering. The filtered air is subsequently supplied by the air handling unit to various rooms in the manufacturing facility. The air supplied to each room is determined by the temperature and humidity that is required in the room. In addition to the Air handling unit, air is additionally filtered through the High-Efficiency Particulate Air (HEPA) systems which guarantee up to 99.995% efficiency. To raise the interior temperature, air is driven through that heat and re-distributed throughout the structure. Warm air is driven across the refrigerant coil of the cooling system when cooling is required. The refrigerant absorbs heat naturally, releasing cool air in its wake. As shown in Figure 2, the pharmaceutical industry rooms are subsequently filled with this chilly air again. When trying to keep an acceptable interior temperature, humidity can be a serious issue. The moisture in the air will evaporate as heat is delivered to the refrigerant inside the cooling system's coil. This is the process of eliminating humidity.

VALIDATION OF HVAC

In the pharmaceutical industry, validation is essential because it guarantees the precision, consistency, and repeatability of results by confirming, optimal systems performance at different levels.

Airflow pattern

- Select the titanium tetrachloride stick
- Ignite the stick on fire.
- Hold the burning stick in front of the air-handling device that is operating.
- The flow of air in the room is checked with the help of smock distribution.
- Make a chart diagram of the flow of air in the room.

Air flow velocity and change per hour

- With the anemometer probe 6 inches from the filter face, scan the HEPA filter.
- Develop four equal, fictitious grids out of the HEPA filter's area for the experiment.
- Note the velocity measurements obtained at the intersection of the dividing lines and in the middle of the grids
- Calculate the average velocity (V in feet per minute)

  $$V=(V1+V2+V3+V4)/4$$
- Each air inlet dimension is measured.
- Calculate the area (A in sq feet) of each air inlet as a product of length and width as:

  $$A= I \times w$$
- Calculate total air volume (T in cubic feet per minute) supplied in each zone:

  $$T=A \times V$$
- Calculate total volume of the room by multiplying the length of room, breadth and height of the room.

  $$Volume = LBH$$
- The air change per hour is calculated by dividing the total air change by the total volume of the room. Complete the form with the record.

Filter leak test

- The velometer should be placed in front of the AHU unit.
- Verify the airflow to every area of the AHU. The airspeed should fall inside the HEPA filter's upper limit.
- To stop air leaks, the gas shutoff is changed if the air velocity exceeds the higher limit.

Particles count

- On the system before one hour of test operation. Take the suitable particle counter and operate it to check the particles in the room at nonworking operation.
- The information is collected from the particle counter and the format should be filled.
- Operate the particle counter when work is in progress in the area. The particles should be counted when more than one hour has progressed in the area.
- The data is recorded in form.
- Operate the particle counter for all rooms maintaining grades A, B, C, and D.

Viable monitoring

- As indicated by the site plan on the reverse of the paper sheet, expose plate count agar and dextrose agar media plates in the sterile manufacturing area.
- Likewise, expose the plates in change rooms two and three, de-gown one twice a week, and once in a week in vial washing, bung washing, and component preparation.
- Monitor the microbiological load on the surface of the sterile manufacturing area using swab sampling and SOP-compliant testing.
- Swab sampling should be done daily in the sterile passage, change room 2, degowning 1, vial filling, vial sealing, sterile buffer, and blending 3.
- Swab sampling should also be done once a week in component preparation, vial washing, bung washing, and change room 1.
- The results are recorded.
- When using the air sampler following the equipment's SOP, insert the media strips or Petri dishes.
- The data is recorded in a format.
- The microbial load is monitor on the suface of the hand gloves in working shift bases the activity is followed as per SOP.
- If failure is observed during the process the corrective action shall be planned and implemented.

Filter integrity test (DOP/PAO test for HVAC)

- DOP or PAO is generated by using aerosaol generator. In the air handling system the direct test aerosol at the supply duct.
- The photometer is on and leave it for stabilize for five mins.
- The HEPA filters upstream concentration should ensure 100% achieved.
- The filter matrix is scanned by passing the probe 1 inch from the filter surface.
- Check if any leak is appeared by overlapping strokes at approximately 10 FPM.
- Record the observation in the format.

Pressure difference

- Manometer is attached to the wall , the room which is under testing is attached with manometer.
- Air system inside the tested area is waited to stabilize the presence in the area.
- The pressure difference from all room and from room to room is observed.
- The data is recorded in the format.

