INDUSTRIAL PHARMACY-I

UNIT IV-PARENTERALS

CLASS:27

TOPIC Production procedure, production facilities and controls

Productionfacilitiesandcontrols:

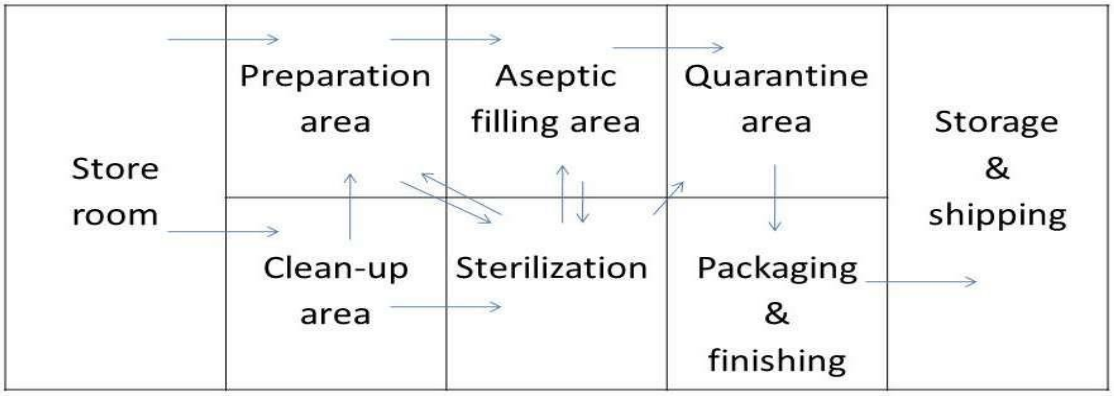
The production area where the parenteral preparations are manufactured can be divided into thefollowing five sections.

1) Clean-uparea
2) Preparationarea
3) Asepticarea
4) Quarantinearea
5) Finishing&packagingarea

Clean-uparea:

- Itisnotasepticarea.
- Alltheparenteralproductsmustbefree fromforeignparticles&microorganism.
- Clean-upareashouldbewithstandmoisture,dust&detergent.
- Thisareashouldbekeptcleansothatcontaminantsmaynotbecarriedoutinto aseptic area.

1. **Preparationarea:**
   - In this area the ingredients of the parenteral preparation are mixed & preparation is made for filling operation.
   - Itisnotessentiallyasepticareabutstrictprecautionsarerequiredtopreventany contamination from outside.



2. **Asepticarea:**
   - Theparenteralpreparationsarefiltered,filledintofinalcontainer&sealedinasepticarea.
   - Theentryofpersonnelintoasepticareashouldbelimited& throughanairlock.
   - Ceiling,wall&floorofthat areashouldbesealed&painted.
   - Theairinthe asepticareashouldbefreefromfibers,dustandmicroorganism.
   - TheHighefficiency particulateairfilters(HEPA)isusedforair.
   - UVlampsarefittedinordertomaintainsterility.
3. **Quarantinearea:**
   - Afterfilling,sealing&sterilizationtheparenteralproductareheldupinquarantinearea.
   - Randomlysampleswerekeptforevaluation.
   - Thebatchorproductpasstheevaluationtestsaretransferintofinishingorpackagingarea.
4. **Finishing&packagingarea:**
   - Parenteralproductsareproperlylabelledandpacked.
   - Properly packingisessentialtoprovideprotectionagainstphysicaldamage.
   - Thelabelledcontainershouldbepackedincardboardorplasticcontainer.
   - Ampoulesshouldbepackedinpartitionedboxes

Controlledenvironmentrequiredforparenteralpreparation:

Clean Room Classified Areas: Due to the extremely high standards of cleanliness and purity that must be met by parenteral products, it has become standard practice to prescribe specificationsfor the environments (clean rooms) in which these products are manufactured. The Critical and General area of clean room: The clean room divides into

1. CriticalArea
2. GeneralArea.

The critical area is the area around the point of the production where contamination can gain direct access to the process. This area often protected by localized laminar flow clean benches and workstations.TheGeneralareaistherestofthecleanroomwherecontaminationwillnotgain direct entry intothe product but should be keptclean because of the transfer of contamination intothe critical area. It is necessary that the critical area be cleaned most often with the best cleaning ability without introducing contamination.

ClassificationofCleanRooms:-

Theclassisdirectlyrelatedtothenumberofparticlespercubicfootofairequaltoor greater than 0.5 micron.

1. Class100,000:Particlecountnottoexceedatotalof100,000particlespercubicfootofasize 0.5µ and larger or 700 particles per foot of size 5.0µ and larger.
2. Class 10,000: Particle count not to exceed a total or 10,000 particles per cubic foot of a size 0.5µ and larger or 65-70 particles per cubic foot of a size 5.0µ and larger.
3. Class1,000:Particlescountnottoexceedatotalof1000particlespercubicfootofasize0.5µ and larger or 10 particles per cubic foot of a size 5.0µ and larger.
4. Class 100: Particles count not to exceed a total of 100 particles per cubic foot of a size 0.5µ and larger.

Class1:Theparticlecountshallnotexceed3000particles/m3ofasize0.5µ.

Class 2: The particle count shall not exceed a total of 3000 particles/m3of a size of 0.5µ or greater; 2000 particles/m3of size 0.5µ or greater; 30 particles of a size 10µ.

Class 3: The particle count shall not exceed a total of 1,000,000 particles of a size of 1µ or greater;

20,000particles/m3ofsize5µorgreater;4000particles/m3ofasize10µorgreater;300particlesof a size of 25µ or greater.

Class 4: The particle count shall not exceed a total of 200,000 particles of a size of 5µ or greater. For the manufacture of sterile medicinal products normally 4 grades can be distinguished:

GRADE — 'A': The local zone for high risk operations. eg. filling zone, stopper bowls, openampules and vials. GRADE — 'B': In case of aseptic preparation and filling, the back ground environment for grade — 'A' zone. GRADE — 'C' & 'D': Clean areas for carrying out less critical stages in the manufacture of sterile products.