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Dust Control in Pharma Industries

G.S. Saraiya

Engineering Manager, Glaxo India Ltd

The control of dust within a pharmaceutical plant presents the HVAC system designer and the user with one of their biggest problems. While air conditioning system designs for most areas in the plant incorporate suitable air filtration systems to achieve GMP standards, the tablet manufacturing area which is the source of maximum dust generation presents the greatest challenge and calls for close coordination between the production/engineering personnel of the plant and the HVAC design engineer, at the initial design stage, the installation/startup stage and the final acceptance trials.

Design of the tablet manufacturing area is complicated by the variety in size of manufacturing departments, process operations, types of products handled and production throughput. Acceptable dust levels, cross contamination limits, dust extraction and monitoring also play a vital role in system design.

Table 1: Range of Capture Velocities for Hood Designs

	Condition of Dispersion of Contaminant	Example	Capture Velocity in FPM
A	Released with practically no velocity into quiet air.	Evaporation from tanks degreasing, etc. Enclosure hood for fume containment	50-100
B	Releasing at low velocity moderately still air.	Powder sieving, intermittent container filling, low speed conveyer transfers, welding, spray booths, powder crushing operation.	100-200
C	Active generation into zone of rapid air motion.	Milling & size reduction operation. Barred filling, conveyor loading.	200-500

D	Released at high initial velocity into zone of very rapid air motion.	Grinding, abrasive blasting tumbling.	500-2000

In each category above, a range of capture velocity is shown. The proper choice of values depends on following factors:

1. Room air currents minimal, favorable or disturbing to capture the contaminants.
2. Contaminants of low toxicity; or of high toxicity.
3. Production volume low or high.
4. Large hood-large air mass n motion or small hood-local control.

Dust Control

Just as prevention of disease is better than cure, so also containment of dust at source is better than its removal after release.

The purposes of any dust control system should be:

- To protect and safeguard the operators from exposure to the pharma product handled.
- To comply with GMP practices.
- Reduce the risk of cross contamination to an acceptably low level.
- Contain dust generated within an area under all operating conditions.
- Provide an efficient means of collecting dust and provide a safe and convenient way for its removal and disposal to protect & safeguard the operators and process.

Dust Capture Velocity

The first design step is to select a capture velocity that will adequately collect the dust at its source; this can be determined by reference tables, past experience, or tests. OSHA guidelines and he Industrial Ventilation Manual put out by the American Conference of Governmental Industrial Hygienist provide minimum capture velocities for many types of dust hoods and pickup inlets for typical equipment sources.

Capture velocity is the velocity at any point in front of the hood necessary to overcome opposing air-currents & to capture the contaminants causing it to flow into the exhaust hood.

Capture velocities will generally range from 50 to 2000 fpm depending on the dust particle size and density, motion of the air in the area, and the hood or the inlet design. (Refer **Table 1**)

Dust containment on a bottle filling machine for tablet packing.
Photo courtesy of Glaxo India Ltd.

With any particular dust a lower capture velocity can be used for nuisance dusts and low-air- motion sources. Higher pickup or capture velocities should be used for output sources that have a lot of air motion in the area and propel or throw the dust out such as a grinding wheel, shaker screen, or drop chute into a container. Critical or hazardous dust products that must be most effectively and safely captured may require higher capture velocities (see **Table 2**) or else a laminar flow dust containment booth.

Dust Extraction Design

The purpose of the dust extraction hoods is to collect, and remove as close as possible to the point of generation dust or other pollutants after their formation at a machine or process.

This is to prevent that atmosphere of the work area from becoming polluted with the resulting hazards to health, safety and product contamination.

Principles

It is assumed that all the available efforts have been made to prevent the generation of the pollutants at the source, i.e., machine or process and he problem still exists. The following points form a basis of design:

- The air capacities can be conveniently estimated based on configuration & geometry of the hood and also the capture velocities Refer **Table 2** for estimation of exhaust volume for different types of hood geometry.
- Where air is extracted care must be taken in ensuring that there is an adequate means of balancing the system with make-up air.
- Every effort must be made to design facilities to minimize the risk of cross contamination of one product with another. For the purpose, air from dust extraction system is to be filtered through HEPA before being recycled to AHU

- The ventilation and dust extraction system must be design to suit the layout, the product therein and to maintain the us at levels within the specified range. From the view point of cross contamination wherever need be, a dedicated extraction system should be provided.
- Ventilation extract griller and respective return air grilles, should be positioned away from a major sources of dust, to ensure that the recycled air (if used) carries a minimum of dust product.

