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Parentearal Drug Manufacturing

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ABSTRACT:-Parenteral preparations are sterile, pyrogen-free liquids (solutions, emulsions, or suspensions) or solid dosage forms containing one or more active ingredients, packaged in either single-dose or multidose containers.
They are intended for administration by injection, infusion, or implantation into the body. The term parenteral derives from the Greek word: para which means outside and enteron which means intestine.

Parenteral preparations may contain excipients such as solvents, suspending agents, buffering agents, substances to make the preparation isotonic with blood, stabilizers, or antimicrobial preservatives. The addition of excipients should be kept to a minimum.
When excipients are used, they should not adversely affect the stability, bioavailability, safety, or efficacy of the active ingredient(s), or cause toxicity or undue local irritation. The manufacturing process should meet the requirements of Good Manufacturing Practice.
The quality of starting materials, the design and maintenance of the equipment and the method of manufacture must be such as to ensure the stability of the active substance and the final product which is sterile and free of pyrogens and particulate matter.
This review describes an overview of parenteral drug delivery system. Firstly, different routes of administration, formulation of parenteral, their types and containers used are pointed out.

In the second part, various Preformulation and pharmaceutical factors affecting parenteral administration, general manufacturing procedure and evaluation tests
of parenteral are reviewed.

I. INTRODUCTION:-

- Parenteral preparations are sterile, pyrogen-free liquids (solutions, emulsions, or suspensions) or solid dosage forms packaged in either single-dose or multidose containers.
- These preparations are administered through the skin or mucus membranes into internal body compartments.
- These include any method of administration that does not involve passagethrough
- The digestive tract.The term parenteral is derived from the Greek word Para – outside and Enterone –Intestine. It denotes the route other than oral.
- Parenteral (Gk, para enteron, beside the intestine) dosage forms differ from all other drug dosage forms, because they are injected directly into body tissue through the primary protective systems of the human body, the skin, and mucous membranes.
- They must be exceptionally pure and free from physical, chemical, and biological contaminants. These requirements place a heavy responsibility on the pharmaceutical industry to practice current good manufacturing practices (cGMPs) in the manufacture of parenteral dosage forms and on pharmacists and other health care professionals to practice good aseptic practices

(GAPs) in dispensing parenteral dosage forms for administration to patients.

- Certain pharmaceutical agents, particularly peptides, proteins, and many chemotherapeutic agents, can only be given parenterally, because they are inactivated in the gastrointestinal tract when given by mouth. Parenterally-administered drugs are relatively unstable and Generally highly potent drugs that require strict control of Administration to the patient. Due to the advent of biotechnology,
- parenteral products have grown in number and usage around the world.
- The requirements of this monograph do not necessarily apply to human blood and products derived from human blood, toimmunological preparations, to peritoneal dialysis solutions or radiopharmaceutical preparations.
- Parenteral preparations are sterile preparations containing one or more active ingredients intended for administration by injection infusion or implantation into the body. They are packaged in either single-dose or multidose

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containers.

- Parenteral preparations may require the use of excipients such as solvents, substances to enhance solubility, suspending agents,
- buffering agents, substances to make the preparation isotonic with blood, stabilizers or antimicrobial preservatives. The addition of excipients is kept to a minimum.
- When excipients are used they do not adversely affect the stability, bioavailability, safety or efficacy of the active ingredient(s), or cause toxicity or undue local irritation. There must be no incompatibility between any of the components of the dosage form.
- Water for injections is used as the vehicle for aqueous injections. Sterilization at this stage may be omitted, provided that the
- preparation is subject to terminal sterilization. For non-aqueous injections, fixed oils of vegetable origin are used as vehicles.
- Unless otherwise specified in the individual monograph, sodium chloride orother

II. TYPES OF INJECTABLE DRUG PRODUCTS:

Injectable drug products can be developed into several different types depending upon the characteristics of the drug, the desired onset of action of the drug, and the desired route of **administration.** The following presentations are typically used:

Injectable solution: a drug dissolved in water (or other solvent) that mayinclude additives, known as excipients, to help stabilize it

Injectable suspension: drug crystals are not soluble in water, so the surface of the crystals are wetted to prevent them from floating on the solution surface; this is typically accomplished using a surfactant; suspending agents are then added to prevent the crystals from settling to the bottom and forming a solid (concretion), which is difficult to re-suspend.