Recovery (temperature & humidity)

- The HVAC system is turn off and the humidity of the area is checked by using hygrometer.
- The humidity of the area is within the specification, increase the humidity by spraying hot water in the area upto 75%.
- Turn on the HVAC system and note down the time.
- Wait to stabilize the humidity in the area is in specification limit.
- The time is noted and recorded in the format.

Temperature and humidity uniformity test

- The thermometer is placed in different location to calibrated the thermometer.
- The HVAC system is operated and time is noted and wait to stabilize the temperature in the area with in the specification.
- The temperature is recorded in format.
- The hygrometer is placed in the different location.
- Note the time and wait to stabilize the humidity in the area with in the specification limit.
- Check the temperature is recorded in format.

Fresh air determination

- On air handling unit is stabilized the air pressure in the room.
- Observe and calculate intake air by dumper in the room

  % Fresh air intake = Intake fresh air/total air change in room ×100
- The data is recorded.

FUNCTION OF HVAC

- The main function of the HVAC system is to manage dust, which is removed by filtration. If dust is not managed, it may lead to contamination during the production process. Airborne particles can cause pollution and interfere with the manufacturing process. They are also present in the air. Microorganisms pose a possible risk to the pharmaceutical processing industry since the plant's atmosphere ought to be sterile. The HEPA systems get rid of microorganisms.
- Maintaining the correct temperature in the production areas. In the pharmaceutical sector, temperature is crucial. Poor temperature regulation can lead to the growth of microbes on employees or in the premises, which could have a negative impact on their health.
- Maintaining proper relative humidity. Desiccant dehumidifiers are installed to control the moisture in the manufacturing facilities. The production of stable medications depends on the room having the proper humidity levels. In most cases, proper relative humidity is required to guarantee high-quality tablet manufacturing [19].

SUSTAINABILITY AND SDG RELEVANCE

The efficient design and operation of HVAC systems in pharmaceutical facilities directly contribute to several United Nations Sustainable Development Goals (SDGs). By maintaining contamination-free manufacturing conditions, HVAC systems support SDG 3 (Good Health and Well-Being) through the production of safe, effective medicines. Technological innovations and modeling approaches in HVAC align with SDG 9 (Industry, Innovation and Infrastructure), promoting resilient and energy-optimized industrial environments. Energy-efficient HVAC designs reduce waste, emissions, and resource use, advancing SDG 12 (Responsible Consumption and Production) and SDG 13 (Climate Action). Collectively, these systems exemplify how engineering controls can strengthen both pharmaceutical quality assurance and environmental sustainability.

CONCLUSION

Aligned with the United Nations Sustainable Development Goals (SDGs 3, 9, 12, and 13), the findings and issues identified in this paper serve as practical guidelines for implementing HVAC projects that enhance pharmaceutical quality while promoting sustainability. The aim of this paper is HVAC systems for keeping pharmaceutical industries' interior spaces cozy and healthful. They are crucial for maintaining productivity since they control temperature, humidity, air quality, and airflow. The development of HVAC technology is seen in the transition from primitive steam radiators and coal-burning boilers to contemporary, energy-efficient systems. A variety of modeling techniques for HVAC systems, including data-driven, physics-based, and grey box models, make it easier to analyze and regulate energy use and indoor air quality. Every method offers flexibility depending on the unique needs and limitations of the HVAC system, but it also has a set of drawbacks and benefits. The Standards for Good Manufacturing Practices place significant emphasis on the need to uphold stringent requirements for environmental control and air quality in these environments. The proper indoor conditions are achieved by the coordinated operation of key HVAC system components, such as air returns, air filters, dampers, compressors, blowers, and coils. To guarantee the effectiveness and durability of HVAC systems, it is essential to comprehend how these parts work and how to maintain them. Plant construction costs, as well as changes to them are constantly escalating, therefore, pharmaceutical companies should maintain the HVAC in good condition to ensure the quality of the product.

ABBREVIATION

HVAC – Heating ventilating and air conditioning.
GMP – Good manufacturing practice.
HEPA- High-efficiency particulate air.
MERV- Minimum Efficiency Reporting Value.
ISO – International Organization for Standardization
ARMAX- Autoregressive moving average exogenous.
ARX- Autoregressive with external inputs
BJ- Box-Jenkins.
AHU- Air handling unit.
VOCs- Volatile Organic Compounds.
ANN -Artificial neural network

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AUTHOR CONTRIBUTIONS

Ms. R. Haripriya and Dr. A. Ajitha contributed equally to the conceptualization, methodology, data analysis, and writing of this article.

CONFLICT OF INTEREST

The authors declare no conflict of interest

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