Principles of Hood Design

Basically, hood design requires sufficient knowledge of a process or operation so that the must effective hood or enclosure can be installed to provide minimum exhaust volumes for effective contaminant control. The more complete the enclosure, the more economical and effective the installation will be. From this complete enclosure concept, familiar hood shapes like booths, side or down-draft hoods with or without side shields are developed. All openings are kept to a minimum and located away from the natural path of the contaminant travel wherever possible.

The following guidelines should be used for hood design.

- Several types of standard hoods are available like lateral draft, enclosure, canopy etc, and a suitable type should be installed. Each hood must not interfere with the running or maintenance of the machine and must be secured to the machine to prevent adjustments by unauthorized personnel.
- Each hood design should begin by allowing a minimum capture velocity as detailed in **Table 1** and should be adjustable to some degree to allow for individual conditions and quantity of pick up.
- Every hood must be easily cleaned and must be positioned in such a way that any build-up of product on/in the hoods cannot fall back into the batch material.

Local hood that do not enclose or confine the contaminant are recommended only as a last resort because exhaust volumes are large and control can be easily upset by cross drafts in the area.

Calculation of Air Volume

After deciding the shape & size of the hood, and capture velocity, volume of air flow required, can be calculated by using following formula

$$V = \frac{Q}{10X^2 + A}$$

Where :

V - Centerline velocity at X distance from hood, in fpm

X - Distance outward along axis in ft (Note: equation is accurate only for limited distance of X)

Q - Air flow, in cfm

A - Area of hood opening in square feet.

As can be seen from this equation and from **Table 2**, there is a rapid velocity decrease with increasing distance from the hood varying almost inversely with the square of the distance.

Table 2 gives the calculation of volume for different types of hoods.

Exceptionally high volume hoods (example, large side-draft shale out) require less air volume than would be indicated by the capture velocity values recommended for small hoods.

This phenomenon is ascribed to:

1. The presence of a large air mass moving into the hood.
2. The fact that contamination is under the influence of the hood for a much longer time than is the case with small hoods.
3. The fact that the large air-volume affords considerable dilution as described above.

Effective control of a contaminant producing process is brought about by first eliminating or minimizing all air motion about the process and then capturing the contaminated air by causing it to flow into the exhaust hood. Flow toward the suction opening must be sufficiently high to maintain the necessary capture velocity and to overcome opposing ir currents.

Elimination of sources of air motion as a first step in hood design is an important factor in cutting down the required air volume and the corresponding power consumption.

The shape of the hood, its size, its location and rate of air flow are important design considerations. In a simple hood the hood static pressure is equal to the velocity pressure in the duct plus the hood entry loss:

$$SPh = H_e + VP_d$$

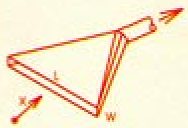
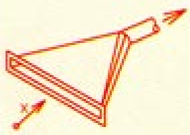
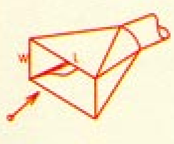
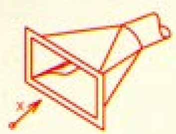
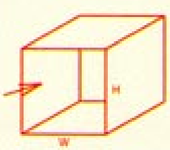
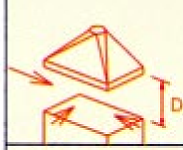
Where:

H_e - Hood entry loss (F_h x VP_d)

F_h - Hood entry loss factor

VP_d - Duct Velocity Pressure

Table 2 : Calculation of Exhaust Volume for Different Types of Hood

HOOD TYPE	DESCRIPTION	ASPECT RATIO W/L	AIR VOLUME
	SLOT	0.2 OR LESS	$Q=3.7\ LVX$
	FLANGED SLOT	0.2 OR LESS	$Q=2.8\ LVX$
	PLAIN OPENING	0.2 OR GREATER AND ROUND	$Q=V(10X^2+A)$
	FLANGED OPENING	0.2 OR GREATER AND ROUND	$Q=0.75V$ $(10X^2+A)$
	BOOTH	TO SUIT WORK	$Q=VWH$
	CANOPY	TO SUIT WORK	$Q=1.4\ PDV$ P=PERIMETER

