Juni Khyat ISSN: 2278-4632 (UGC Care Group I Listed Journal) Vol-13, Issue-04, No.01, April : 2023 OPTIMIZATION OF QUALITY CONTROL OF "ATORVA STATIN POWDER" BY AIR HANDLING UNIT

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ABSTRACT

In many pharmaceutical companies, the requirement and availability of fresh air to the production block and required area is important mainly in the production of ATORVA STATIN powder, which is used to prevent cardiovascular disease(related to heart and blood vessels) in those at high risk and to treat abnormal lipid levels. The production of ATORVA STATIN powder should be done only in a clean environment. Here the problem is to maintain the room with clean/fresh air without any impurities and moisture. In order to maintain them at the required levels a AHU(Air Handling Unit) would be the solution. The temperature in the room should not exceed 25°C, Humidity NMT 65% for human comfort, and Differential Pressure is based on the room design to avoid cross contamination, powder production quantity, etc.

AHU is used to supply the air in the production area. AHU consists of the components like Chiller, Blower, Filters and Dehumidifiers.chillers are working based on Vapour Compression Refrigeration Cycle. These chillers will provide the cooling temperature in AHU by chilled water. Humidifiers and Dehumidifiers are used to maintain the humidity in the required area. Blower is the component to supply the air. The sizes of AHY filters will maintain the particulate of air quality in the clean room. The AHU is based on the re circulation mode. The AHU is to be designed on the basis of air velocity and air changes in the required area, which supply the air and takes the fresh air from the atmosphere and passes the air through cooling coil and dehumidifier. The air flows through the filters in the AHU and supplied to the required area with the help of ducts. So, an optimized quality control is requires in order to prepare a good quality ATORVA STATIN powder by proper maintenance with the Air Handling Unit.

KEY WORDS: Atorva Statin Powder, Heating Ventilation and Air Conditioning, Air Handling Unit, CFM, Chiller.

INTRODUCTION:

AHU abbreviation is Air Handling Unit. The AHU is the main component in the HVAC section. Air Handling Unit's are SUPPLY AHU, EXHAUST AHU and INTERMEDIATE AHU. The Supply AHU circulates the air and supplies to the required clean room, this circulated air goes to the Exhaust Air Handling Unit or Supply Air Handling Unit based on required production.

RECIRCULATION MODE:

In recirculation mode, the air enters into the dampers which are provided at outside the Air Handling Unit, it controls the volume of air entering into the Air Handling Unit. From there it passes through the filters and then motor blower. The filters removes the dust in air, blower increases the air speed and sends to the filters and dampers which are provided outside the Air Handling Unit. From here, it goes to the clean room or required room. After entering the air into the clean room, the air goes to the either Exhaust Air Handling Unit or Supply Air Handling unit.

If there are any impurities present or nitrogen content is high then the air from the clean room goes to the Exhaust Air Handling Unit. From here it goes to the atmosphere. If nitrogen content becomes more then there will be a breathing problems for humans so air is sending outside. At this

time, the air shortage occurs at the Supply Air Handling Unit. So, the auto damper starts working and sucks 100% air then the air circulation process will be normal.

If there are no impurities present or nitrogen content is sufficient then the air from the clean room goes to the Supply Air Handling Unit. At this time shortage of air will not be there. So 80% air enters through the recirculation duct and 20% from the atmosphere through the manual duct. And the process is recirculation.



Figure 2. Exhaust AHU

LITERATURE SURVEY:

Atorva Statin powder was invented by the Roth in the year 1986. Atorva Statin, sold under the brand name Liptor among others, is a statin medication used to prevent cardiovascular disease in those at high risk and to treat abnormal lipid levels. For the prevention of cardiovascular disease, statins are a first-line treatment. It is taken by mouth. Atorvastatin belongs to a group of drugs called HMG CoA reductase inhibitors, or "statins". Atorvastatin is used together with diet to lower blood levels of "bad" cholesterol(low density lipoprotein, or LDL), to increase levels of "good" cholesterol (high density lipoprotein, or HDL), and to lower triglycerides(a type of fat in the blood). In 1954, R.L. Berger filed a patent for Chrysler, titled simply "air handling unit". This patent's objective was to improve upon several parts of the young AHU invention, including a damper mechanism, the heat exchange apparatus, a condensate tray and a mounting for the blower mechanism. To make the production of the Atorva Statin powder there is a need of Air Handling Unit, Already Atorva Statiin powder production is there. To optimizing the production of Atorva Statin powder.

