FORMULATION AND PRODUCTION MANAGEMENT

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INTRODUCTION

- Optimal growth of any unit is result of harmonization of proper production facilities with a sequential organization, layout and plant site selection.

- These factors should be so balanced that they couple in harmony leading to proper progress of a pharmaceutical industry of any firm / unit in the era of cut throat competition.

- Even of a particular unit has all the potential for production facilities but without any organizational capability of the key position holders then it would lead to a mess and misutilization and loss of all the resource.

PLANT SITE SELECTION

- A plant is a place where MEN, MATERIALS, MONEY, EQUIPMENTS, MACHINERY etc are brought together for manufacturing products.

- The basic requirements for setting of a pharmaceutical industry is the availability of a feasible, approachable site which necessitates the requisites for manufacturing facilities and eliminate the expected untoward experiences which might hamper the progress of an industry with respect to the manufacturing sight.

So it makes clear that as to why plant site selection is of paramount importance !!

- The problem of the plant location arises when a new concern a during the expansion of the existing plant.
- Plant location means deciding a suitable location, area, place etc, where the plant or factory will start functioning.
- Plant location involves two major activities. First to select a proper geographic region and second, selecting a specific site within the region.
- Plant location plays a major role in the design of the production system as it determines the cost of geographical region.
  - Getting suitable raw material
  - Processing raw material to finished goods.
  - Finished products distribution to customers

FACTORS GOVERNING PLANT LOCATION

- In deciding a new site location for manufacturing range of its produces, a company has embarked on a considerable CAPITAL INVESTMENT PROGRAM which will have a profound effect on its operation in the next 20 years.

- This decision is not easily reversed, and therefore it is essential to define the guidelines by which the new site will be selected.

- Usually the decision to look for a new location is based on a number of facts concerning the existing facilities …….

1. Availability of raw material.
2. Nearness to the market.
3. Transport facilities.
4. Availability of power and fuel.
5. Nearness to the labor supply.
6. Nearness of the capital supplies.
7. Existence of the relative industries.
8. Climatic conditions.
9. Financial and other aids.
10. Availability of water.
11. Absence of restrictions.
12. Land
13. Community attitudes.
14. Location economics.

1. AVAILABILITY OF RAW MATERIAL:

- The drugs, excipients, packing materials and equipment for manufacturing of pharmaceutical should be easily available near the site of pharmaceutical industry because it will reduce the cost of transporting raw materials from the vendors end to the plant.

- Especially those plants which consume raw material the bulk must be located close to the source of raw material.

2. NEARNESS TO THE MARKET:

- The cost of advertisement, distribution and customer service should be economical. Hence it is better to setup pharmaceutical industry near to the commercial place.

- It reduces the cost of the transportation as well as the chance of the finished products getting damaged and spoiled in the way.

- Moreover a plant being near to the market can catch a big share of market and can render quick service to the customer.

3. TRANSPORT FACILITIES:

- A lot of money is spend both in transporting the raw materials and finished goods so as suitable method of transportation like road, rail etc is selected and accordingly the plant location id decided.

- The transportation cost of the raw materials, and workers should be kept minimum.

- Hence it is better to set up a pharmaceutical industry in a place nearer to the railway station and nearer to the main road.

4. AVAILABILITY OF POWER AND FUEL:

- Depending upon the process the requirement of power and fuel is achieved, accordingly the site has to be selected.

- Mainly the electric power is used in the pharmaceutical industry so it is of course essential that the electric power should be remained available continuously in proper quantity and at reasonable rates.

5. NEARNESS TO THE LABOUR SUPPLY:

- The cost of transportation of the labour should be cheaper. The plant site should be at appropriate place where both skilled and unskilled labour are available at a economical rate.

6. NEARNESS TO THE CAPITAL SUPPLIES:

- The business will survive when there is a free flow of capital. Hence it is very essential to set up a factory at appropriate place where capital is available easily.

7. EXISTENCE OF RELATED INDUSTRIES:

- Many industries are related either by process or by product. Many pharmaceutical industries are existing in urban cities like Mumbai, Calcutta, Ahmedabad, Delhi and Madras.
- The main advantage of concentration of the industries at a particular place help for easy availability of experienced labour and machinery.
- Many ancillary industries are also located near by urban cities.
- The raw materials are also available easily in these areas.
- The maintainece of the industries is also easy because of availability of required service facilities.
- The waste and products of the industries can also be processes easily.

8. CLIMATIC CONDITIONS:

- As the stability of many drugs are effected by hot climate it is very difficult to maintain a storage conditions at this place without any air conditioning systems setting up a pharmaceutical industry in a place having a cold climate may be advantageous to reduce the storage cost.

- For the manufacturing of many pharmaceutical preparation also cold conditions and climate may be better.

9.FINANCIAL AND OTHER AIDS:

- Certain states give aids as loans, feed, money machinery, build up sheds etc to attract industries.

10.AVAILABILITY OF WATER:

- Pure hygienic water should be available at regional cost, near the pharmaceutical industries as many steps of pharmaceutical manufacturing require adequate amount of water.

11. ABSENCE OF RESTRICTION:

- Few years back there was haphazard growth of industrial place all over the country.
- The govt. may put some restriction for setting up industries at urban areas. Because of environmental pollution and other hazards.
- On the other hand Govt. is encouraging to set up industries, at backward areas giving suitable incentives.
- While selecting a specific place for setting up the pharmaceutical industry, it is necessary to look into the matters of restriction and availability of incentives.

12.LAND:

- Topographically area the shape of site, cost, drainage and other facilities, the probability of floods, earthquakes (from the past history) etc, also influence the selection of plant location.

