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REVIEW ON: AUTOMIZATION AND DEVELOPMENT OF AIR HANDLING UNIT IN PHARMACEUTICALS

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Abstract :-

An air handling unit is a device that distributes and conditions air throughout a building. HVAC systems need a combination of Good Manufacturing Practices (GMP) and Good engineering practices (GEP). By automating an outdated HVAC system it is possible to operate the air conditioning in many zones and lower the power cost. Advanced technology like a sensors, automation and algorithms for machines learning may be integrated into smart HVAC system to enhance comfort, energy saving and overall performance.

Keywords :- Automization, AHU, HVAC, Filters.

1. INTRODUCTION :-

1.1 Air handling unit (AHU) :-

A device that distributes and conditions air throughout a building is called an air handling unit, or AHU. After removing moisture from the air, it can be cleaned, heated, cooled, humidified, dehumidified, and other processes carried out on the air. Following treatment, the air is pushed out of the AHU and into "Zones," or specific parts of the structure, via ductwork. The target temperature(s) of the air in the building's zones and the air brought into the AHU determine whether to heat or cool it as well as Humidifying or dehumidifying it in the same way. Once the zones have received the treated air, the "dirty" air is extracted from each zone and returned to the AHU via the ducting. Afterwards, to increase efficiency, it is either recycled again to the system or released into the atmosphere[1].

More thought must go into designing of air handling units for the pharmaceutical sector, especially when it comes to creating a hygienic and secure atmosphere. HVAC systems need a combination of Good Manufacturing Practice (GMP) and Good Engineering Practice (GEP) and can account for a significant amount of a facility's energy consumption. The primary objectives of HVAC systems are to ensure the comfort of employees and safeguard the surrounding environment and workers from potentially dangerous airborne contaminants[2].

1.2 Principle of AHU :-

An AHU operates on a fairly basic concept. Air from the return duct or externally is drawn in by the air handler. It goes through many filters to get rid of contaminants or particle debris. Next, overheating or cooling coils are used to raise or lower the air's temperature to the appropriate level. Ultimately, the cycle continues when the conditioned air is ducted throughout the structure[3].

1.3 Automization of AHU :-

It is possible to operate the air conditioning in many zones and lower the power cost by automating an outdated HVAC system. This also increases energy efficiency.

i. Installation :- Actuators, sensors, cables, controllers, and drives were ordered by the Smart HVAC system. The volume control dampers and the newly designed, aesthetically pleasing aluminium extruded grills have been replaced with new units, replacing the outdated manual ones. In every volume control damper, actuators were mounted on the shaft. In every room and hallway throughout the building, accessible locations for temperature control and other amenities like an on/off button were to be provided along with controllers and temperature sensors. Adjacent to the actuators were the controllers mounted. The HVAC system ordered actuators, sensors, wires, controllers, and drives. The out-of-date manual volume control dampers and the beautifully crafted, aluminium extruded grills have been changed with brand-new components. Actuators were installed on shafts in each volume control damper. Controllers and temperature detectors were to be placed in easily accessible places, along with additional conveniences like an on/off switch, in each room and hallway across the building. The controllers were positioned next to the actuators.

ii. Testing :- If the room temperature reached 22˚C, the controller would send an alert to the actuator to shut the damper. This would occur if the intended temperature was set to that level. In order to slow down the AHU appropriately, the controller would simultaneously transmit a signal to the variable frequency drive panel[4].

1.4 New trend in AHU :-

Advanced technologies like as sensors, automation, and algorithms for machines learning may be integrated into smart HVAC systems to enhance comfort, energy savings, and overall performance. Via integration with other intelligent appliances and home automation platforms, these systems dynamically adjust their operation based on user preferences, ambient conditions, and even occupancy patterns.

> The newest 2023 smart HVAC technology examples are as follows :-

Learning thermostats**,** Zoning systems**,** Advanced air quality monitoring and management tools**,** Predictive maintenance alerts**,** Demand Controlled Ventilation[5].

2. TYPES / CLASSIFICATION OF AHU :-

Table 2.1 :- Classification according to the nature in which the components are placed[6]

Horizontal Unit	**Vertical Unit**
Every unit is positioned at the same horizontal level. It requires a larger area for installation, and it includes an outlet and an inlet. After conditioning, the air enters through the inlet and moves through each component. At last, the outlet lets out air. Separate floor space is required for every AHU component. Therefore, a higher floor requirement is needed. Careful control of noise and vibration is required.	Some or all of the parts of vertical units are stacked on top of one another. The horizontal levels at which the components are placed differ. Compared to horizontal units, this type of vertical AHU requires less floor space. Vertical Units are often located in the AHU or fan rooms.

Table 2.2 :- Classified on the basis of the location of the fan with respect to the cooling coil[6]

Draw-through Unit	**Blow-through Unit**
The supply fan is located in the draw-through unit after the cooling coil section. Over the coil section's whole surface, the conditioned air is dispersed equally. Draw-through unit are therefore recommended if and equal dispersion of air required. This AHU'S are the most often utilised ones. Boost productivity. But compared to the Blow- through unit, the draw- through unit cost more.	The cooling coil component of Blow-through unit is situated after the supply fan. Located after the fan is the cooling coil. Air enters the cooling coil segment after being partially cooled by the fan. Upon passing through the fan, the air temperature is lowered to a certain degree. It then cools down much more by passing through the cooling coil. In most multi-zone AHUs, blow-through units are employed.