Injectable emulsion: a drug that is not soluble in water so it is dissolved in an oil, which is then added to water with an emulsifying agent.

Pre-Formulation and Formulation Development:-

There is a significant amount of time, effort, and expense required when identifying a new drug molecule, whether it is a small molecule or a large bio-molecule. However, once the molecule is identified and a process to mass produce the molecule is created, the final product development work begins.

The initial goal is to get the product to a semi-formulated state so it can be administered to animals for safety/toxicology studies (pre-clinical). For the early phases of animal and human studies (clinical trials) it is common to use drug products that are not in the final formulated state, as they need to be stable only through the course of the trial. While these early phase studies are conducted, development scientists work to identify the final formulation that willoffer the best stability, safety, and efficacy.

Pre-Formulation studies may include:

- pH stability
- pH solubility
- identifying a stability indicating analytical method
- thermal stability
- oxidation potential
- light stability
- hydrolysis potential

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Formulation studies may include:
entifying both the need for and appropriate strength of a buffer system to control pH

□ identifying both the need for and appropriate strength of a surfactant

□ identifying both the need for and appropriate strength of a stabilizer
need for and appropriate strength of a bulking agent

□ identifying both the

III. CONTAINERS:-

- Containers are in close contact with the product. Both the chemical and physical characteristics affect the stability of the product, but the physical characteristics are given primary consideration in the selection of a protective container.
- Glass containers traditionally have been used for sterile products, many of which are closed with rubber stoppers. Interest in plastic containers for parenterals is

increasing, and such containers are being used for commercial ophthalmic preparations and IV solutions.

1 Plastic Containers:-

(Fig Plastic Container)

- The principal ingredient of the various plastic materials used for containers is the thermoplastic polymer.
- Although most of the plastic materials used in the medical field have a relatively low amount of added ingredients, some contain a substantial amount of plasticizers, fillers, antistatic agents, antioxidants, and other ingredients added for special purposes.
- These ingredients are not usually chemically bound therefore, may migrate out of the plastic and into the product under the conditions of production and storage.
- Plastic containers are used mainly because:
- Light in weight
- Non-breakable
- When low in additives have low toxicity and low reactivity with products.

Drawbacks:-

- Tissue toxicity can occur from certain polymers, but additives are a more common

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cause.

- Reactivity due to sorption (absorption and/or adsorption) has been found to occur most frequently with the polyamide polymers, but additives leached from any ofthe plastic materials may interact with ingredients of the product.
- Most polymers are adversely affected by the elevated temperatures required for thermal sterilization and have a relatively high permeability for watervapour.
- Significant permeation of gases including oxygen may occur with some materials. Ex: polystyrene

Polypropylene:-

- It is the most widely used.
- It is a linear polymer that can be produced to be highly crystalline. Because of its crystallinity, it has a high tensile strength, a high m.p. of 165°C and relatively low permeability to gases and water vapours.
- It is translucent, abrasion-resistant, and has high surface gloss.
- Withstands normal autoclaving temperatures.
- Flexible polyethylene containers are used for ophthalmic solutions to be administered in drops and flexible polyvinyl chloride bags for IVsolutions.
- The newer group of polymers, the polyolefins has made possible the development of bottles that are rigid enough to hold their shape during processing but can collapse under atmospheric pressure as outflow of a solution occurs during IV administration to the patient.

USP Procedure for Evaluating the Toxicity of Plastic Materials:-

1. Implanting small pieces of plastic materials intramuscularly in rabbits
2. Injecting eluates using sodium chloride injection with an withoutalcohol intravenously in mice and injecting eluatesusing PEG400 and sesame oil intraperitoneally in mice
3. Injecting all four eluates subcutaneously in rabbits. The reaction from the test samples must not be significantly greater than non-reactive controlsamples.