It is difficult to attribute the invention of Air Handling Unit(AHUs) to a single individual, as the development of these systems has been a gradual process over many decades. The first mechanical air conditioning systems were developed in the early 20th centuary, and AHUs were an important part of these systems However, the modern AHUs as we know them today were developed in the mid 20th centuary, when HVAC systems became more common in commercial and industrial buildings. The use of AHUs became widespread as buildings became larger and more complex, requiring centralized systems for air conditioning and ventilation. Some of the early poineers in the development of air conditioning systems include Wills Carrier, who invented the first modern air conditioning system in 1902, and Stuart Cramer, who coined the term "air conditioning" in 1906. Other important figures in the development of AHUs includes David Rivinus, who developed the first modular AHU in 1947, and Richard C. Starkey, who invented the first multi - zone air conditioning system in 1954. Since the design and technology of AHUs have continued to evolve, with ongoing research and development focused on improving their performance, energy efficiency, and sustainability.

Air Handling Unit is a device used to regulate and circulate air as part of heating, ventilating and air conditioning (HVAC) system. Several studies have focused on the design and performance of the air handling units. Researchers have investigated the impact of design parameters, such as airflow rate, temperature and humidity, on the performance of AHUs. They have also examined the effect of different type of filters, fans and heat exchangers on the efficiency of these units. Energy efficiency is a major concern for AHUs, as they consume a significant amount of energy in HVAC systems. Many studies have explored strategies to improve the energy efficiency of AHUs, such as optimizing the control of fans and pumps, using variable speed drives, and integrating heat recovery system. The quality of indoor air is closely linked to the performance of air handling units. Several studies have investigated the impact of AHUs on indoor air quality, including the removal of airborne pollutants and the control of humidity levels. /researchers have also studied the effectiveness of different types of filters and air cleaning technologies in AHUs.

AHU TYPES:

Generally there are two types of Air Handling Units are there. They are:

- I. Blow Through Air Handling Unit
- II. Draw Through Air Handling Unit

The difference between the two Air Handling Unit's are the air flow is based on the arrangement of blower, heating coils and cooling coils.

I. Blow Through Air Handling Unit:

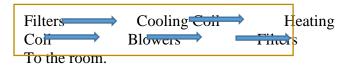
In the Blow Through Air Handling Unit, the air circulation process is as same as previous. The arrangement in Air Handling Unit is



To the room.

II. Draw Through Air Handling Unit:

In the Draw Through Air Handling Unit, the air circulation process is as same as previous. The arrangement in Air Handling Unit is



WORKING:

In this we are using Freon because it will freeze upto -250° C and it can easily evaporate. In the compressor, freon is in the vapour form. The vapour in the compressor at 90 - 120°C. This vapour moves from the compressor to the condenser. In the condenser freon is in liquid state. There is a cooling tower. This cooling tower supplies the water to the condenser. The temperature in the condenser is 30 -35°C. From the condenser, the liquid moves to the chiller. This chiller will act as a evaporator. The chiller has a temperature from 5 - 10°C. In the chiller, freon is in vapour form.

This vapour moves from the chiller to the cold well. The vapour from the cold well, the vapour moves from the cold well to the cooling coil which is in the air handling unit at 5°C. From the cooling coil, the freon moves to the hot well. The temperature from cooling coil and hot well is 8-12°C. The air from the air handling unit moves to the clean room.

The clean room maintaining the temperature at 20°C. From the clean room, air moves either to atmosphere or again to the air handling unit. When the air moves to atmosphere from the clean Page | 176 Copyright @ 2023 Author

room then it is called once through mode. When the air moves to the air handling unit from the clean room then it is called Re circulation mode. From the hot well, the freon moves to the evaporator having 10-15°C. The air flows from the hot well to the chiller with the help of the pump. Similarly, the air flows from the cold well to the cooling coil in the air handling unit with the help of pump only. The air handling unit has heating coil, cooling coil, dampers, ducts,etc.,

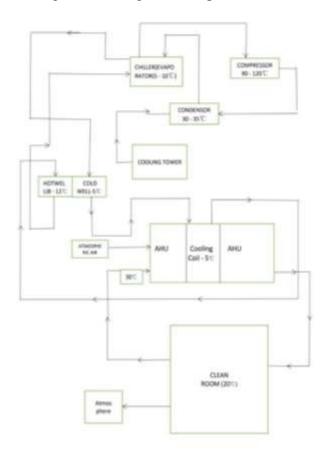


Figure 3. Working

CHILLER PROCESS:

Chillers are used to produce cool air by using the vapour compression refrigeration cycle. To produce cool air liquid is using. This liquid circulates and sends the heat to atmosphere. Then we can get cool air.