VARIOUS SITES FOR PHARMACEUTICAL INDUSTRY

- There are five sites for the pharmaceutical industries.
  - City sites
  - Sub urban sites
  - Small town cities
  - Rural sites
  - Industrial estates

CITY SITES

- In city efficient cheap rail, road transport, communication facilities are easily available.
- There is also good labour supply.
- The municipal service of water, gas, sewage, public health and education are readily available.
- Technical and commercial institutions are available for training of staff and workers.
- The cost of operation of factory in a planned industrial centre is also economical. However, the cost of living and rate of taxes may be high in the cities.

Main Advantage of City sites:

- A city is very well connected by rail, road and air.
- It provides a good market also.
- Right labour force is also available.
- Power and water is easily available.
- It has good hospitals, marketing centers, schools, banks, post offices, recreation clubs etc.
- The factory can be set up in an existing available building.
- Worker's and foremen's training classes and many other educational facilities can be found in cities.
- Service of experts ansd specialist are easily available.
- Many other small industries existing near by can work as ancillaries.
- Security is there

Disadvantages of City sites:

- Land available for building is limited in area
- Cost of land and building construction is high
- Expansion of industry is seldom possible
- Local taxes are high
- Labour salaries are high
- Union problems are more
- Employee-Employer relations are not so good

SUB URBAN SITES

- In these places land is cheaper and there is more availability of space for expansion.
- It is better to locate the industry nearer to rail, road, main road, for easy transportation.
- The labour supply is done by near by place.
- Government may give loans for setting up industrial estates in these areas.

RURAL SITES

The main advantage of the rural sites are as follows:

- Plenty of land is available for building construction and expansion purpose.
- Land is cheap.
- Unskilled labour is available which can be trained to suit the requirements of the concern.
- Employee – employer relations are good.
- No union problems.
- Undesirable manufacturing neighbors are not likely to be present.
- Municipal and other regulations and taxes are not much more like city site.
- Government gives inducements as it wants to develop the under developed areas.

Disadvantage of the rural sites are as follows:

- Skilled labour is not available.
- Rail, road and air links may not be thee at all or may not be adequate.
- Power is not available.
- Rural areas far from selling markets.
- Hospitals, educational and amusement centers are not available.
- Ancillary services cannot be obtained.
- Expert and specialist advise is not available.
- High grade executives may not like to live in rural areas.

- An alternative between the urban and rural areas is Sub Urban Sites which being a compromise between two is probably the most suitable.
  - It possesses the good points of both urban and rural locations.

SMALL TOWN SITES

- Site may be available in small towns at cheaper rates, labour supply may also be efficient.

- The rate of taxes may be minimum; various maintenance servicing, housing, health and education facilities may be minimum.

INDUSTRIAL ESTATES

- The problems of service facilities, power, transport, health, education and training are minimized by setting up factories in industrial estates as basic amenities and infrastructure are arranged by Government Industrial authorities.

- Many industrial estates are having facilities like bank, post office, telephone exchanges, shop dispensaries, recreation facilities, buildings, libraries, transport facilities, work shops, ancillary industries etc.

- The machinery and equipments are also supplied efficiently to these industrial estates.

- Government may also build good factory layout having sufficient water supply, electricity, lighting etc.

PLANT LAYOUT

- Plant layout means the disposition of the various facilities like equipments, material, man power etc and service of the plant with in the area of the site selected previously.
- Plant layout begins with the design of the factory building and goes upto location and movement of a work table.
- All the facilities like equipments, raw materials, machinery, tools, workers etc are given a proper place.
- In deciding the place for equipment, the supervisors and workers who have to operate them should be consulted

OBJECTIVE OF A GOOD PLANT LAYOUT

In a good plant layout:

1. Material handling and transportation is minimized and efficiently controlled.
2. Work stations are designed suitably and properly.
3. Suitable spaces are allocated to production centers and service centers.
4. The movement made between workers are minimized.
5. Waiting time of the semi finished product is minimized.
6. Working conditions are so far better (well ventilated rooms) and improved.
7. There is increased flexibility for changes in product design and for future expansion.

8. There is utilization of cubic space (i.e. Length, width, height).
9. There are improved work methods and reduced production cycle times.
10. Plant maintenance is simpler.
11. There is increased productivity and better product quality with reduced capital cost.
12. A good layout permits materials to move through the plant at the desired speed with the lowest cost.
13. The layout should be such that the number of handling is minimum. The working conditions should be better. Congestion should be eliminated and it should provide better service facilities. The labour cost should be minimum. Manufacturing cost should be economical.
14. The layout should also be appropriate having minimum safety hazards.

MATERIAL HANDLING IN PHARMACEUTICAL INDUSTRY

- Material handling involves the movement of materials manually or mechanically either individually at a time or in batches within the plant.
- Well planned storage and manufacturing facilities reduce the operational cost of pharmaceutical industry.
- All materials of store should be accessible easily.
- The receipt, movement, placement and issue of material should be done at minimum cost efficiently.
- Spoilage, damage and losses should be minimized and avoided.
- Similar items should be kept together.

- Popular fast moving items should be stored nearer to manufacturing section.
- By storing items one above the another storage space utility increases.
- The pharmaceutical materials can be categorized as
  - Hazardous materials
  - Sensitive materials
  - Perishable materials.
- Stock in hand, receipts expected, type of packing, total maximum stock and size of packages…etc help to plan the storage space required for the pharmaceutical industries.

- The availability of material handling equipments and space for movement of the materials are also essential factors.
- There should be sufficient space for the easy movement of men and flow of materials.
- Space has to be provided for the incoming materials, which will be stored at a quarantine place before they are released from the quality control department.
- Sufficient storage space should be provided for the finished products.