A= AREA OF HOOD OPENING. P= PERIMETER OF WORK
V= CAPTURE VELOCITY Q= VOLUME OF AIR FLOW
X= DISTANCE OF DUST SOURCE

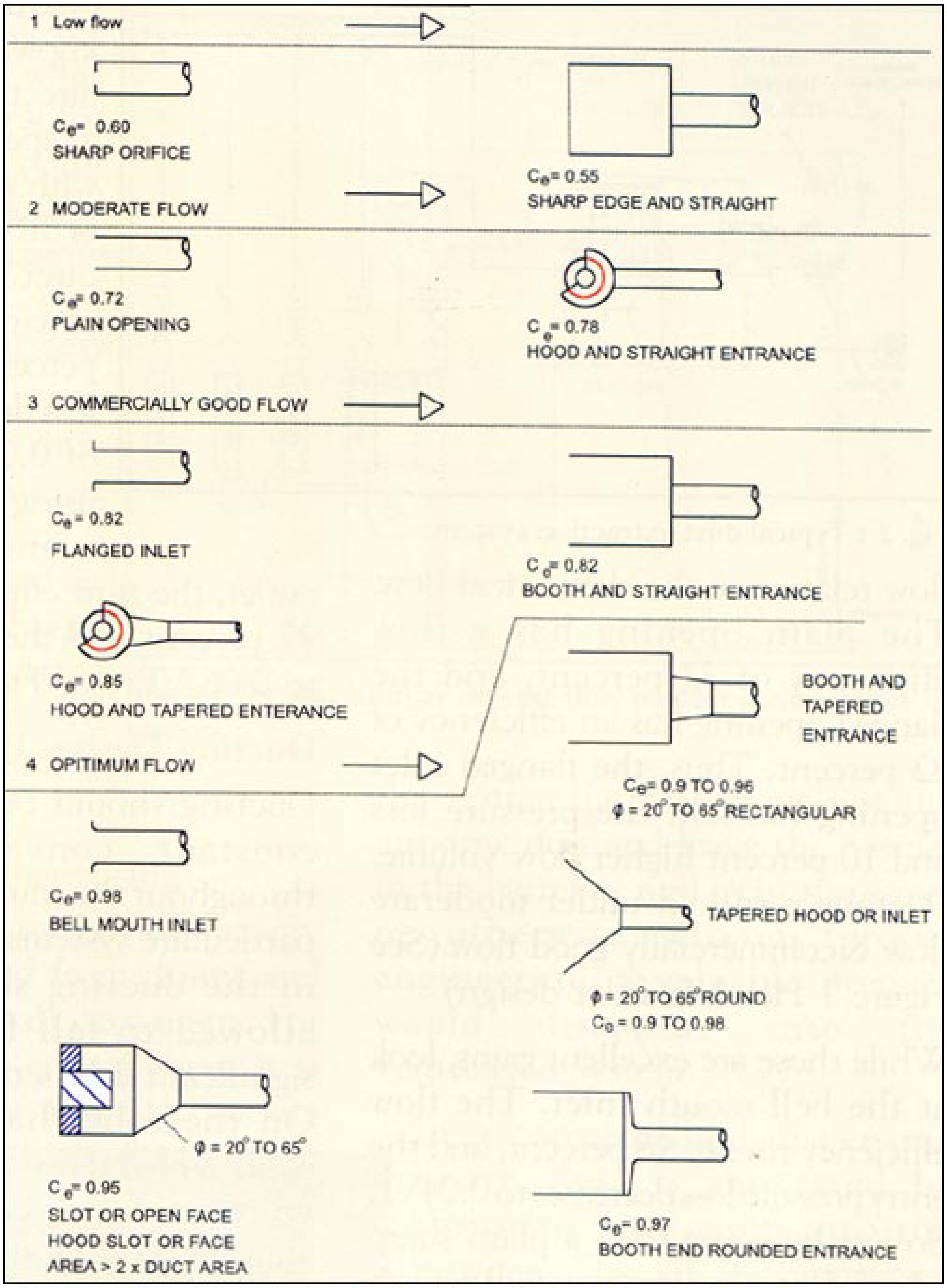


Fig. 1 : Hood and inlet design for efficient flow, with typical entry loss coefficients C_e

Hood and Inlet design

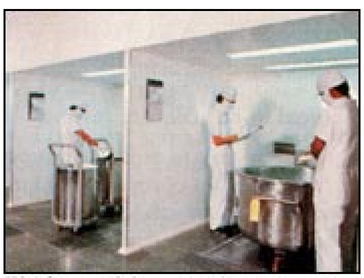
The second essential design step is to develop an effective hood or inlet design and locate it as close as possible to the dust source for adequate collection. The capture velocity most be maintained across the full-face area of the hood for effective pickup. A good average will not necessarily be effective enough, since each dust particle has to be captured by a n adequate velocity.