2 Glass Containers

(**Fig** glass container)

- It is the preferred material for injectable products.
- Is composed principally of silicon dioxide tetrahedron, modified physico- chemically by such oxides as those of sodium, potassium, calcium, magnesium, aluminium, boron and iron.
- The two types of glass commonly used are: soda lime and borosilicate glass.

Chemical Resistance:-

- The USP provides the powdered glass and the

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- water attack test for evaluating the chemical resistance of glass.
- The test results are the measurement of the amount of alkaline constituents leached from the glass by purified water controlled elevated temperature conditions.

Similarly powdered glass test is performed on ground, sized glass particles and water attack test is performed on whole containers.

- Water attack test is used only with containers that have been exposed tosulfur dioxide fumes under controlled humidity conditions.

On the basis of results from the official test glass are classified as:

- Type I
- Type II
- Type III
- NP (Non parenteral)
- Type I is preferred most for the sterile products.
- Type II and III may be used when the product has non-aqueous vehicle or the period of contact with aqueous vehicle is brief, as with dry powdersreconstituted just prior to use/ if the non reactivity between the glass and product has been established.

IV. PRODUCTION:-

- Production process includes all the steps from accumulation and combining of the ingredients of the formula to the enclosing of the product in the individual container for distribution. Intimately associated with these processes are the personnel who carry them out and the facilities in which they are performed.
- To enhance the assurance of successful manufacturing operations, SOP is very essential.
- Extensive records must be kept to give assurance at the end of the production process that all steps have been performed as prescribed, an aspectemphasized in the FDA's Good Manufacturing Practice.
- In-process control is essential for assuring the quality of the product, since these assurances are even more significant than those from product release testing.
- In the initial step, the formula ingredients, container components and processing equipments that have been released for use are drawn from their respective storage areas. The ingredients are compounded according to the master formula in an environment designed to maintain high level of cleanliness. And if the product is solution, it is filtered during transfer to the asceptic filling room.
- Process equipments and container components are cleaned thoroughly, assembled in a clean environment, sterilized and depyrogenated prior to theuse.

is then packaged. Outer wrapping of the packages should be loosened. All supplies must be introduced into the aseptic filling rooms.

- After this the containers are sealed.
- It is then transferred to the packaging area. This room must be clean. Packaged products are kept in quarantine storage until all tests have been completed andinprocess control records have been evaluated.

Then the product is released for distribution.

1. Facilities
2. Environmental control
   - Traffic control
   - House keeping
   - Surface disinfectant
   - Air control
3. Personnel
4. Processing
5. Water for injection
6. Storage and distribution
7. Cleaning equipment and containers
   - Rinsing new containers
   - Cleaning rubber and plastic components
   - Sterilization of equipment
8. Compounding the product
9. Filtration of solutions
10. Filling procedures
    - Filling equipment for liquids
    - Filling equipment for solids
11. Sealing
    - Sealing ampoules
    - Sealing bottles, cartridges and vials
12. Automation of processing
13. Sterilization of the product
    - Freeze drying
14. Packaging
15. Stability
16. Quality control
    - Leak test
    - Clarity test

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17. Pyrogens and pyrogen test

Facilities

- Should be designed for the control of cleanliness environment appropriate for each step.
- Surrounding area should provide a buffer area in which standards of cleanliness are only slightly lower than those for the ascetic rooms.

The prevention of contamination must be the primary objective.

- The ceiling, walls, and floors should be constructed of material that is easyto clean and non porous, to prevent the accumulation of debris andmoisture.
- Spray-on-tile is a ceramic epoxy finish applied by spraying or painting to form continuous, smooth, seal coating on the ceiling and walls.
- Ceramic-plastic cement is the best materials for floors.
- Glass is used in partition to permit supervisory view of operation as well as to provide more pleasant, better lighted, less confining surroundings for the operators.
- Furniture should be of non-porous, hard surfaced materials, preferablystainless steel.
- The basic designs and construction features have been continued with the HEPA filtered laminar airflow capabilities. Laminar airflow is most frequently added to a clean room to achieve greater environmental control in local areas.

