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Powder Processing Area and its Classification in Pharmaceutical Industries

Manender Mukhija

Centrient Pharmaceuticals Pvt Limited

ABSTRACT

Powder processing area is a controlled area to prevent airborne particle to enter by maintaining positive pressure in the area or we can say that it's a particulate free environment. A cleanroom's cleanliness is measured by how clean the air is and by the number and size of particles permitted per volume of air. It must be constructed and used in a manner that minimizes the introduction, generation, and retention of particles & microbes inside the room and in which other relevant parameters such as temperature, humidity and pressure are controlled as necessary. According to the clean room classification the room must be maintained to meet the specification cleanliness, Temperature, Humidity, Pressure, Number of air changes/hr and Flow rate (CFM).

INTRODUCTION

Powder processing area is always a critical area in pharmaceutical manufacturing industries in terms of cleaning and microbial check I.e fungus. Many companies have stopped production because of fungous growth observed in the manufacture of finished bulk drug. Clean rooms are classified according to ISO classification numbers starting from ISO class 1 to ISO class 9 but only ISO class 7 to ISO class 9 for 0.5 µm and 5.0 µm are applicable in pharmaceuticals. Area is to be maintained by cleaning reagents which are to be changed by weekly basis so that bacteria's are no longer habitual.

ISO Cleanroom Classification Table

	ISO classification	Highest levels of particle concentrations (particles/m³) equal to or greater than the parameters listed as follows.					
		0.1 µm	0.2 µm	0.3 µm	0.5 µm	1.0 µm	5.0 µm
Certify every 6 months	Iso Class 1	10	2	-	-	-	-
	Iso Class 2	100	24	10	4	-	-
	Iso Class 3	1,000	237	102	35	8	-
	Iso Class 4	10,000	2,370	1,020	352	83	-
	Iso Class 5	100,000	23,700	10,200	3,520	832	29
Certify every 12 months	Iso Class 6	1,000,000	237,000	102,000	35,200	8,320	293
	Iso Class 7	-	-	-	352,000	83,200	2,930
	Iso Class 8	-	-	-	3,520,000	832,000	29,300
	Iso Class 9	-	-	-	35,200,000	8,320,000	293,000

CALCULATION OF NUMBER OF PARTICLES

These number of particles are calculated for every class and for all particle sizes by the formulae given below:

$$C_n = 10^N \times [0.1 / D]^{2.08}$$

C_n = The maximum permitted concentration (in particles per cubic meter of air)of airborne which is rounded to the nearest whole number.

N= ISO classification number, which shall be from 1 to 9.

D: The considered particle size in micrometer I.e 0.1 µm to 5.0 µm.

0.1= Constant.

SAMPLE VOLUME OF AIR FROM EACH LOCATION

How many liters of air need to be sampled at each location in the cleanroom

Formulae :

Vs = (20/Cnm) X 1000

Vs = The minimum single sample volume per location, expressed in liters

Cnm = The class limit (number of particles/m^3) for the largest considered particle size specified for the relevant class.

20 = The defined number of particles that could be counted the particle concentration were at the class limit.

This formula will calculate how many litres of air need to be sampled at each location in the cleanroom. Here's an example to clarify:

Let's say we're certifying an ISO class 8 cleanroom. The largest considered particle size for this class is 5.0 µm of which the cleanroom must have less than 29300 particles/m^3.

Vs = (20/29300) x 1000

If we calculate the formula, we come up with Vs = 0.68. So in order to certify this cleanroom we need to sample 1 litre of air at each measuring point.

TYPES OF AIR LOCKS

Clean rooms are designed according Air flow pattern and designed Air Lock type.

Airlocks: Airlocks are closed rooms having two or more doors between two different controlled areas having different cleanliness levels. These airlocks prevent the direct airflow between these areas during the entry of material or personnel. There are three different types of Air locks designed according to the manufacturing facilities. Details are as under:

Cascade Airlock: These airlock are very common having higher pressure on one side and lower pressure on another side. In this system positive air pressure flows from the higher pressure internal zone to be airlock and from the airlock to the lesser lower pressure grade area. This prevents to entry dust and contamination from outside to airlock and from airlock to inner side.