The easiest way to reduce pressure drop is to use an optimum hood or inlet design that has a low entry loss $\mathbf{H_e}$ and a high coefficient of entry $\mathbf{C_e}$

The flow or pickup efficiency which is known as the coefficient of entry $\mathbf{C_e}$ is the ratio of the actual rate of flow relative of the theoretical flow. The plain opening has a flow efficiency of 72 percent, and the flanged opening has an efficiency of 82 percent. Thus, the flanged inlet opening has half the pressure loss and 10 percent higher flow volume. Details furnished under moderate flow & commercially good flow. (See **Figure 1** Hood & Inlet design)

Where those are excellent gains, look at the bell mouth inlet. The flow efficiency rises to 98 percent, and the entry pressure loss decreases to 0.04VP. So just by going from a plain sharp inlet, the efficiency of flow volume increases from 72 to 98 percent, and the pressure loss drops from 0.93 VP all the way down to 0.04 VP.

A square shoulder inlet to a booth or a dust collector enclosure, or an outlet, has an efficiency of flow of 82 percent and an entry pressure drop of 0.50VP, equivalent to the flanged opening. This is also known as a straight or direct inlet. By going to a tapered or flared under with an included angle of 30° to 60° in a round duct, the flow efficiency goes up to 95 percent and the entry loss drops to an average of 0.07VP. Finally by using a bell-mouth or rounded inlet, or outlet, the flow efficiency goes up to 97 percent and the entry loss drops to 0.06 VP. (See **Figure 1**).



Weighing and dispensing booth for tablet bulk material and actives.
Photo Courtesy of Glaxo India Ltd.

Ducting Design Principles

Ducting should be sized to give a constant conveying velocity throughout the transport system. For particulate systems, the gas velocity in the ducting should never be allowed to fall low enough for significant dust settlement to occur. On the other hand, excessively high velocities are wasteful of power and may cause accelerated abrasion and more noise. As ducts seldom operate at a single gas throughput condition, the designer must consider both the extremes of the velocity that will be acceptable for all known plant conditions.

- Ductwork must be designed with dust conveying principles in mind. A target conveying velocity of 3000 fpm. (15 m/s) is recommended, velocities below 2500fpm (12.5 m/s) should not be used.

- Only circular ductwork should be used, constructed to operate at a negative pressure of not less than 12 in wg (3.0kPa)

When the project and ducting layout if firmed up, then a final design and estimate can be made on static pressure requirement with the *equivalent length or velocity pressure methods*.