Table 2.3 :- Classification depending upon the number of zones served by an AHU[6]

Single-zone AHU	**Multi-zone AHU**
As the name implies, single-zone AHU only covers one zone. Considering they service a single zone, they are little in size. These AHUs have a low capacity.	Since multi-zone AHUs service many zones, their capacity is expected to be higher. In addition, their size is larger than that of single-zone AHUs.

Table 2.4 :- Classification depending upon the manufacturing of the AHUs[6]

Factory-fabricated AHU	Custom-built AHU
Made in a factory As the name implies, AHU are made in factories. They are well constructed. Because every component is well-designed and produced in bulk, they are less expensive.	More structural, component selection, size, and other flexibility is offered by custombuilt AHUs. Depending on the dimensions, the weather, etc., they are made on-site. These AHUs cost extra since every component is made to order.

Table 2.5 :- Classification depending upon where the AHU is placed[6]

Rooftop AHUs	Indoor AHUs
They are fixed to the roof. They are composed of heavy gauge aluminium or steel sheets that have been galvanised, and they are weather- and corrosion-resistant. They must endure several extreme weather events, such as high temperatures, rain, etc. really costly. Additionally, the likelihood of component degradation and failure increases due to their exposure to the environment. Thus, every part is positioned inside the housing.	They are positioned in either the AHU or the fan room. These AHUs can also be suspended from the ceiling if their size is extremely small.

3. SIGNIFICANCE / PURPOSE OF AHU IN PHARMACEUTICALS :-

Within a building, air handling units distribute and condition the air. They bring in clean, fresh ambient air from the outside, purify it, heat it, humidify it, and then drive it through ductwork to the designated regions of a structure. The used, unclean air is then drawn from the rooms and returned to the AHU, where a fan releases it back into the environment. This is often done via an extra duct run on most units. We'll look at it later in the piece. Some of this return air may be cycled back into the fresh air supply to conserve energy. Thermal energy can be captured and delivered into the fresh air intake in cases when that isn't feasible[7].

4. DESIGN / STRUCTURE / LAYOUT OF AHU :-

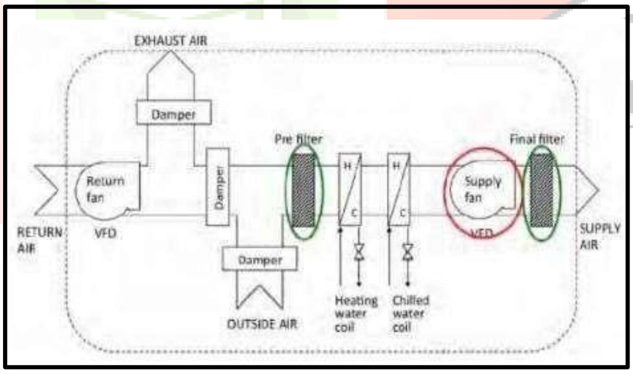

Fig.4.1 :- Layout of AHU [8]

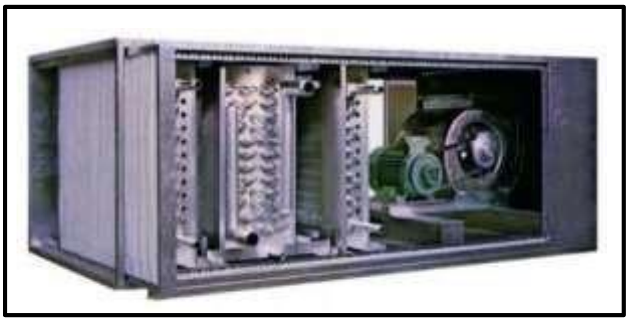

Fig.4.2 :- Layout of AHU In 3D[9]

Air handling units come in many sizes and varieties. Some AHU components can be installed on a building's roof or in a closet, while others need to be put in a mechanical room[9].

5. ACCESSORIES / PARTS OF AHU :-

Grill / Air intake screen, Dampers, Frost Protection (Pre Heating) Coil, Filters, Air Washer Cooler, Aluminium louvers, Fans, Humidifiers, Control Panel, Compressor spares, Mixing Box, Cooling and Heating Coils, Motor, Attenuator[1].

6. MATERIAL OF CONSTRUCTION (MOC) :-

Double-skinned insulated panels, often called insulated sandwich panels, make up an air handling unit's casing, commonly referred to as the "box."

> Rectangular pharmaceutical AHU and HVAC boxes are composed with - Aluzinc, Aluminium, Stainless steel (SS) and Mild steel (MS), Galvanised steel supporting frames are the most popular framing materials. Sandwich Panel PU, Mineral wool or injected sandwich PU (Polyurethane) foam are the materials utilised to insulate the panels[10].

