

Source of Contamination & their prevention

• There are various source of contamination in Aseptic area $\Rightarrow$

[DEPTH OF BIOLOGY]

- ① Atmosphere
 - ② operator
 - ③ Raw material
 - ④ Equipment
- ① Atmosphere $\Rightarrow$

Air is the major source of contamination as it contains dust particle, Microbes, spores etc.

[DEPTH OF BIOLOGY]

$\rightarrow$ It may be reduced by Chemical disinfection, U.V Light, filtration & Gaseous agent & also by air locked doors

[DEPTH OF BIOLOGY]

② Operator ⇒

⇒ The skin, hair & clothing of operator are potent source of microbial contamination.

[DEPTH OF BIOLOGY]

Or
Operator do any Manual Contamination, maybe due to lack of training or focus.

- It may be reduced that operator is in proper uniform & operator may be skilled.

③ Raw Material ⇒ (Starting Product).

* It account for a high proportion of microbial contamination into pharmaceutical products. (water is the Major Source)

— It may be due to Improper Sampling, Inadequate storage condition etc.

[DEPTH OF BIOLOGY]

- It may be reduced by ideal treatment, filtration & other sterilization process in raw material.
- Water may be treated by U.V Light.

[DEPTH OF BIOLOGY]

④ Equipment $\Rightarrow$ The equipment are Utensil used in processing, Holding, transferring & packaging are all common source of Contamination of Aseptic area.

- It is due to Improper design, Material lead to Corrosion, Improper Cleaning, Lack of Sterilization etc.
- It may be reduced by Heat, Gaseous agent or Chemicals
- Some are also Sterilized by Steam Under pressure [Autoclave].

Clean Area Classification $\Rightarrow$

* A Clean room is defined as a room in which the conc. of air borne particle is controlled.

- (It may be controlled by Hepafilter & air locked entry system)
- It is established by measurement of the Number of Particle with size 0.5μ or greater, that are contained in 1 ft^3 (Cubic foot) of sampled area.

• Accord. to U.S federal standard association.

Classification of Clean room. [DEPTH OF BIOLOGY]

⇒ Class 100 (Standard applicable to application)

Class 1000

Class 10000

Class 1,00,000

This Classification is used in Pharmaceutical Industry

Accord. to European Community Guidelines
it classified into →

Grade

A, B, C, D

[DEPTH OF BIOLOGY]

More pure

Less pure.

X

X

X