- The material handling is movement of the materials from one place of operation to another.
- Least handling of the material is the best handling method and this can be achieved by properly designing the stores and manufacturing layout.
- The mode of handling depends upon the size, weight and volume of the materials.
- The principle of the utilization helps in better movement of the material.
- The material handling may be manual or mechanical.

- The mechanical handling may be with the help of powered equipments or manually operated equipments.
- Manual handling is flexible.
- The material handling should be done carefully considering various safety precautions.
- With the efficient material handling system, we can reduce the cost of manufacturing.
- In any manufacturing operation about 10 to 20% of the cost may be due to material handling.

- With the efficient material handling systems there is quick delivery of materials, improved customer satisfaction, less damage and more consumption.
- Material handling should be more convenient to the operators.
- If the store layout and manufacturing layout is well planned, it may help in reducing the material handling cost.
- The movements should be straight and short.
- Materials should be moved to the nearest point before stopping the movement.
- Whenever possible, the handling operation should be either combined or eliminated and should be based on basic motion study principles.

- Conveyor systems may be used for fixed path continuous or semicontinous movement of bulk of the small unit materials.
- Portable conveyors are useful for loading, unloading purpose.
- The engineering and economic factors of material handling are related to operating methods, materials to be handled, handling equipments and money factors.

Selection of Material Handling Systems Equipments depends on….

1. Design of the equipment, its strength, capacity, rigidity…., etc
2. Method of installation, operation control, facilities…, etc
3. Method of operation under normal and abnormal conditions.
4. Use of Power.
5. Use of automatic control devices.
6. Avalilability of spare parts.
7. Maintanence of the equipments.
8. Nature of the materials to be transferred.
9. Avalilability and cost of labour.
10. Amount to be handled and distance to be covered.
11. Speed of operation.

- The material handling systems are divided into three categories….
  - Lifting and loading
  - Transporting
  - Combination of lifting and transporting.

The various material handling equipments are…

1. Conveyors – Belts, Chains, Cable, Rollers, Screw, Pipelines and vibrating.

   The conveyor system is mostly used in material handling of Pharmaceuticals and Packaging departments.

2. Cranes, Elevators, Hoists, Locomotives…, etc.
3. Positioning, Weight and Control Equipments.
4. Industrial Vehicles.
5. Motor Vehicles.
6. Railway Carriers.
7. Marine Carriers.
8 .. Containers and supports

UNIT LOAD, PALLETISATION AND CONTAINERSATION

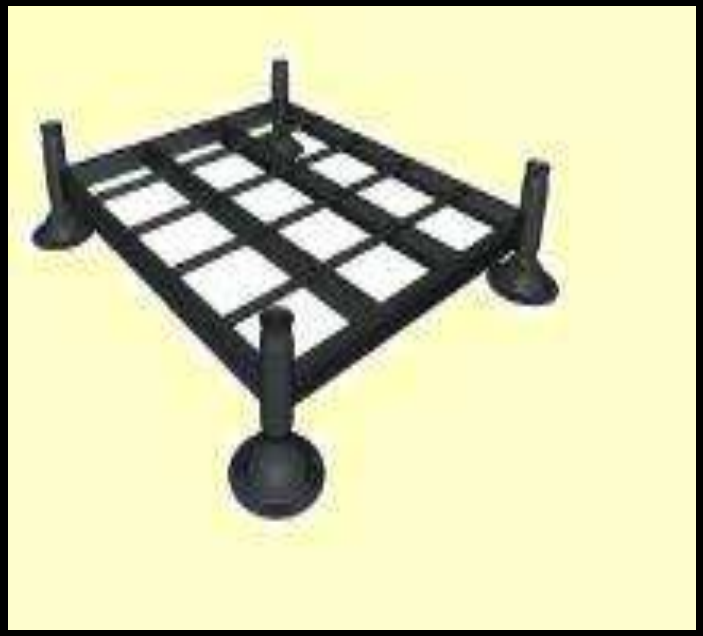
- It is easier and faster to move a hundred small parts by grouping them into one unit than moving them individually one by one….. Collectively known as **UNIT LOAD**.

  Ex: Formulation of Tablet….number of ingredients…weighed…..packed individually and loaded onto a **PALLET**, thus Pallet is a **UNIT LOAD**…..which are moved to production department by suitable handling system (Platform truck with low lift).

- Depending on the type of items to be transferred, a suitable Pallet can be designed.

  Ex: Items of irregular in shape are liable to be damaged by crushing…for such items…a **POST PALLET** is useful.

POST PALLET

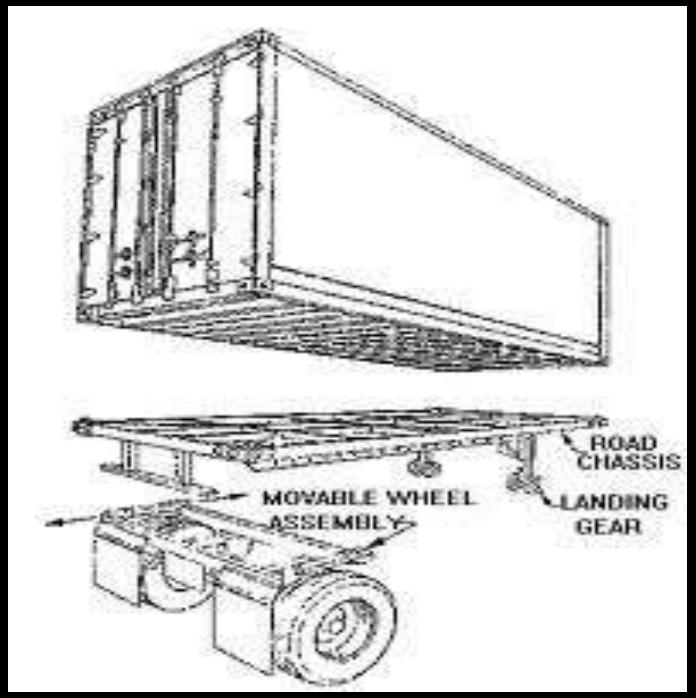


POST PALLET (with wheels)

- Small items can be placed in a **WIRE- MESH BOX**….which also facilitates the processing of ingredients in the production of a lot size.