6.1 AHU Construction and Components :-

It is made up of a rectangular box with two skins, one without insulation and the other with PUF insulation in thicknesses of 25 mm, 50 mm, and 60 mm, or as needed. It has the following components –

> HVAC System :- The whole set of AHU units with air carriers (duct), air distribution and collection in the room (riser/grill and diffusers, volume control system (dumper), terminal filters with, cooling and heating coil for temperature and humidity control sometimes with maintaining room temperature facility.

> HVAC Utility :- The surrounding system for HVAC system to work in operation ranges is its utility, for example, DG set, boiler, chiller, air conditioning compressor, air compressor, cooling tower, vacuum, refrigerant gas, and outdoor heating.

6.2 MOC (Material of construction) :-

i. Filters :- Filters aid in preventing cross-contamination since they are used to reduce air pollution. In order to prevent foreign items from harming the coils and fan, air handlers are equipped with filters that may capture dust, lint, insects, paper, and other airborne particles.

ii. Blower :- This air section is from the horizontal side, and air supply is from the top side. It is a DIDW (double inlets double width) system. The air section known as SISW (single input single width) receives its air supply from a single horizontal side.

iii. Heating coil :- To heat the air and increase the dew point for humidity management, pharmaceutical AHUs and HVAC systems are also available. According to the amount of air needed for heating and the desired depth—two or four rows—these are electric heaters or steam coils. Installing the coil in the AHU is needed.

iv. Fan type (blades) :- The FDA-forward angle (for low static < 100 to 125 mm w.g.{millimeter water gauge}). Efficiency :- The performance curve for this application between CFM Vs. efficiency and CFM Vs. static pressure.

v. Cooling :- Chilled water (7 °C inlets) or DX coil is offered in AHUs based on the required room temperature. If a heating coil is included, the cooling system comes just after the blower. The cooling coil comes before the blower if there isn't a heating coil. Split air conditioners are occasionally utilised to cool the compressor, condenser, and FCU that make up the non-production unit. The compressor is installed outside the room, while the fan coil unit (FCU) is installed within. Both FCU and the compressor provide the cold air in the room.

vi. Volume Control Dumper, or VCD :- VCDs are helpful for balancing pressure. GI and aluminium are the building materials. CFM units of capacity are used.

vii. Gasket :- To prevent air leaks between the joints of the duct and VCD, a rubber gasket is utilised.

viii. RTV :- Joints in the duct's air route are sealed with this room temperature vulcanised sealant.

ix. Duct :- An air carrier is a rectangular or round-shaped duct. There are many standards available for construction, with MOC being GI or SS (22, 24, 26, and 22 gauge being thick, and 26 gauge being thin sheet).

x. Pharmaceutical AHU and HVAC Insulation :- Drop ducts are properly insulated with the right kind of material to prevent overheating. Aluminium, nitrile rubber, and SCP (send cement plaster) are the three types of insulation available. xi. Distribution system :- These are the components that allow air to be distributed around the space via ducts. Grills, diffusers, and a terminal HEPA with filter screen comprise the air distribution system.

xi. Return Air Risers :- Return air ridders are essentially little boxes with mesh covers and filters. To collect air from the room, they are mounted in the wall at the bottom and linked to the return air duct. MOC is powder coated aluminium, stainless steel, and glass fibre. CFM equivalent of capacity.

xii. Dampers or Valves :- Adjustable dampers, which let varying volumes of air enter and exit specific apertures, are frequently found in larger AHUs. Multiple revolving metal sheets make up the dampers. The airflow can be limited by their ability to shut, which stops air from entering or leaving, open, which lets air pass through completely, and change their position in between. Monitoring equipment used are :- Thermometer, Hygrometer, Pressure Gauge, Inclined Manometer[11].

7. FILTER TYPE :-

The AHU's intended purpose and location will determine this. A filter's efficacy is determined using ISO 16890 standards. Particles of sizes ranging from 10 microns to 0.3 microns may typically be captured using filters.

> There are several types of filters available for AHUs are as follows :-

i. Filters types based on microns are :- Coarse filter, Intermediate filter, Prefilters, Fine filter, Mini pleat HEPA[11].
ii. Bag filters iii. Pleated Panel filters iv. Compact filters
v. EPA, ULPA and HEPA filters
vi. Electrostatic filters vii. Carbon filters[12]

> From which HVAC filters are made, however :- Fiberglass And Pleated Cotton[13]

7.1 Filter size :-

An improperly sized furnace or vent filter will prevent the filter from performing as intended. The air filter will be loose and some air (and debris) won't pass through if it is too narrow. When the filter is in place, that is precisely the opposite of what must occur. However, a too large filter will cause the frame to collapse, air flow to be impeded, and lifespan to be reduced. Limiting airflow also increases energy costs and shortens the life of your HVAC system.

> Most Common Air Filter Sizes are as follows :-

There are often 10–20 size variations available for filters at a home supply store. The return air vents that draw or push air into your HVAC system are sized to match the most popular sizes[14].