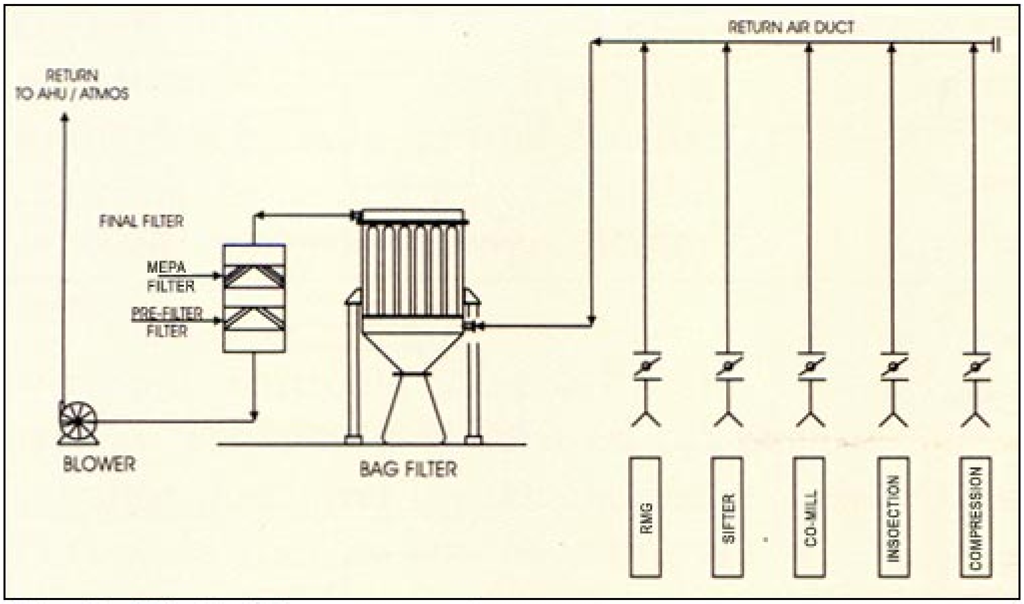


Fig. 2 : Typical dust extraction system

Fan Selection Considerations

The air or gas in any dust collection system will be propelled by a fan. By far the most commonly used prime mover in industrial dust collections systems is a centrifugal fan at operating static pressures up to 10 to 20 inches of WG depending upon the dust centrifugation. For higher pressures, a narrow bladed centrifugal fan can be efficiently used for a volume up to 20000 cfm.

Some important items to consider when selecting a fan are:

1. Volume of the total air stream from the hood and ductwork pickup or from volumes land resistance process volume requirements.
2. Fan static pressure required for the ductwork system.
3. Type of dust or bulk solid material to be handled, and whether it is corrosive, flammable or explosive in nature.
4. Temperature, altitude and humidity of operation.
5. Optimum fan rating for selection for size and horsepower, direct or V-belt drive suitability for maximum efficiency, whether variable-speed control has advantages.

6. Corrosive materials' effect on the choice of fan materials of construction, from carbon steel, to stainless steel or other alloys, spark-resistant construction, fiberglass, polyvinyl chloride (PVC), or coated steel.
7. Spark-resistance fan construction as classified by the Air Movement and Control Association (AMCA) may be needed to handle explosive or flammable materials.

Dust Control Applied to Specific Processes in Tablet Manufacturing

Tablet manufacturing operations compromise a series of process operations in straight sequence.

Operations in cubicles can be grouped as sifting/weighing, mixing granulating, drying blending, compression, stripping & packing. The schematic flow diagram of a typical dust extraction system is shown in **Figure 2**. As shown, the dust is contained and extracted at source by providing suitable hoods directly on the machine. The extracted air from various rooms/process is filtered in a fabric filter and later recycled to the air handling systems on further passing through HEPA filters.

Powder Sieving

- When scooping out of the bowl or drum to load the sifter.
- When tipping from the scoop into the sifter.
- From the action of sieving.
- From the product falling from the sieve into the receiving vessel.

This is a notoriously dirty operation. Conventional vibrating sieves tend to produce dust at the vibrating wall of sifter. A dust extractor situated at this point may removes more than the acceptable quantity of dust and compromise process yields.

Effective dust extraction is achieved by way of providing a "fish tail" type hood on Vibro sifter (see **Figure 3**). Lids may be fitted to the sieve to minimize the product loss.