2 Environmental Control

- For environmental control both the physical and chemical isessentials.
- Allowance must be made for variations in control associated with the seasonal
- The standards of environmental control varies depending upon the area involved and the type of product prepared aseptically maintained under the most rigid control that the existing technology permits.
- High standards of cleanliness, excluding daily use of the disinfectingprocedures are usually acceptable for clean up and packaging areas.

Traffic Control:

- Carefully designed arrangement to control and minimize traffic particularly in and out of the aseptic area is essential.
- Access by personnel to the aseptic corridor and aseptic compounding and filling rooms is only through an airlock.
- Personnel should be permitted to enter aseptic areas only after following rigidly prescribed procedures.
- Unauthorized personnel should never be permitted to enter the asepticarea. Housekeeping:
- Cleaning personnel must be imbued with the philosophy that not one remaining particle of debris is acceptable.
- All equipment's and surrounding work area must be cleaned thoroughly at the end of the working day.
- The ceiling, walls and other structural surfaces must be cleaned with a frequency Commensurate with the design of the facility.
- All cleaning equipment's should be selected for its effectiveness and freedom from lint-producing tendencies.

Surface Disinfectant:-

- After thorough cleaning, all surfaces should be disinfected, in the asceptic areas.
- An effective liquid disinfectant should be sprayed or wiped on allsurfaces
- UV rays may be particularly useful to irradiate the inside, exposed surfaces of processing tanks, surface under hoods, surface of conveyor belts, underside of conveyors and the inside of containers.
- Ultraviolet lamps must be kept clean and care must be taken to check for decrease in effective emission, natural occurrence due to a change in theglass structure with aging.

Air Control:-

- A spun glass, cloth or shredded polyethylene filter may be used for preliminary cleaning operation.
- To remove finer debris down to the sub-micron range including microorganism, a High efficiency particulate air (HEPA) filter, as defined as 99.7% efficient in removing particles of 0.3 µmsize.
- Air passing through these units can be rendered virtually free from foreign matter. Another air cleaning system washes the air with a disinfectant and controls the humidity at same time.
- Blowers should be installed in the air ventilation system upstream to the filters so that all dirt-producing devices are ahead of the filters. The clean air is distributed to the required areas by means of metal ducts.

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- The two types of rooms employed are:

- Class 100
- Class 10,000

- Class 100 clean room is defined as a room in which the particle count in the air is not more than 100 per cubic foot of 0.5µm and larger in size. The airflow must be uniform in velocity and direction throughout any given cross section of the area. The air velocity employed should be 100±20 ft/ min.
- This class is mostly specified for critical aspects/ clean operations.
- This is expensive and requires effective maintenance and monitoring.
- Class 10,000 rooms are defined as one in which the particle count is no more than 10,000 per cubic foot of 0.5µm and larger in size.

Personnel:

- The people who produce sterile products are usually non-professional persons, supervised by those with professional training.

Manufacturing:-

The manufacturing process should meet the requirements of good manufacturing practices (GMP). The following information isintended to provide broad guidelines concerning the main steps to be followed during production.

- The quality and grade of starting materials, the design and maintenance of the equipment and the method of manufacture must be such as to ensure the stability of the active substance and of the final product and that the final product is sterile and free ofpyrogens and particulate matter.
- During development the effectiveness of any antimicrobial preservative present in the preparation shall be demonstrated to thesatisfaction of the relevant regulatory authority.

(Fig manufacturing machine)

- For the sterilization of parenteral preparations follow 5.8 Methods ofsterilization. Heating in an autoclave (steam sterilization) it
- the method of choice for aqueous preparations and should therefore be used whenever possible. When a parenteral preparation is liable to deterioration dueto

oxidation the operation of filling may be performed in an atmosphere of suitable sterile inert gas, such as nitrogen, whereby the air in the container is replaced by this gas.