WIRE~ MESH BOX (with wheels)

- **CONTAINERISATION** uses the principle of **UNIT LOAD**…..where a big metal container is filled with a number of small products…many such containers are placed on a truck or trailer that is pulled by a Tractor or Truck, such containers can be loaded on railway trailers and transported.




FORMARK
LYS-LINE
MAN


Fed

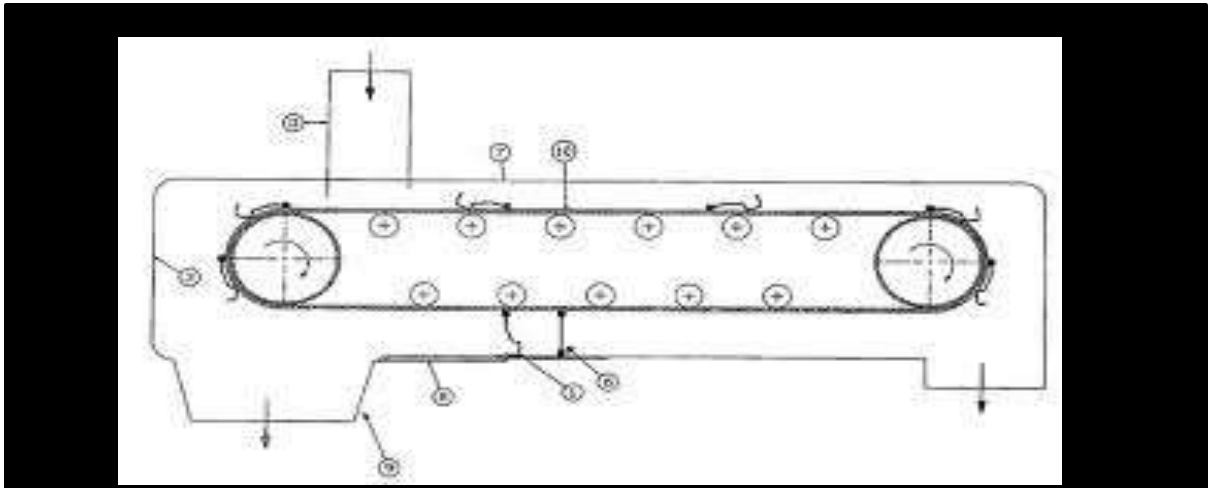
TYPES OF MATERIAL HANDLING SYSTEMS

CONVEYORS

- **Conveyors** are employed for transport ting materials in a fixed path, which may be horizontal, vertical or inclined to different locations of a factory.

- If the flow of material is continuous…..economical.

- Belt Conveyors are used in transporting containers(bottles) for filling, capping, sealing, labeling, pasting, visual inspection…etc in production of injectables, liquid orals, ointments and jellies.