1. $20 \times 20 \times 1$	6. $16 \times 25 \times 4$
2. $16 \times 25 \times 1$	7. $20 \times 30 \times 1$
3. $20 \times 25 \times 1$	8. $12 \times 12 \times 1$
4. $20 \times 25 \times 4$	9. $14 \times 14 \times 1$
5. $16 \times 20 \times 1$	10. $14 \times 20 \times 1$

7.2 Storage of ahu filters :-

Storage for six months or more beyond the date of shipping is considered long-term storage; nevertheless, storage should not exceed thirty six months. To keep it protected from the weather, the AHU must be housed indoors or behind a tarp or other covering. Refrain from using plastic covering to keep the device from becoming rusty and from collecting moisture. > Indoor AHUs and Outdoor AHUs the following is a list of requirements for the long-term storage of Indoor AHUs :- • In indoor AHU the device must never be kept outside for storage.

- After examination and before to outdoor storage, recover AHUs.
- To shield all components and porous materials from snow, rain, and moisture, set the AHU outside on blocks.
- To avoid deformation, keep the AHU stored on a level, hard surface.
- The recommended temperature range for storage is -40 F (-200˚C) to 1130 F (450˚C).
- There must be no condensation and a relative humidity of less than 95% for storage. The maximum relative humidity in the presence of corrosive gases is 60%.
- Keep the item stored away from stress loads and vibrations. Put on the damping substance as needed.
- Store between 0.7 and 1.05 atmospheres, or 70 kPa to 106 kPa, of atmospheric pressure.
- Make sure every electrical part is kept in a dry, clean atmosphere.
- Before storing, rotate the fans.
- To stop liquids and other objects from getting into the device, close the outlet connectors and the water coil input.
- To prevent the introduction of microbiological development into the AHU, decontaminate or replace components as needed[15].

7.3 Change control of filters :-

Maintaining regular air filter replacements can be difficult, especially if you might be spending more of your maintenance time on value added maintenance. Keeping your manufacturing plant hygienic, operating at peak efficiency, and maintaining a healthy level of Indoor Air Quality (IAQ) all depend on regular air filter replacements.

> Points that fit this description are as follows :-

i. Type, style or design of the air filters
ii. Air filter efficiency
iii. Location & design of the air handling system
iv. Age & condition of the air handling system
v. Temperature of the operating / manufacturing environment
vi. Cleanliness & maintenance programme of the ductwork & extraction systems
vii. Internal operations & environment
viii. Manufacturing compliance requirements
ix. Audit compliance requirements

x. Form of production & manufacturing xi. Geographical location & external influences[16].

8. AHU / HVAC SYSTEM VALIDATION TESTS :-

i. Air flow pattern :- A titanium tetrachloride stick is burned and positioned in front of the AHU to determine the air flow pattern. It is seen how smoke is distributed. It ought to be consistent.

ii. Air flow velocity and changes per hour :- Using four fictitious grids to partition the HVAC area, the air velocity is measured at each grid, and the average air velocity (V) is computed. Determine each air inlet's Area (A) in square feet by multiplying its length by its breadth. Utilising the following formula, get the Total Air Volume (T in cubic feet per minute) delivered in each zone :-

$$T = A \times V$$

where, A = Area of particular Air inlet in square feet.

V = Average air velocity at particular air inlet in feet per minute.

By multiplying the room's length, width, and height, you may find the overall volume of the space. To calculate the air change each hour, divide the total air change by the room's volume.

iii. Filter integrity (dop/pao) test :- An aerosol generator operating at 20 psi air pressure produces a PAO aerosol, which is then allowed to flow upward to test the integrity of the HEPA filter. Once the aerosol has been allowed to flow upward 100% of the time, the amount of reversed aerosol is measured by monitoring the HEPA receptor probe. It must not surpass the HEPA filter's upper limit. Microelectronics and the pharmaceutical sectors both have access to these. According to IES-RP-CC-001-86 & ISO 14644, all filter integrity tests were carried out. With both Poly Alpha Olefin (PAO) and Di–Octal Phthalate (DOP), we are prepared to conduct HEPA Filter Integrity Tests. Optimising performance requires testing and assessing filters at least once a year and potentiality twice a year. Accurate certification and supporting paperwork are given.

iv. Fresh air determination :- On the fresh air dumper, the intake of fresh air is measured at the input. One calculates the overall air change. To calculate the percentage of fresh air that the HVAC system in each individual room intakes on each cycle, the intake fresh air is divided by the total air change in the room and multiplied by 100.

v. Uniformity test of temperature and humidity :- A calibrated thermometer is used to check temperature uniformity, whereas a manometer is used to measure humidity. The two parameters are recorded in the format, observed daily, and stabilisation is guaranteed within the designated range. There are two temperature and humidity test levels.

vi. Filter leak test :- The air velocity is measured at each corner of the AHU system using a velometer, which is used to verify the HEPA filter's leak test. The air velocity must not exceed the HEPA filter's upper limit. If it turns out to be higher than that, a silicon gas cut is utilised to reduce the leakage.