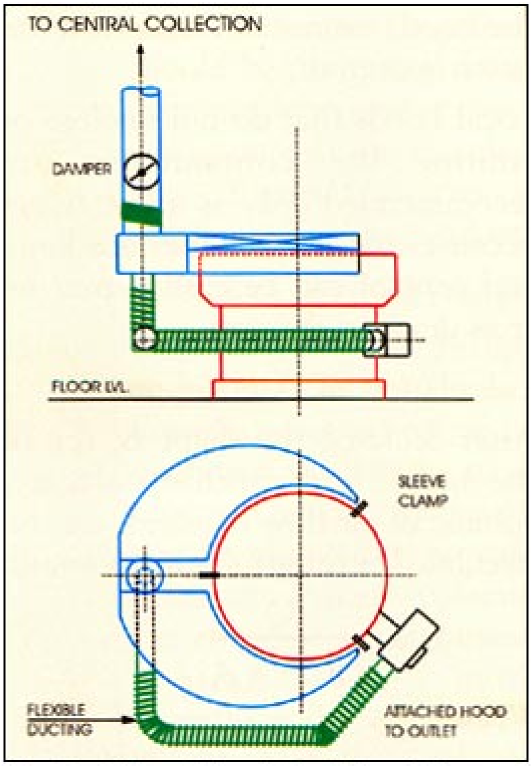


Fig. 3 : Fish tail hood for Vibro Sifter

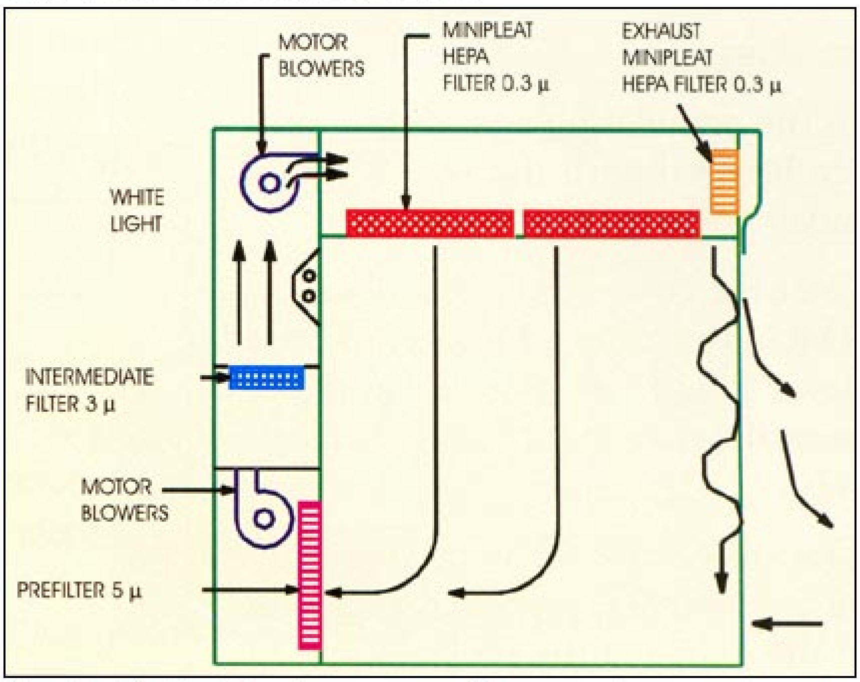


Fig. 4 : Vertical laminar reverse flow powder containment station

Weighing and Dispensing

In the weighing room, powders are manually scooped from drums and transferred to small containers. For effective powder containment it is common to use a booth system (enclosed on three sides) with an exhaust system at its top and back.

The combination of local hoods and the exhaust booth provides dust control while transferring and weighing materials. Dust generated and made airborne as a result of the powder being agitated during the scooping operation is immediately drawn into the hood.

It should be remembered here that the system has to remove just the airborne dust and leave the powder in the barrel as well as in the scoop or otherwise without proper engineering, a valuable product would disappear into the ventilation system.

In a conventional dispensing booth dust is generated by thrusting the scoop into the powder. The air is compressed and then blown through the powder causing a dust cloud. The faster the product is scooped the more dust is generated. A careful operator can normally scoop quite successfully without generating dust.

The new concept is to use a "reverse flow laminar booth" that effectively controls the average airborne dust within the area. For details on "reverse flow booth" refer to **Figure 4** and also the photo below.

Reverse flow laminar dust containment booth with active dispensing table.
Photo courtesy of Teknopak, Mumbai

The laminar flow from the HEPA plenum effectively contains the dust at source while dispensing. It is clearly evident that air borne dust if any will be drawn in through the pre-filter in the reverse flow booth and will be recycled through HEPA before being delivered. The operator is clearly protected as the dust propels away from his breathing zone.

Granulation

In the granulating area, ingredients are blended with the use of "rapid mixer granulator" (RMG).

Once the compound is granulated in RMG, it is unloaded into a fluid bed dryer bowl. A fishtail hood is generally provided at RMG discharge valve.

The objective is to control the outflow and the particulate directly at the source of the problem and to prevent contaminants from ever reaching the work area. Here again airflow is critical- too powerful an exhaust will remove the product, too weak an exhaust will not control contaminates.

Compression

A well set up compression machine produces very little dust.

The greatest source of dust on most presses is during the loading of the hoppers. Granule is traditionally tipped into the hopper by a scoop. The hoppers are high up for most operators and it is difficult for the operator to lower the scoop into the hopper Granule is therefore tipped from a height causing a dust cloud, which settles over the machine. For effective dust containment refer to tablet press loading system **Figure 5**.