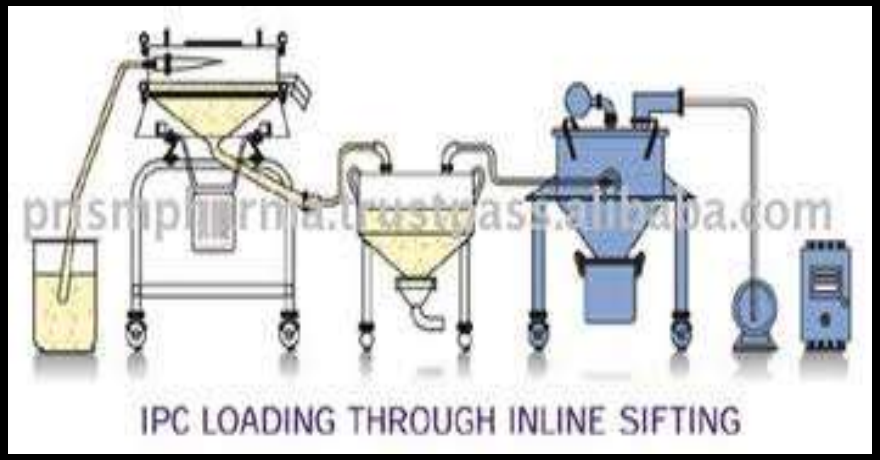


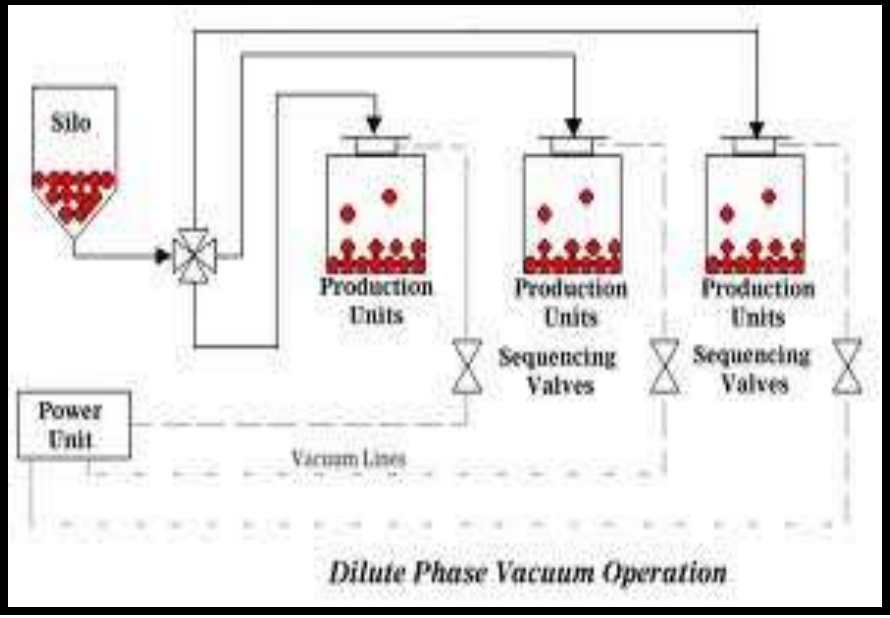
BELT CONVEYORS

PNEUMATIC CONVEYOR

- **Pneumatic Conveyor or Pipeline Conveyor** is one of the most commonly used handling techniques in Chemical/ Pharmaceutical industry.
- Pneumatic Conveyor is employed when the material is light and bulky….(Powdered Insufflations).
- Pneumatic Conveyor is a **closed system**…..handling of unpleasant and injurious substances is easy.
- Pneumatic Conveyor is used for transporting granular (Wheat) or pulverized material (Salt) through pipes.

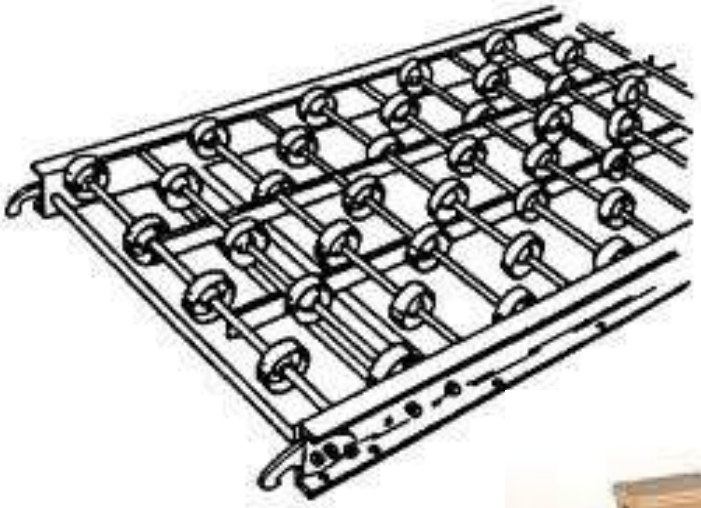
PNEUMATIC CONVEYOR


IPC LOADING THROUGH INLINE SIFTING


Silo
Production Units
Production Units
Production Units
Sequencing Valves
Sequencing Valves
Power Unit
Vacuum Lines
Dilute Phase Vacuum Operation

ROLLER CONVEYOR

WHEEL CONVEYOR

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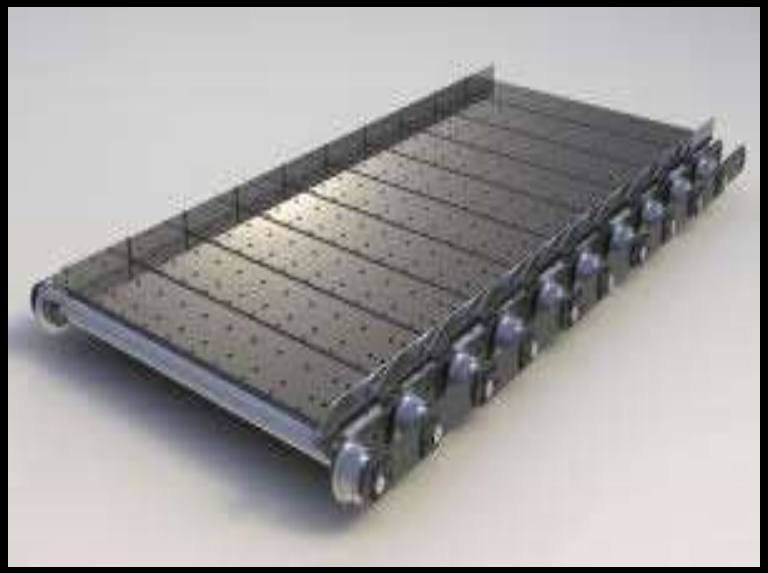
APRON CONVEYOR

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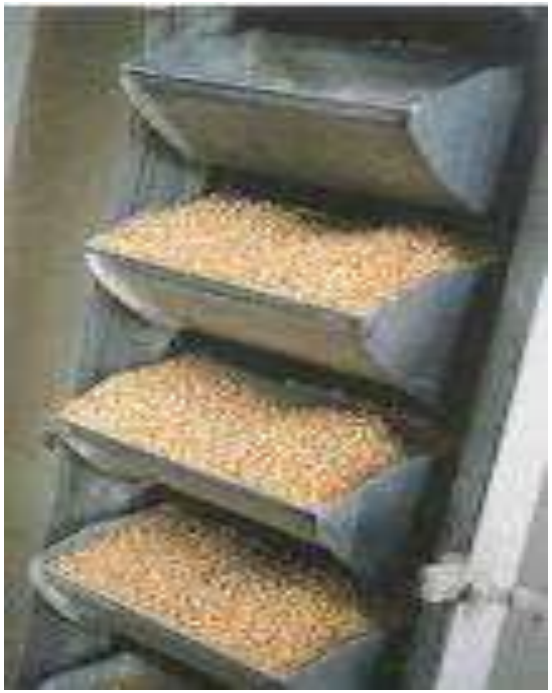
SLAT CONVEYOR

BUCKET CONVEYOR




Pendulum bucket conveyor
means transport
Without... breakage,
drust,
segregation
compression!
powder
coffee
stone
glass splinters

PUSH BAR CONVEYOR

FORK – LIFT TRUCKS

- Fork lift trucks consist of **Forks** attached to a column of the truck.
- Forks can be lifted upto the desired height with material (boxes) on them.
- The material can be stacked at the proper place very close to the roof in warehousing and shipping area.
- Fork lift trucks are used for short distance (40 – 70 meters)
- Used for **indoor** applications.