vii. Particle Count :- A particle count is obtained both before to and during the procedure. Particle counts in the Grade A, B, C, and D areas should fall within the specified range. Complete airborne particle count cleanliness classification is provided by Particle Count Test. According to ISO 14644, EU GMP, the test determines particle count based on As-Built, At-Rest, or Operational.

viii. Viable monitoring :- Using the swab test and nutritional agar medium for microbe incubation, viable monitoring is carried out every day. Every production segment, including the reverse air duct of the HEPA filter at the rear of the cubicle, has exposed media plates. Should the microbe count be detected to be outside of the specified range for two consecutive occasions, appropriate remedial and preventative measures will be implemented.

ix. Recovery :- By using filtered air to purge the space, these experiments show that the clean room can effectively eliminate particle matter. This involves turning the HVAC system off and checking the temperature and humidity. After turning on the HVAC system, the temperature and humidity are measured once more, this time reaching a humidity of 75% and a temperature of 40°C. The time needed for the temperature and humidity to stabilise is also recorded.

x. Difference in pressure :- The manometer that is fastened to the nearby area's walls is used to compute it. Typically, the pressure differential is maintained between 5 and 20 mmHg[17].

8.1 Clean room / hvac validation / evaluation test to check performance of ahu :-

For all room classes, QA Tech conducts HVAC validations in accordance with ISO 14644, EU cGMP, US Federal Standard 209E, USFDA, Schedule M (National Regulatory Body), WHO Geneva, TGA (Australia), European (EMEA), and MHRA (European Countries) requirements.

> Air Velocity Measurement :- The airflow grid velocities are totaled and then divided by the number of observations to get the average airflow velocity.

> Room Pressurization Test :- This test measures the pressure within a room. This test confirms that a pressure differential satisfies the standards as part of the validation procedure.

> Airflow Visualization Test :- This test aims to display the real airflow pattern in the unidirectional clean room. The test can also be used to show how equipment affects airflow. the test that uses ISO 14644 guidelines to determine the airflow patterns inside a room. This visual monitoring service is crucial for the following :- clean room laminar flow tests; airflow balancing; fuming hoods; point exhaust tests; personnel safety exhausts verification; leak identification in ducts.

> Light Intensity Test :- The lighting intensity tests are conducted to confirm that the installed light levels and uniformity fulfil the required standards. Contemporary testing devices that measure lighting intensity and lux levels.

> Noise Level Test :- Conduct this test to gauge the pressure of the sound. The measures will change according to the state-of-the-art clean room's occupancy. Although the goal may change, the testing methods remain the same.

> Air Exchange Rate: In a clean environment, testing for air exchange rate measure the total volume of air entering the space. The air volume passing via grills, diffusers, and registers is measured by the hood. These air capture hoods are lightweight— just 3.5 kg— making them convenient to use and transport. These hoods read direct supply or exhaust airflow on the huge digital display by just holding the balance up to a diffuser or grill.

> Containment Test: This test is performed to make sure that leaks in the building materials do not allow airborne pollution to enter from a higher pressure region next to the clean room[18].

9. MAINTENANCE OF AHU :-

Maintenance is essential to an AHU's optimal operation. To prolong its life and boost its performance, one must have a thorough understanding of the machinery[19].

> Air handling unit maintenance checklist :- Regular AHU cleaning and maintenance lowers operating, downtime, and troubleshooting expenses in addition to extending the equipment's lifespan.

Make sure you follow the maintenance checklist below :-

> Examine :- Humidity, belt, electrical disconnect, control panel and boxes, control set points, return air dampers, relief air dampers, filter section, heating coil, drain line & pan, cooling coil, supply air fan, supply fan motor, return air fan, return air fan motor, exhaust air fan, exhaust air fan motor, heating section, heater safeties, hot and cold batteries, other accessories, > Inspect :- Outside air dampers, face & bypass dampers,

> Lubricate :- Fan bearings, supply fan motor bearings, exhaust fan bearings, exhaust fan motor, Fan bearings on return fan, return fan motor, > Check :- Belts and sheaves on supply fan and exhaust fan, return fan, temperature split across coil, expansion valve, contactors/starters, fan's rotation,

> Clean :- Heating coil, cooling coil, drain line & pan, supply fan and housing, Return fan and housing, exhaust fan and housing,

> Change :- Filters, Thermostat Batteries

> Record and Check operating amps

> Tighten electrical

> Log amp readings

> Periodic maintenance / the maintenance frequency of ahu's :-

The needs of your particular system, the manufacturer's recommendations, and the surrounding climate all affect how frequently you should maintain your air-handling equipment. Generally speaking, AHUs need to be maintained at least twice a year[20].

10. SOP FOR AIR HANDLING UNIT (AHU) :-

Standard operating procedure for managing the air handling equipment that keeps the space where pharmaceuticals are made clean.

A. Responsibility and Personnel :- Executive/Officer of Engineering

B. Accountability / Personnel :- Engineering Manager

C. Procedure :- The Engineering Manager will be in charge of carrying out this SOP. The compliance of this SOP shall be the responsibility of the Head QA or designee.