Parts of chiller:

- 1. Compressor
- 2. Condenser
- 3. Evaporator(Expansion valve present inside the evaporator).

COOLING TOWER:

Cooling tower is used to cool the water and supplied it to the condenser in chiller. Fan is provided inside the cooling tower. This fan removes the moisture present inside the cooling tower and supplied to the duct which is connected to the condenser in chiller. Here we are using induced cooling tower.

HOT WELL AND COLD WELL:

Cold well and hot well are located side by side. Cold well is a tank used for carrying the chilled water which is coming from the evaporator. Cold well is also used for storage purpose also Chilled water is coming from evaporator to the cold well tank and from cold well tank chilled water

is supplied to the AHU cooling coil. Chilled water return from AHU will be collected in the hot well tank. From hot well water is circulated to the evaporator and it will be cooled to 5°C .temperature. The same amount of water will supply to the AHU by the pump. The process repeats.



Figure 4. Hot Well and Cold Well

AHU WORKING:

The fresh air entering from dampers and return air into the air handling unit through ducts. The air passes through the pre-filters of 20 micron. These filters removes the dust particles of 20 micron size. After passing through this filters again passing through the 5 micron filters which are provided after the 20 micron filters. These 5 micron filters removes the dust of 5 micron size dust particles. The passed air from the filters moves to the blower motor.

The blower motor sucks the air from the filters and supplies to the cooling coil. In cooling coil, the air gets cooled and humidity increases as per the requirement. Then this air enters into the heating coil. In this coil, the air gets heated up and dehumidifies as per the requirement. From the heating coil, the air enters to the HEPA filters I.e. 0.3micron size filters. In this HEPA filters, the air gets free from the dust as this HEPA filters removes very very small size particles say 0.3 micron particles. After passing through this HEPA filters the air gets cleaned ad supplies to the clean room or required area.

From clean room, the unwanted air or any impurities present then the air goes to the exhaust air handling unit with the help of the ducts. In this exhaust air handling unit, the process of supply air handling unit is as same as the exhaust air handling unit. The air from the exhaust air handling unit sent to the atmosphere. If unwanted air or any impurities are not present then the air goes to the supply air handling unit with the help of return air duct. Again the process repeats. In clean room, with the help of this cleaned air atorva statin powder production occurs.

CLEAN ROOM:

A clean room is a controlled area where the production activity is carried out. In clean room area the room temperature, room pressure, humidity and particulate matter is controlled. In clean room, where the atorva statin powder production process will be done.

The clean room is maintaining very clean without any impurities and moisture. A product quality is very important in the mean of human safety and efficacy. The temperature in the room should not exceed 25°C and pressure is based in the room size, powder production quantity, etc. Pressure is vary from room to room, it will be 0.6mmWC to 3.6mmWC(water column). Temperature and pressure is to be maintained as per the production requirement and human comfort by AHU. Relative Humidity is maintained below 65 in the clean room and it is controlled by the Dehumidifier or hot water coil. The manufactured drug product is directly affected to the human body. So, that the clean room is maintained highly cleaned.

CALCULATIONS:

1. No.of locations:

No.of locations can be calculated in 2 cases. **Case1:** If room area is $>1000m^2$ then use the following formula. NL = $27 \times [A/1000]$ (A = clean room area) **Case2:** If room area is $<1000m^2$ then refer below table.

Area of clean room less than or equal to (m ²)	Minimum number of sampling locations to be tested (NL)	Area of clean room less than or equal to (m ²)	Minimum number of sampling locations to be tested (NL)
2	01	76	15
4	02	104	16
6	03	108	17
8	04	116	18
10	05	148	19
24	06	156	20
28	07	192	21
32	08	232	22
36	09	276	23
52	10	352	24
56	11	436	25
64	12	636	26
68	13	1000	27
72	14	>1000	Refer above formula

Our clean room area $10 \times 10 = 100 \text{m}^2$.

