

# # Source & types of Microbial Contamination

This microbial Contamination of pharmaceutical product is Influenced by the environment in which they are manufactured & by the Material Used in their formulation.

- Source & types are described as follows ⇒

## (a) Atmosphere ⇒

[DEPTH OF BIOLOGY]

Microorg. are carried into the atmosphere suspended on particles of dust, skin, clothing, moisture or sputum following Coughing or sneezing.

[DEPTH OF BIOLOGY]

- The microbial content of the air may be used during the handling of contaminated material during dispensing, blending & formulation.

- Microbes commonly isolated from the atmosphere are bacteria & fungi.

[DEPTH OF BIOLOGY]

eg ⇒ Staphylococcus, Bacillus, Penicillium etc.

## (b) Water ⇒

It is one of the main constituents of many product & it is also used for washing & cooling process.

- Diff. types of Microbes are  $\oplus$  in fresh water

& some microbes may contaminate the H<sub>2</sub>O

eg  $\Rightarrow$  Streptococcus faecalis, pseudomonas etc.

- Softened water is often used for washing containers

& for formation may be contaminants through, Bacillus

& Staphylococcus.

[DEPTH OF BIOLOGY]

### (C) Raw Material $\Rightarrow$

$\rightarrow$  Raw Materials, Particularly of Natural origin are a potentially rich source of microorganism.

- Products from animal sources such as Gelatin,

Pancreas, Cochineal etc. Maybe contaminated with

diff. Pathogens.

[DEPTH OF BIOLOGY]

[DEPTH OF BIOLOGY]

• Some plants origin material such as Agar, starch

acacia etc. are used for pharmaceutical source of microbial contamination.

- It contain mainly Bacteria & fungi.

eg  $\Rightarrow$  Bacillus spp. —, Pseudomonas spp. etc.

abreviation  $\rightarrow$  for several species  $\rightarrow$  mer. & species plural

#### ④ Process Operator ⇒

Microorg. maybe transferred to Pharmaceutical formulation from operators.

[DEPTH OF BIOLOGY]

- Natural skin, flora microbes are the main source of contamination.

Eg ⇒ Staphylococcus aureus, Saccharo sp. etc.

#### ⑤ Equipment ⇒

The equipment & utensil are used in processing, holding etc. are the common source of pharmaceutical microbial.

It is due to Improper cleaning & calibration of equipments. Contamination

[DEPTH OF BIOLOGY]

#### ⑥ Packaging ⇒ Microbial Contamination of packaging

material is dependent upon its composition & storage condition, glass container etc. carry diff. types of microb. if not treated (sterilized) with suitable method.

Eg ⇒ Bacillus, Penicillium etc.

[DEPTH OF BIOLOGY]

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## Buildings →

Diff. molds & few bacterial species are the most common floor of wall & ceiling.

[DEPTH OF BIOLOGY]

Eg ⇒ *Aspergillus Niger*.

→ It is also due to rough walls, floors & poor ventilation.

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## Assessment of Microbial Contamination

— It is the determination of & Spoilage microbe  $\oplus$  in a given product & the level to which it is deteriorated or degraded.

[DEPTH OF BIOLOGY]

### ① Physical & Chemical Changes ⇒

Physical & Chemical changes of diff. Pharmaceutical formulation indicates microbial contamination & spoilage.

- Changes in viscosity, pH, emulsion stability etc. indicate microbial spoilage.

[DEPTH OF BIOLOGY]

### ② Identity Test ⇒

— These are those test which confirms that the product are free from all microorg.

— With the help of this test we can identify the microbial contamination & spoilage of products.

- But, It is Important that materials are to be tested for identity are not subjected to contamination from the environment during the course of the test

### ③ Assessment of Viable Microorg. in Non-Sterile Products ⇒

[DEPTH OF BIOLOGY]

- Non-sterile products are tested for Viable microorg. for-detection of Pathogen & total Viable Counts.
- This can be identified through "Microbial Limit Tests".

### ④ Estimation of Pyrogen ⇒

[DEPTH OF BIOLOGY]

- Pyrogen → which cause rise in body temp. (fever).
- Two main procedure use for this detection of pyrogen
- The BP Pyrogen test → which req. administration of the injection to laboratory rabbits

In which, their body temp. is monitored for a period of time.

[DEPTH OF BIOLOGY]

The LAL Test → (Limulus Amoebocyte Lysate test).

in which, pyrogen containing sample causes gel formation in the <sup>the</sup> lysis product of Amoebocyte Cells of the Giant.