> Prestart Check-Up Are As Follows :-

i. Verify that the pulley is securely secured into place. Additionally, see whether the motor belts are damaged or switched off.

ii. Replace the damaged belts right away.

iii. Verify that all of the doors, filters, fresh air damper, CHW (chilled water) intake and outlet, and visibility for chocking and damage are completely closed to prevent any air leaks.

iv. Verify that the by-pass valve is closed and the 3-way valve in the chilled water return circuit is appropriately opened. Only when a 3way valve is used for breakdown or preventative maintenance is the by-pass valve activated.

v. Verify the pressure and temperature gauges are fitted correctly, and that the chiller plant is running constantly to supply chilled water to the AHU at a temperature of no more than 20ºC.

Table 10.1 :- Starting and Closing Down the machine[21]

Starting the machine	Closing down the machine
1. Verify that each AHU main panel and every AHU panel has a power supply. 2. Turn on the power source. 3. Verify the operation of the modulating valves. 4. Inspect all of the filters for chocking by checking the manometer level.	1. Verify the pressure differential between the pre filter (4 to 8 mm WC) and fine filters (8 to 12 mm WC) before the AHU is turned down, and enter the information in the AHU operating log. 2. Turn off the device. 3. Verify if the pulley and belts have any obvious damage. 4. Make sure that every AHU door is closed properly.
5. Verify if the dampers have been opened to their correct positions. 6. Record the readings from the Magnehalic gauge in the log book and check it for pressure differences between the pre filter (4 to 8 mm WC) and fine filters (8 to 12 mm WC). 7. Check the readings from the Magnehalic gauge for the pressure differential across the HEPA filter (25 to 50 mm WC) and record the data in the log book. 8. To make sure the filter is clean, replace it if the readings are below the limit. 9. Verify and document the findings.	5. The recording of RH and differential pressure is prohibited when the area is at cleaning temperature. Production in charge will make sure that the necessary environmental conditions are maintained prior to production beginning, and this will be documented in the BMR. Should there be any deviations, he will promptly notify the engineering department so that remedial action may be taken. 6. The AHU of every corridor must be started first at the beginning of each shift or day. Other AHUs will thereafter be initiated. Ensure that all passage/corridor AHUs start in auto mode initially in the event of a power outage and after it is restored by DG power. This will stop cross-contamination. The next step is to manually start each additional AHU one at a time. Before manufacturing activity resumes, the production in-charge will make sure that the necessary environmental requirements are satisfied. Every AHU in dry powder injection will begin operating in auto mode. 7. The HVAC operator shall notify the engineering manager right away if the AHU does not start following power restoration for any cause or defect, and the manager will confirm preventive actions with the production department. The HVAC engineer will notify the production charge once the defect has been fixed, allowing production to resume.

11. AHU MANUFACTURER IN INDIA AND FOREIGN COUNTRY :-

Table 11.1 :- AHU Manufacturer[22,23]

USA manufacturers	Indian manufacturers	Worldwide manufacturers
1. Carrier Corporation 2. Goodman Manufacturing Company 3. Rheem Manufacturing Company 4. Trane Inc. 5. York International Corporation 6. Lennox International, Inc. 7. Nortek Global HVAC 8. Honeywell International Inc. 9. Johnson Controls	1. Symphony Limited - Best Air Cooler In India 2. Voltas Limited 3. Eta Engineering Private Limited 4. Blue Star Limited 5. Flaktgroup India Private Limited Johnson Controls-Hitachi Air Conditioning India Li Manufacturing (Machinery & Equipments) 7. Aarkays Air Equipment Pvt Ltd 8. Vts Tf Air Systems Private Limited	1. Daikin 2. Ingersoll Rand 3. Johnson Controls International 4. LG Electronics 5. United Technologies Corporation 6. Midea 7. Electrolux 8. Mitsubishi Electric Corporation 9. Toshiba Corporation 10. Samsung Electronics 11. Lennox International 12. Panasonic Corporation

12. CLEANING OF AHU :-

I. Definition :- These guidelines, which exclusively address air-handling unit cleaning, adhere to the standards of ČSN EN 15780: Ventilation in buildings, Air ducting, and Air-handling equipment cleanliness. Please refer to the procedures for maintaining the cleanliness of the air-handling equipment. The device's operator is required to carry out these tasks in compliance with the standard ASN EN 15780.

II. Dry Cleaning :- A dry cloth or hand brushing and vacuuming with the proper suction pressure are used for this. Assembly cleaning is done by blowing compressed air (blowing).

III. Wet Cleaning :- This is accomplished by vacuuming the droplets with the proper suction pressure or by hand brushing with a brush that's wet and a damp towel. You can use common cleaning supplies with a neutral pH. Using common cleaning equipment, pressure water cleaning may be done via water jetting. Chemical cleaning (disinfection) can be done manually (with a cloth), with a pressure washer, or with a gas generator. Gaseous or liquid chemical agents (do not use dry agents) are applied.