TWO WHEEL TRUCKS

FOUR WHEEL TRUCKS

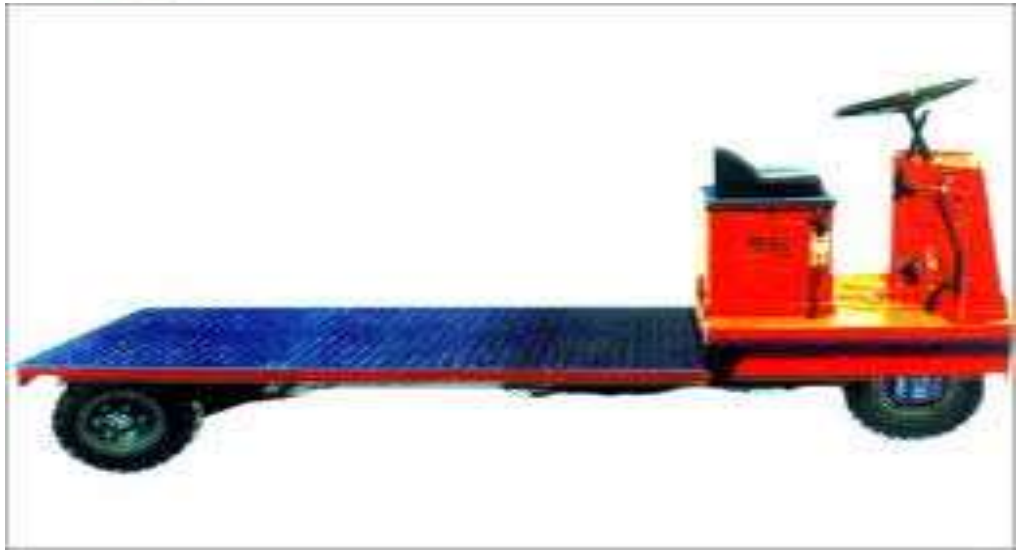
PLATFORM TRUCK

- Platform truck (low lift) is used for transporting the palletized raw materials of a lot size manually from the warehouse to the production area.

- Platform truck (high lift) is used for loading the tablet granules into double cone blender.

Plat form Truck (Low Lift)

Plat form Truck (High Lift)



FORK LIFT TRUCK


10

FORK LIFT TRUCK (Counter Balance Type)

CRANES

- Cranes are employed for lifting and lowering of bulky items, packages and boxes.
- These find applications in heavy engineering industry and generally in intermittent type of production.
- Several variations are available.

Jib Crane

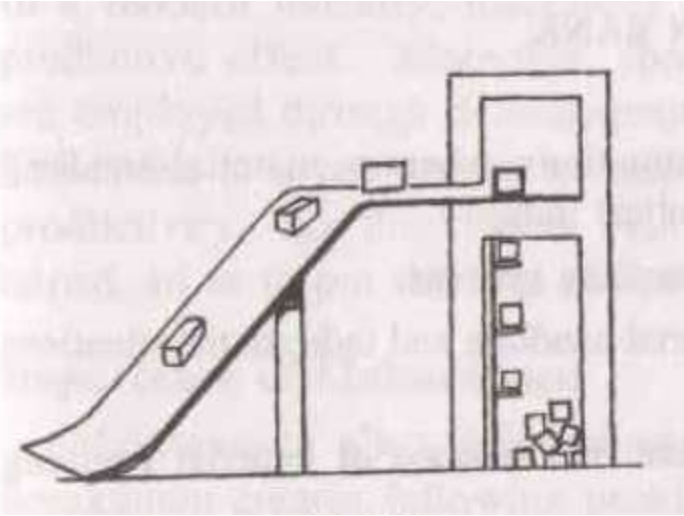
GRANTY CRANES

HOISTS

- Hoist means lift or pull something up to a higher place (overhead position) with ropes.
- This equipment is mounted on single rail fixed at the height nearer to the roof.
- Hence materials are transferred along fixed path.
- Hoist find applications in industries employing chemical cleaning.

SLIDES

- Slides can be straight, spiral and vibrating… and made up of wood or steel.
- Slides transfer small jobs than can slide down under gravity.
- Vibrating slides transport material up and down and inclined