Application:

Any manufacturing facilities where the product requires protection from particulate but the people outside the clean-room do not need protection from the product in the clean room.

Bubble Airlock: These types of airlock having higher pressure inside the airlock and lower pressure both outside. It creates a barrier where contaminants within either area pushed back into their own respective areas.

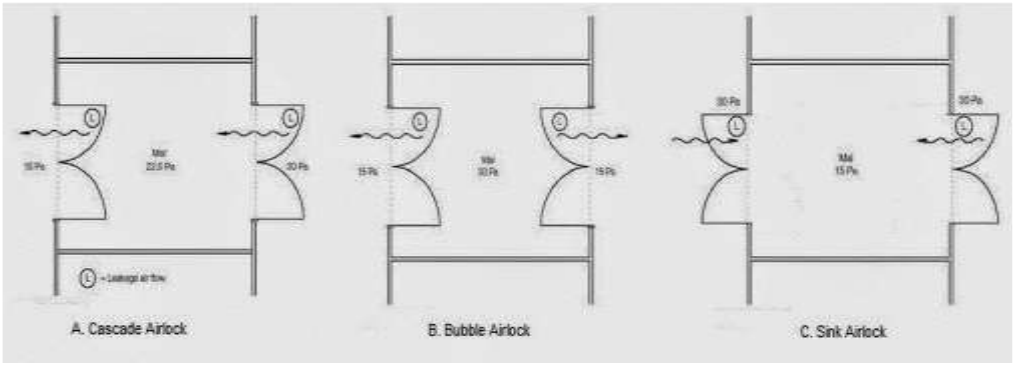
Application:

Used in, areas where the product needs protection and the people external to the cleanrooms require protection from the product, to reduce the possibility of viable articulate from entering the lesser pressure clean-room. Area such as higher potency, compounding areas terminal sterilization is not an option.

Sink Airlock: Airlocks having lower pressure inside the airlock and higher pressure on both sides of the airlock. This airlock pulls air from both adjacent areas creating a low pressure barrier and reduces the opportunity of contaminations passing to the internal zone.

Application:

In many research facilities, substance that are experimented on are highly dangerous, and it is essential to keep them from being exposed. During a few type of production process in a clean-room, air from a contaminated area has to be contained one place.



PRECAUTIONS NEED TO BE ENSURED

1. Doors of the airlocks should be open to higher pressure side which help to close the door.
2. Interlocking system should be provided to prevent the opening of both doors at a time.
3. An alarm should be provided to indicate that one door is opened. It helps to prevent the entry of contamination through the airlocks.
4. Higher air changes per hour rate should be maintained in the airlock, it should be minimum 20 air changes per hour. It helps to remove the contaminants entered from the outside easily.
5. Airlocks should be kept empty, material such as garments, shoes covers etc. should not kept in the airlocks.

CALCULATION OF NUMBER OF AIR CHANGES PER HOUR

CFM: Cubic feet per minute, the volume of air currently delivered to the room.

ROOM VOLUME: Volume of the room in cubic feet, which is calculated by finding the height, length, and width of the room in feet and multiplying these numbers together.

Formulae for calculating ACPH(Air Changes Per Hour)

(CFM X 60)/Room Volume.

Multiply the CFM by 60. This number will tell you how many cubic feet of air your device moves per hour.

DEFINITION AND CONCLUSION

Cleaning	The removal of Gross contamination of organic material and debris from the premises or respective structures via mechanical means like sweeping (Dry Cleaning) and/or the use of water and disinfection reagent (Dettol/Savlon) wet cleaning. The goal is to minimize organic material so disinfection can be effective.
Disinfection	Methods used on surfaces to destroy or eliminate a specific spice of infectious microorganism through physical or chemical (e.g., disinfectant) means.
Virus Elimination	Cleaning and disinfection measures conducted with the primary purpose to destroy or eliminate all viruses on the premises as efficiently as possible.

It is therefore concluded that area is to be maintained regularly to meet the ISO classification.

REFERENCES

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