IV. Cleaning the Chambers of Air-handling Units :- 1. Cleaning the Filtration Chambers :-

a. Filter Inserts
b. HEPA Filter Cleaning
2.Humidifier Cleaning
3.Heat Exchanger and Drop Eliminator Cleaning
4.Condensate Tray and Condensate Drainage Cleaning
5.Fan Cleaning
6.Attenuator Cleaning
7.Cleaning the Unit's Inner Walls
8.Cleaning the unit's outer walls
9.Cleaning the Condensate Drainage Siphons.

V. Safety of Work :- All relevant safety regulations must be observed when cleaning the air-handling equipment. encompassing both general safety precautions and equipment-user-specified safety guidelines.

1. Equipment for Personal Protection :- The finest overall work attire includes protective eyewear, gloves, a respirator, safety work shoes, and working pants.
2. Workplace Safety :- Lighting in the workspace, efficient ventilation, and organisation in the office.

VI. Tools for Work and Cleaning Supplies :- Water bucket, towel, dish soap, pressurised bottle with sprayer, Adequate disinfectant. The vacuuming manually operated instruments, instruments run by batteries, Platforms and work step-ladders[24].

13. DOCUMENTATION / RECORD KEEPING OF AHU :-

> List of various type of documents used in AHU :-
A. HVAC Vendor's documents required respond by Owner IFR / IFD / IFC
B. HVAC documents and / or comment sheet required to respond by HVAC Vendor IFR / IFD / IFC
C) HVAC documents and / or comment sheet under yard review IFR / IFD / IFC
D) HVAC document issued for construction (IFC) obtain code 1
E) HVAC document and / or comment sheet to be removed
F) HVAC vendor's document not issued for IFR / IFD / IFC
> List Of Content For Final Documentation – HVAC System :-

1. Final Documentation - HVAC System
2. Spare Parts List - HVAC System
3. Master Equipment List - Refrigeration System
4. Operation Manual and Maintenance Manual For Refrigeration System
5. NR-13 Dossier - Refrigeration System
6. List Of Content For Final Documentation and Spare Parts List of - Refrigeration System
7. Factory Acceptance Test Procedure- Refrigeration System (For Electrical Control Panel)
8. Standard User Manual For Refrigeration system
9. HVAC Philosophy
10. Vendor Document - Dampers - Machinery
11. Pressure Loss Calculation - Air Distribution System
12. HVAC Electrical Block Diagram
13. Electrical Drawing - Accommodation And Machinery Areas Pneumatic Fire Dampers and damper panel, as well as Air Conditioning System - Battery Room A & B.
14. Operation Philosophy - Refrigeration System[25].

14. GMP GUIDELINE OF AHU :-

For pharmaceutical items, air is one of the main causes of contamination. According to GMP (Good Manufacturing Practices), increasing the efficiency and capacity of the AHU (Air Handling Unit) requires careful design, monitoring, and maintenance.

> Tips for Good Practices of Air Handling Unit (AHU) :-

- The AHU system should be created in accordance with the specifications listed in the new schedule "M" or any other relevant standards.
- It is important that the AHU system be placed in a tidy and appropriate area with enough room for upkeep and cleaning.
- Fitting the right size filters into an AHU will provide the required class of air quality. Different places should have distinct AHUs.
- Fully atomized, PLC-based temperature and humidity controllers are recommended. The installation of an alarm system that is not up to code is required.
- The construction material for the AHU should not produce any kind of contamination.
- Installing an AHU in a shed rather than an open area is advised.
- AHU systems have to be fitted with fire and safety equipment.
- There should be instruments accessible to measure temperature, humidity, pressure, and air velocity.
- Regular documentation should be maintained, along with periodic cleaning, preventative maintenance, and validation.
- The right pressure to discriminate, airflow patterns from cleaner to dirtier, air changes, heat load, and occupancy should all be taken into account when designing AHU systems for parenteral and other formulations.
- Where necessary, pipes should be installed correctly and have no leaks, as well as the AHU and duct's fabrication quality checked.
- Provide a systematic drawing that includes the kind of duct, diffuser, grills, elbow, dust size, and branching.
- To show the interior room pressure, manometers have to be fitted.
- Any class filter should be placed at the terminals, and AHU filters should be put in locations that are vital but not sterile.
- Keep track of air velocity records.
- Leaks may be prevented by installing filters correctly and using the right gaskets.
- The atmosphere shouldn't be exposed to production-related dust from exhaust.
- For items like pills, powder, capsules, etc. that are exposed to dust, return air ducts should have sufficient filtration.
- Validation (DQ, IQ, OQ, PQ) with SOP should be recorded prior to the system being used in the production area.
- Good practices for the Air handling unit should be trained to staff members, and documentation must be kept up to date.
- Accurate writing, observance, and presentation of SOP are required close to AHU.
- Records of preventative maintenance and filter cleaning have to be kept.
- In the powdery operation area, diffusers, grills, and risers should be cleaned often.
- When manufacturing is underway, AHU should be in the "ON" position.
- The start-up time, which is required to attain the targeted air quality class, must to be determined and documented.
- If applicable, out-of-specification should be documented.
- To ensure the integrity of the filter, the pressure drop over it has to be monitored and documented.
- Every airlock should have a sufficient supply of air.
- Manometers' working ranges should be shown in green; similarly, the monometer's green and red zones should be highlighted[26].