- In the manufacture of preparations containing dispersed particles measures are taken to ensure a suitable and controlled particle size with regard to the intended use. In the manufacture of liquid preparations measures

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are taken to ensure that the volume of the preparation in the container is sufficient to permit withdrawal and administration of the nominal dose using a normal technique as demonstrated by5.6

Extractable volume for parenteral preparations:-

- Throughout manufacturing certain procedures should be validated and monitored by carrying out appropriate in-process controls. These should be designed to guarantee the effectiveness of each stage of production.
- In-process controls during manufacture of parenteral preparations should include monitoring of environmental conditions (especially with respect to particulate and microbial contamination), bacterial endotoxins, pH and clarity of solution, freedom from particulate matter and integrity of the container-closure system (absence of leakage, etc.).
- For powders for injections controls should also include uniformity of mass, moisture content and the ease of reconstitution of a solution or suspension.
- The validation of the manufacturing process and the in-process controls are documented.

V. STORATE AND DISTRIBUTION:-

- The storage and distribution of WFI is as important as production.
- A closed system with air exchange through a filter that removes microorganism, dirt and vapours from the air as the tank is filled and emptied.
- WFI should not be held for more than 24 hr at room temperature before it is used, but if held at 80°C.
- The distribution may be by direct withdrawal from the tank, or in large plants through a pipe system.
- When a pipe system is used precaution must be followed to prevent the contamination/ construction with welded stainless steel pipe, elimination of elbows/ pockets in which water can stagnate for long periods and thorough cleaning/ sanitation at frequent intervals.

Cleaning Equipment and Containers:-

- Equipments and containers to be used should be scrupulously cleaned.
- Debris should be removed by hot detergents. Live steam can sometimes be used to loosen debris effectively, particularly in area where it is not accessible.
- After cleaning, it should be rinsed with WFI.
- A new method for large tanks, pipelines and associated equipments that can be isolated and contained within a process unit has been developed and identified as a CIP (Clean in place) system. Cleaning is accomplished with high pressure rinsing treatments delivered automatically within the equipment which is followed by steam sterilization.
- The glasswares and metalwares is automatically conveyed, usually in aninverted position through a series of rigorous, high pressure treatment including hot detergent, hot tap water and final rinses with distilled water.

Compounding of the Product:-

- The product should be compounded under clean environment conditions.
- The accuracy of compounding should meet the rigid standards accepted in pharmaceutical procedures, regardless of the batch size, recognizing that small multiple errors may be additive.
- Similarly in large batch particular attention must be given to achieve and maintain homogeneity of solutions, suspension and mixtures maintaining a given temperature and accelerating cooling.

VI. FILTRATION:-

At this point in the manufacturing process the formulated drug product enters the Class A clean room. It remains under these conditions until the product is filled, stoppered, and capped. Only then does the product exit the clean room, unless it is destined to be freeze-dried, at which point the product is aseptically transported to the freeze-dryer.

There are four primary types of filters used in the parenteral and biopharmaceutical industry (the type of filter chosen depends on the type of material to be removed). The filter types include:

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- clarifying filters—large particles
—bacteria and yeasts (used for injectable drug products)
- microfilter
—viruses
- ultrafilter
—small organic compounds and ions
- nanofilter

The injectable drug industry uses microfilters to remove particles in the 0.1 to 10 micron size range from the formulated drug product. Several different types of membranes are available in this pore size range to accommodate different types of formulations, including water based formulations (hydrophilic) and solvent based formulations (hydrophobic). It is up to the development scientist to conduct studies for

(**Fig** Filtration Machine)

filter compatibility in order to determine thecorrect filter and filter surface area for the particular product. For most parenteral products, a hydrophilic (water loving) filter is used and may include:
egenerated cellulose

- modified regenerated cellulose
- polyamide (nylon)
- cellulose acetate
- cellulose nitrate
- polyethersulfone
- polysulfone
- polyvinylidene difluoride (PVDF)
- polycarbonate