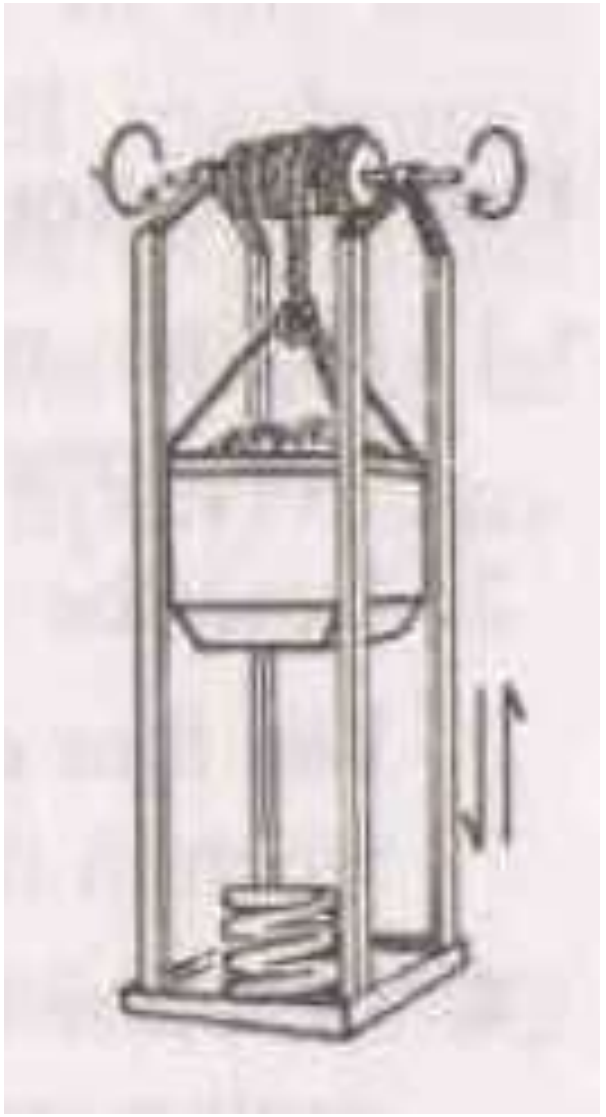


CHUTES

- Chutes have sheet metal or roller base for transferring components down the incline.
- Chutes generally deliver the feed material directly onto the Conveyor to reach the destination further.
- Spiral Chutes are used for transporting sealed vials from aseptic area to packaging section using gravity principles.

LIFTS

- Lifts are used to transport materials up in multi- storeyed plants.
- It is a fast and flexible equipment for floor to floor travel..
- Buckets or trays are mounted on the endless chain running from the ground floor to top floor.
- The material can be loaded into the trays automatically.



PREVENTIVE MAINTENANCE

IN PHARMACEUTICAL INDUSTRIES

- Preventive maintenances functions of Pharmaceutical industry play major role in smooth functioning and keep the economy of the company within limits.

- Proper selection and choice of pharmaceutical machineries require for production and instruments for quality control, their suitable arrangements and layout, procurement of suitable efficient tools and spare parts for these equipments and instruments and proper maintenance and planning.

- Scheduling is very important in pharmaceutical industries.

- Pre planned systemic maintenance, organization and methods are needed for smooth functioning pharmaceutical industries.

- A regular systemic routine inspection planning for equipments and instruments of pharmaceutical industry is required.
- According to needs the adjustments, repair and lubrication of the machineries are designed.
- If sufficient numbers of maintenance people are employed, routine inspection, repair and replacement of required spare parts can be done more efficiently and production break down delay etc., can be avoided.
- Break down and delay of production of pharmaceuticals resulting from poor maintenance may cause huge loss to the industry.

MAINTENANCE ACTIVITIES

- Checking of bearing of motor,
- Tightening of screws,
- Adjustment of clutches,
- Cleaning and replacement of the washers and belts,
- Adjusting the alignment of the machineries,
- Lubrication, polishing, cleaning and repair of the die and punch sets of the tablet compression machine and other spare parts of tabletting and granulation equipments and filling machineries,
- Testing and repair of motors,
- Checking of the wiring,
- Cleaning, servicing and lubrication of spare parts etc.,

- If maintenance functions are systematically carried out, the service expenses for electricity, steam and water can be reduced.

- Pre-planning of the maintenance operation reduce the storage space and excess spare parts and improve the economy of the company.

- Repair of the defective equipments at the right time may improve the efficiency and performance of the machine.

- A full time Maintenance Engineer with the support of suitable number of work force can pre plan the maintenance functions systematically to maintain the pharmaceutical machineries and instruments to keep them in efficient working conditions.

- Routine inspections, adjustments, repair, lubrication, replacement of the spare parts, keeping the production department well informed about the installation of the new machineries and instruments, new processes and methods are the main functions of maintenance department.

- The maintenance of the building and lay out is also the responsibility of Maintenance Engineer.

- He should also inspect and maintain water supply, drainage, sanitation work, heating, ventilation and lighting of the building and the working area, plumbing etc.

- There should be suitable fire protection arrangement for the industry, which should be supervised by the maintenance department.

RESPONSIBILITIES OF MAINTENANCE DEPARTMENT

- The maintenance of .....
  - Pharmaceutical machineries,
  - Instruments,
  - Boilers,
  - Stem heating systems,
  - Air conditioning equipments,
  - Incubators,
  - Ovens,
  - Stabilizers,
  - Material handling equipments,
  - Distillation equipments,
  - Air handling systems,
  - Environmental control and
  - Production area specially in sterile manufacturing area

- The above equipments and service facilities should be inspected periodically, the lubrication, repair and replacement should be done periodically.

- The safety instillation, fire fighting equipment, warning signals should also be kept inspected periodically.
- The roads, track, sheds, drainage systems of factory should also be maintained by suitable methods.
- The maintenance of electrical power plants of pharmaceutical industry, wiring, switch boards, lightning, battery charging and motor etc are also responsibility of maintenance department.

- Maintenance functions may be broadly classified as ....
  - Civil,
  - Mechanical,
  - Electrical and
  - Other general maintenance activities.

- Depending on the size of industry and work load, maintenance are staff employed.

- Planning of the maintenance functions should be done on long term basis.

- Work orders should be issued to the staff daily, sufficient spare parts tools should be kept in stock for repair functions.

- The records of inspection, repair and replacement should be maintained in systematic manner.