Where neither method is practical the dust can be collected as it is generated. This is normally achieved by a tapered hood.

Dust control hoods are also located at the tablet chute as well as at the container receiving the finished tablets. The tablets are discharged into the container through a Deduster.

Table 3 : Basis of Design

Equipment	Dust Load gm/min.	Qty. of air provided to handle dust (cfm)
MFG.ROOM :		
Cad mill	2.5	500
Sifter	2.5	550
Dumping Bowl	5.0	1100
Mixer	5.0	1100
Per Mfg. Room Total	-	3250
Compression Cubicles & Inspection Room:	1.25	200
Weighing Cubicles:		
Type of system, booth or reverse flow.	3.0	400

This table specifies the dust levels generated for different equipment in various manufacturing operations & also details approximate air capacities required.

Cross Contamination

Cross contamination is the introduction, by whatever means, of material (usually dust particles) from one product into a second product. Correct "housekeeping" methods are of vital importance particularly with respect to the operating of the HVAC system.

The risk of cross contamination increases when air is recirculated between various parts of a facility. The level of air filtration must be commensurate with the need to reduce the risk of cross contamination.

Fabric Dust Collectors

In almost every case where extraction is necessary a filter must be included to trap of filter is used for the dust concerned. In practice the air will take the easiest path through the filter but as a 'cake' of the dust builds up on the filter the efficiency will change. Therefore the details of dust burden and particle size become important criteria for filter selection. Additionally, consideration must be given at the design stage to methods and frequency of filter changing and/or cleaning. Filters that have to be cleaned frequently for good performance and cause difficulty to the operator may be left uncleaned, thus reducing the efficiency of the system.

Exhaust Filtration

In the most installations consideration must be given to removing contaminants from the air stream. The degree of the removal required, quantity and type of contaminant all have a bearing on the selection of the air cleaning devices. These cleaning devices may vary from simple fabric filters to more sophisticated electrostatic precipitators. The selection of the device will depend on:

- Concentration and particle size
- Degree of collection required
- Characteristics of the air stream
- Characteristics of contaminants
- Energy requirements
- Methods of disposal

Bag filters are widely used for dust removal in industrial atmosphere, the most common form being a cylindrically shaped woven fabric sleeve, with or without stiffening rings. Dust capture can be provided on the internal or external surface of the sleeve, as best suited to the application. Different systems can also be used for removal of collected dust, e.g. mechanical shaking, backwashing with compressed air, or collapsing the sleeve and shaking.

Electrostatic properties must be considered particularly when filtering potential explosives dust/gas mixtures, play a vital role from safety point of view. In the latter case auto-ignition or explosion due to sparking from electrostatic charges can be eliminated by the use of antistatic materials - e.g. synthetic fibers interwoven with metallic or carbon fibers.

All fabric collectors employ the same method of separating particulate from the air stream. Dust-laden air flows through a cloth tube or envelop, where particles larger than the fabric interstices are deposited by simple sieving action. A mat or 'cake' of dust is quickly formed on the air-entering surface of the fabric. The dust cake acts as a highly efficient filter, capable of removing sub-micron dusts and fumes, while the fabric serves principally as a supporting structure for the cake.

In terms of efficiency rating, non-woven (felted) fabrics are more efficient than woven fabrics are more efficient than woven fabrics since the open areas are smaller. Similarly any type of fabric can be made more efficient by using smaller fibre diameters, closer weaving or packing and a greater weight of fibre per unit area of fabric.

Increasing efficiency, however, naturally means a reduction in permeability and also in cleanability.

Types of Fabric Collectors

The two most common types generally in use are i) Mechanical shaker ii) Reverse pulse jet type. Among the two because of batch operations in pharma industry the former finds a wider use. The two most common forms of fabric collectors are tubes, and envelopes (or flat bags). Pleated cartridge forms are also used, but to a lesser extent. The performance of tubes and envelopes is essentially similar for the same materials & air-to-cloth ratio, the main difference being in the method of cleaning. The sizing or rating of the fabric filter is given directly by the air-to-cloth ratio expressed in terms of ft^3/min per ft^2 of cloth (for other consistent units). This ratio, in effect, represents the average velocity of the gas stream through the filter medium and thus can also be expressed directly as filtration velocity. Typically this may range from 4fpm to 10 fpm. The lighter the dust concentration and/or the more frequent the intervals the higher the filtration velocities that may be employed Air-to-cloth ratio is also influenced by the type of dust involved and the method of cleaning employed.