The next step in the process is to sterilize the solution using one of the filters listed above. Note that products that are either suspensions or large particle-sized emulsions cannot be sterile filtered and have to be aseptically formulated—all components are pre-sterilized individually and then brought together in a sterile environment. The filters are available as either flat disks or as cartridge filters, which significantly increase the filter surface area when extremely large volumes need to be filtered.
To ensure that the filter membrane is completely intact (no holes), integrity testing must be performed both before and after filtering the product

Filling Equipments for Solids: -

- The rate of flow of solid materials tends to be slow and irregular whereas small, granular particles flow most evenly. Containers with large openings must be used even the filling rate is slow and the risk of spillage is present.
- When the solid is obtained in relatively free-flowing form, machine methods of filling may be employed. This method involves the measurement and delivery of volume of solid material which has been calibrated in terms of weightdesired.
- Another filling machine consists of an adjustable cavity in the rim ofthe filling wheel which is filled by vacuum as the wheel passes under the hopper.The contents are held by vacuum until the cavity is inverted over the container when a jet of sterile air discharges the dry solids.

Sealing Ampoules:

- Ampoules may be closed by melting a portion of the glass of the neck to form either bead-seals (tip seals) or pull seals. Tip seals are made by melting sufficient glass at the tip of

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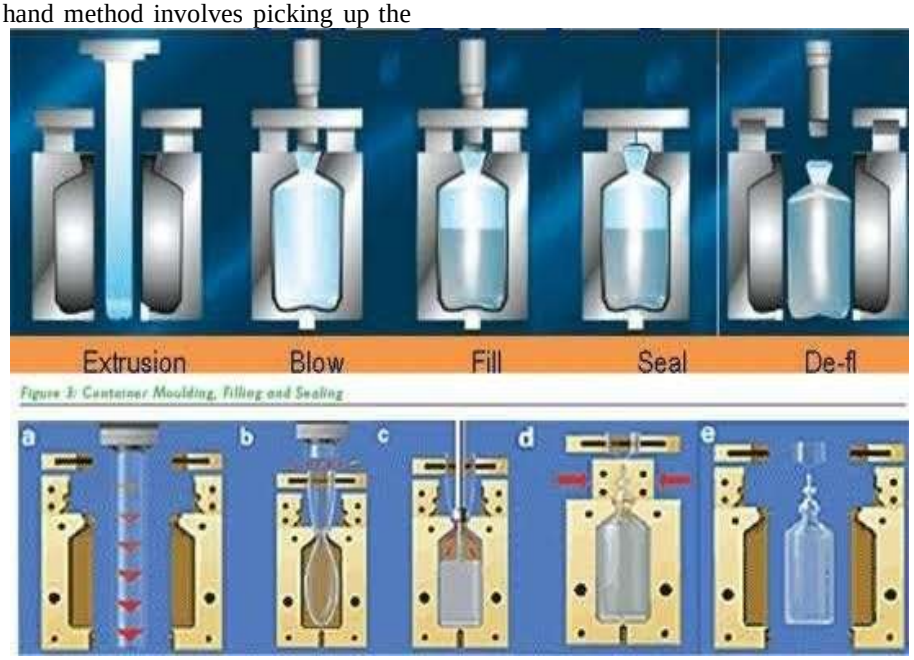
the ampoule neck to form a bead of glass and close the opening.

- Pull seals are made by heating the neck of a rotating ampoule below the tip, then pulling the tip away to form a small, twisted capillary just prior to being melted closed. It is a slower process but the seals are more reliable than that form tip-sealing.
- The heating with high temperature gas-oxygen flame must be even and carefully controlled to avoid distortion of the seal.

Sealing Bottles, Cartridges and Vials:-

- Rubber closures must fit the opening of the container snugly enough to produce a seal.
- A faster hand method involves picking up the closure and inserting it into a vial by means of a tool connected to a vacuum line.
- When closures are inserted by machine, the surface of the closure is usually halogenated or coated with silicone to reduce the friction.
- Aluminum caps are used to hold rubber closures in place. Single caps contains hole/ center that is torn away at the time of use to expose the rubber closures. Whereas the double aluminum caps usually have an inner cap with permanent center hole, which in use is exposed when the entire outer cap is torn off. The triple aluminum caps are used for large bottles with rubber closures having permanent holes for attachment to administration sets.