15. TECHNICAL ISSUES / COMMON PROBLEMS WITH AIR HANDLING UNITS :-

Common problems encountered with air handling units include :- Leakage and Ductwork Issues, Control System Failures, Air Filter Issues, Fan Motor Malfunction, Coil Fouling, Belt and Pulley Problems[20].

Table 15.1 :- Failure of AHU Equipment[27]

Category	Device	Typical Faults
Equipment	Fan	Pressure drop is increased. Overall failures of supply and return fans. Decrease in the motor efficiency. Belt slippage.
	Duct	Air leakage
	Preheating coil	Fouling and reduced capacity
	Heating coil	Fouling (fin and tube) leads to reduce capacity
	Cooling Coil	Fouling (fin and tube) leads to reduce capacity

Table 15.2 :- Failure in Actuator[27]

Category	Device	Typical faults
Actuator	OA, RA and EA dampers	A damper is stuck or a faulty position is operated. Air leakage occurs at fully open and closed position.
	Heating coil (HV), cooling coil (CV) and preheating coil valve (PV)	A valve is stuck, broken or wrong operated position. Leakage occurs at fully open and closed positions of the valve

Table 15.3 :- Failure in Sensor and feedback controller[27]

Category	Device	Typical faults
Controller	Motor modulation Sequence of heating and cooling coil valve. Flow difference Static pressure	Unstable response Unstable response Unstable response
Sensor	SA, MA, OA and RA temperature MA, OA and RA humidity OA, SA and RA flow rate	Failures of a sensor are offset, discrete or drift. Failures of a sensor are offset, discrete or drift. Failures of a sensor are offset, discrete or drift.

16. REFURBISHING OR REPLACEMENT OF AHU :-

- Cleaning the blower and heating/cooling coils.
- Eliminating and substituting insulation. - Using coatings with antibacterial agents.
- Repairing, restoring, or painting the inner surfaces of all parts, such as drain pans, fan blades, dampers, etc. (including coatings for rusted metal surfaces and damaged fiberglass).
- Filters need to be replaced[28].

> Why Purchase New?

There are several uses for the new units that are offered. Additionally, new models may include lifetime guarantees on the newest case materials, such as composite and aluminium.

> Benefits of the New AHU : -

- Adaptable to a variety of uses.
- There are choices for very efficient heat recovery.
- The units are custom-designed to fit existing areas.
- There are alternatives for lifetime casing.
- Enhances unit capacity - Utilises low energy and high-efficiency fans.

> What on the AHU can be Refurbished?

There can be significant gains with badly maintained equipment. After completion and with adequate maintenance, a quality refurbishment may extend the operating life of current equipment by about 15 to 20 years. Eg :- Gas Heaters, Heating and Cooling Coils, Filters and/or Filter Racks, Dampers, Fans[29].

> REPLACE OF AHU :-

In light of an AHU breaking down, the downtime is significantly shorter as arrangements would have already been made for the ideal time for the switchover. However, there are numerous factors to take into account when the decision is made to replace the AHU. The best course of action is advised when air handling refurbishment or replacement is necessary because qualified personnel with years of expertise in many settings and locales are able to anticipate issues before they emerge.

- Ecologically friendly is the use of the current plant.
- There won't be much disturbance to the building.
- Upgrading costs are far lower than buying new equipment.
- Rebuilding an air handling equipment requires more downtime than maintenance[30].

17. THE FUTURE OF HVAC TECHNOLOGY :-

The growing need for ecologically friendly and energy-efficient solutions is driving the HVAC industry's fast evolution into the future. In order to maximise HVAC performance and anticipate any maintenance issues before they worsen, cutting downtime and raising overall efficiency, sophisticated AI algorithms will become increasingly important as smart technology continues its fast progress. Eco-friendly HVAC technology research and adoption is another topic of interest for HVAC technology in the future. Smaller, more energy-efficient HVAC systems will be possible thanks to insulating materials based on nanotechnology and aerogel, which have better thermal performance and less thickness. The total carbon footprint of HVAC systems is decreased as a result of these developments. Future HVAC technology will be significantly impacted by growing urbanisation and the demand for space-saving alternatives. Engineers and architects are working together to create integrated, multipurpose HVAC systems that optimise space usage while blending in seamlessly with contemporary building designs. Urban landscapes may benefit from the functional and aesthetic integration of HVAC technology, as exemplified by vertical farming, green roofs, and living walls. A new age characterised by smarter, greener, and more efficient systems is about to dawn for the HVAC sector[5].

18. CONCLUSION :-

Advanced technologies like as sensors, automation, and algorithms for machines learning may be integrated into smart HVAC systems to enhance comfort, energy savings, and overall performance. Via integration with other intelligent appliances and home automation platforms, these systems dynamically adjust their operation based on user preferences, ambient conditions, and even occupancy patterns.

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