- During the selection and procurement of the new machinery and equipments, the maintenance engineer should be informed and consulted for his advice and he may be requested to keep the required stock of spare parts for further replacements.
- Trained and skilled staff should be employed in the company for periodic inspection repair and replacement of the spare parts.
- Preparation of weekly maintenance schedule and shut down of the machineries in a suitable systematic manner for repair work may improve the production efficiency.
- Suitable work order systems for inspection, repair lubrication and replacement may be evolved.
- The equipment record should be maintained which may be helpful in future for repair and reference work.

- The doubtful spare parts should be replaced and repaired at appropriate time which will help in avoiding breakdown during production.
- The physical deterioration of machinery happens due to impact, vibration corrosion and erosion etc.
- The shock absorbing elements reduce the impact of the machines .
- The vibration of the machine cause damage to the machine which may be prevented by suitable methods.
- Corrosion of equipments may be avoided using resisting materials or by suitable protective coating or by correcting the environmental causes for corrosion.

- Stainless steel red and yellow brass are less corrosive.
- Glass lined vessels are resistant to acids and they are useful in bulk drug manufacturing. Suitable coating, with paint and lacquer help to prevent corrosion.
- Galvanising protect steel parts from corrosion, iron pipes, subject to electrolytic corrosion are protected by thin coating of concrete.
- Periodic training to workers and supervisors for efficient handling of equipment may be needed to prevent abuse and misuse.
- In the inspection records of machineries, data like name, date of purchase, installation cost, model, conditions, should be written correctly.

- The buildings should be inspected every 6 months
- Roof, floor, electrical fitting are inspected every three months.
- Fire fighting and auxiliary equipments are inspected daily.
- All pharmaceutical machines are inspected at least weekly. The maintenance of different equipments can be done in definite cycle.
- All the constructions, water, air, gas, oil, steam pipe lines, electric wiring, fire doors and safety functions are inspected routinely.
- Pressure tanks, exhaust and blowers are maintained weekly.
- The cranes, elevators, conveyors, hoists, trolley, chains, switch boards of power house, tunnels, ovens, furnaces, power transformer, machine tools etc., are inspected and maintained monthly.
- Heavy electrical items are inspected quarterly.

- For the calculation of maintenance budget-labour cost, tool cost, operational and other material costs, periodic inspection costs, maintenance costs for contract, repair cost, lubrication costs, replacements costs, overhead charges etc, are taken into consideration.

- If inspection and preventive maintenance is not undertaken, it may cause major hazards due to breakdown and also extra costs for emergency maintenance work and labour, cost of additional materials, delay in supplies to customer etc.

- There may be few week spots in any machinery which has to be inspected, rectified, otherwise it may cause major break down and loss to the production. The safety aspect is also improved when preventive maintenance done properly.

- The inspection is done as per the schedule and the defective item is corrected.
- The case history of the each machine is reviewed.
- The corrective action is necessary for many pharmaceutical machineries like autoclave, boilers, vacuum pumps, steam pipeline etc.
- Maintenance manager should adopt suitable method and plan the working of his department for inspection, lubrication, replacement and repair etc.
- Machine lubrication is a very important function.
- Correct quantity of the lubricant having proper quality should be used, and properly stored.

- The lubrication of the tablet punches and dies and other parts of the tablet compression machines, polishing of die and punch sets are also important functions of maintenance department.

- The abrasion and damage of the metallic spare parts of the machines should be avoided.

- The lubricants should adhere well, it should not contaminate the tablet formulation, the punches and dies should be properly stored without damage in suitable boxes.

- The instances of the entire break down in the factory should be recorded and critically reviewed and corrective measures should be taken which may eliminate the repetition of the break down.

  This will improve the economy of the organisation by avoiding overtime, improving safety and reducing maintenance cost and spare parts cost.

- The quality if the product will also include with reduction in the rejection and improvement in the equipment life and improvement in the overall image of the company.

- The preventive maintenance should be periodically reviewed by the manager with the help of inspection report and record, repair cost, production loss, back log, shut down and over hauls if any etc.

ANALYTICAL EVALUATION OF PREVENTIVE MAINTENANCE

Inspection incomplete/inspection schedule x 100

Jobs resulting/inspection completed x 100

- Sufficient spare parts should be stored for preventive maintenance, to reduce the loss of production.
- Time depending upon the availability.
- Imported spare parts should be available on request.
- Locally available spare parts should be available on request.

- Locally available spare parts need not be stored to avoid shortage of space. The spare parts should have suitable code number which may help in identifying them when ever required.
- The stock card should be having same identification number.
- The location of the spare parts should be at appropriate place.
- The tool boxes, lubrication items, belts, pulleys, chains, fuses, electrical wiring, tablet dies and punches, wire meshes for sieving and shifting machines, U.V. lamps, air handling filters should be stored in advance to enable the maintenance functions of pharmaceutical machinery and production facilities.

- The punch handling boxes or metal trace with perforated wooden tops may be utilised for storing tablet and punches.

- The cleaning, lubrication and polishing and rust proof oil application for the dies and punches should be done carefully to improve the shelf life.

- The maintenance of production facilities like cleaning and GMP aspects, cleaning of tanks, pipes, and other equipments and spare parts are also responsibilities of maintenance department.

- The electricity, gas, water, steam, compressed air, air conditioning, oxygen, nitrogen, vacuum system etc, are to be maintained by suitable methods.

- Whenever there is a change over from one batch to other batch or from one product the equipments used for production should be carefully and thoroughly cleaned.

- The swab or the extract should be tested by the quality control department for any impurities with the help of HPLC or GC methods to ensure proper cleaning.

- If cleaning is not sufficient, suitable steps should be taken to correct the cleaning schedule and maintain GMP.