(fig.filling& sealing)

Stoppering:-

Once the vials have been filled, they travel down the filling line to have pre-sterilized stoppers inserted. If the product is not scheduled to be freeze-dried, a stopper is fully inserted into the neck of the vial and the vial is transported to the capping station. If the product is going to be freeze-dried, a special stopper with a vapor port is partially inserted into the neck of the vial.

The freeze-drying process, described in more detail below, allows for the removal of water; the ice created during the freezing phase of the process is converted to water vapor, which leaves the product via the open port in the specialized lyophilization stopper.

Capping:-

If the vials are not scheduled to be freeze-dried they travel down the filling line to the capping station. Caps are used to secure the stopper in the neck of the vial to prevent the stopper from coming out either over time or during handling. The caps are comprised of a plastic cap and an aluminum skirt

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(Fig.aluminium cap)

- The caps are fed down a chute to the vials as the vials travel down the filling line. One cap is loosely placed on the top of each vial.
- The vials then travel to the crimping station where rotating blades crimp the bottom of the aluminum skirt around a lip on the neck of the vial, producing a tight fit that locks the stopper into the neck of the vial. At the time of use the plastic cap is removed; this exposes the top of the stopper, which is then pierced with a needle to remove the contents inside the vial. At this point in the production process the vials exit the Class A environment through a port in the wall and are ready for inspection and final packaging.

Sterilization of Product :- Freeze-drying: -

- It is a drying process applicable to the manufacture of certain pharmaceuticals and biological that is thermolabile or otherwise unstable in an aqueous solution for prolonged storage periods, but is stable in dry state.
- The rate of drying depend on the thermal conductance of the frozen product, rate at which the vapour can diffuse through the progressively thicker layer of dried porous material and the rate of transfer of vapour through the system to the condenser surface.

(Fig Sterlization machine)

- In production, large freeze driers are usually operated by an automatic control system. The product is usually processed until there is less than 1% moisture in the dried material.
- Freeze driers also may be equipped for stoppering vials within the drying
- Numerous biologic preparations, tissue sections and viable microorganismare being

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preserved in the freeze dried state. Multiple vitamin combinations, antibiotics, hormones are other examples.

- **Labeling:-**

Once the product is released from Inspection by Quality Assurance, it moves to Labeling. Labeling is performed in order to provide accurate information regarding the product and avoid misrepresentation of the ingredients or effects of a drug, whether accidental or intentional. Stringent controls are placed on the printing and handling of labels in order to prevent errors.

(Fig.labeling)

- Both the label and the information on the label must be approved by the FDA, and each batch of labels to be used for a drug product must be inspected, approved, and released by QA before labeling begins.
- Small batches of drug product may be labeled by hand, but in most cases labeling machines are used. The machines also inspect the labels and insure they areplaced correctly and contain the

correctinformation.

- **Packaging :-**

- The package is an extremely important part of the product, for it presents the product to the user.
- It must be particularly dignified, neat and attractive appearance if it is to convey to the user the quality, purity and reliability.
- The labeling should be legible and the identity and strength of the drugshould be distinguishable.
- The packaging should protect the product against physical damage during shipping, handling and storage and should protect light-sensitive substances from ultraviolet radiation.

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(Fig Packaging)

VII. CONCLUSION:-

There are also significant benefits related to successful parenteral drug production, including:

- Knowing that you helped produce medication that will save a life or will fight life-threatening diseases.
- Becoming a skilled employee with multiple options in the bio tech industry; an industry forecasted to continue to grow significantly in the future.Aseptic processingof parenterals involves a number of interesting challenges, including:
- Protecting the sterility of the product as it moves through several phases of formulation, filtering, filling, and packaging.
- Development of the experience and technical knowledge to trouble-shoot issues as they occur.
- Maintaining consistent compliance with CGMP regulatory requirements to protect product SISPQ

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