Our clean room area is $<1000m^2$. So taking case2.

No. Of locations for 100m² are 16.

2. COOLING LOAD CALCULATIONS:

Cooling load of an air handling unit is the amount of heat that needs to be removed from the air passing through the AHU to maintain the desired indoor temperature. The cooling load depends on various factors such as size of the space being cooled, the ambient temperature and humidity, the heat generated by equipment and people in the space, and the ventilation requirements.

Clean room volume = $10 \times 10 \times 3m^3 = 300m^3$.

20people are occupied in the room.

The outdoor temperature is $T1 = 35^{\circ}C$.

The indoor temperature is $T2= 22^{\circ}C$.

The AHU is designed to supply 100% fresh air at a rate of 10ACPR.

The heat generated by the people is approximately 100W.

The heat generated by the office equipment is approximately 200W per square meter of floor area. Floor area is $100m^2$.

Heat load = $(20 \times 100) + (100 \times 200) = 22000$ W.

Sensible heat load is the amount of heat that needs to be removed to maintain the desired temperature. Sensible heat load = [Volume \times Air density \times Specific heat \times (T2 - T1)]

The air density and specific heat of air depends +on the temperature and humidity. For a temperature of 22°C and a relative humidity of 50%. We can use the values from a psychometric chart to calculate the air density and specific heat of air.

= 300×1.2×1005×(22-35)

Sensible heat load = -45270W

Since the sensible heat load is negative, this means that AHU needs to supply heat to the room to maintain the desired temperature. However, in this case, we are interested in the cooling load, which is the amount of heat that needs to be removed. Therefore, we take the absolute value of the sensible heat load.

Cooling load = |sensible heat|+ Heat load

Cooling load = |45270|+22000 = 67270W

Therefore, the cooling load of the AHU is 67270W. This means that the AHU needs to remove 67270W of heat from the air passing through it to maintain the desired indoor temperature.

3. OPTIMIZATION OF AIR QUALITY IN AHU :

Clean room volume = $300m^3$. 20peoples occupied in the room. The AHU is designed to supply 100% fresh air at a rate of 33.76ACPR. Outdoor temperature = 35° C. Indoor temperature = 22° C. The relative humidity is 50%. Air changes per hour is the number of times the air in the room is replaced in one hour. ACH = (air flow rate×60)/volume Where : Airflow rate is the amount of air supplied by the AHU in cubic meters per how

Where ; Airflow rate is the amount of air supplied by the AHU in cubic meters per hour(m^3/h). Volume is the volume of the room In cubic meters(m^3).

In this case, the volume of the room is 300m³. since the AHU is designed to supply 100% fresh air at a rate of 10 air changes per hour.

Air flow rate = (volume \times ACH)/60

Air flow rate = $(300 \times 10)/60 = 50 \text{m}^3/\text{h}$.

Next, we need to calculate the concentration of outdoor by the AHU. Assuming the outdoor concentration of PM2.5 particles is $50\mu g/m^3$. We can use the following formula to calculate the concentration of PM2.5 particles in the air supplied by the AHU.

Concentration = (airflow rate×outdoor concentration)/supply air volume.

Where; outdoor concentration is the concentration of outdoor of pollutants in $\mu g/m^3$.

Supply air volume = airflow rate \times 3600

Supply air volume = $50 \times 3600 = 180000 \text{ m}^3/\text{h}$.

Concentration = $(50 \times 50)/180000 = 0.0139 \mu g/m^3$.

The air quality index(AQI) can be calculated based on the concentration of PM2.5 particles using the following equation.

 $AQI = (concentration/national ambient air quality standard) \times 100$

Assuming the national ambient air quality standard for PM2.5 is $12\mu g/m^3$, the AQI is

AQI = (0.0139/12)×100 = **0.116%**.

Since the AQI is very low, the air quality can be considered to be good.

CONCLUSION:

Production of atorva statin powder, the air handling unit and refrigeration and air conditioning plays a crucial role in the process of our atorva statin powder to maintain the desire temperature, humidity, pressures in the blocks is provide dust free environment. To process the bulk drug the facility is used like production area, ware houses, process area, material storage and dispensing, quality department. It is very important to maintain the area and block to be cleaned. AHUs are installed in all these areas to control the atmospheric and climatic conditions.

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