Reconditioning (cleaning)

Common methods used for cleaning are by mechanical shaking, low pressure-reverse air, and high pressure-reverse jet (pulse jet).

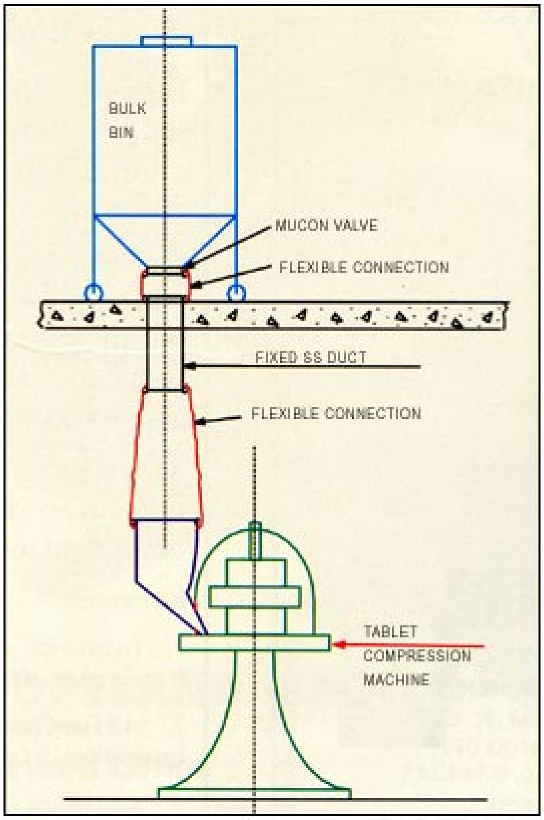


Fig. 5 : Loading tablet press using bulk bin

Reverse-pulse cleaning

Cleaning by the application of reverse-pulses of high-pressure air is normally applied to tube and envelope collectors employing felted fabrics. The high pressure pulses come directly from a compressed air supply. In the latter case the type is normally called a pulsejet collector.

For reverse-pulse cleaning of all types, including tube collectors, dust collects on the outside and flows from outside to inside. Internal supports are thus necessary to prevent the bags from collapsing. The pulse of cleaning air is then introduced at the clean airside, the resulting reverse flow snapping the bags away from their supporting cage, breaking the dust cake and blowing the fabric clean. The complete pulse cleaning cycle occurs very rapidly - i.e. within a tenth of a second or less, after which normal flow is restored. Effectively, therefore, the collector operates continuously, with pulse cleaning frequency adjusted as required, on an automatic sequential controller.

Bag type dust collector
Photo courtesy of Laxmi Air Control Ltd., Mumbai

Make-up Air

An adequate supply of outsides air is essential in any air handling system for removing contaminated air.

It is essential to design the make up air system so that the correct air balance is maintained to:

- Ensure the system operates correctly
- Eliminate high velocity cross draughts
- Maintain differential pressure in manufacturing zones & also air capacities.

Establishing performance

After installation, acceptance trials should be undertaken to establish the operating performance of the system. Contractors who haves the necessary expertise to design and install effective systems normally carry out the acceptance trials. These should include flow rates and pressure drops across the system, details of the fan characteristics and filter specifications etc. Environmental Monitoring provides the final check.

This performance data can then be used in future as a means of ensuring that the system of control does not deteriorate. The most important element is the quantity of air move at varying points in the system, generally measured with some form of anemometer or orifice devices. Details of methods for measurement can be found in most Ventilation textbooks.

Equally vital is adherence to the agreed filter specification. It is common for filter specifications to be changed for operational reasons, without due consideration of the environmental factors.

Once a system has been established, routine inspections and monitoring at appropriate intervals should be carried out to ensures the system is maintained at the required standard. This might include the use of smoke tubes and anemometers.

The regular recording of levels will also provide a fair indication of the efficacy of equipment such as dust extraction and air conditioning.

References:

1. Industrial Ventilation - 19th Edition (1984) - American Conference of Governmental Industrial Hygienists
2. A User Guide to Dust and Fume Control (1985) - Publication of Institution of Chemical Engineers
3. Filter Dust Collectors (1995) - McGraw - Hill Inc.