Role of microbiology In Pharmaceutical Industries

Abstract

Many topics to go through when we talking about the role of Microbiology in pharmaceutical Industries. For an overview. We have a track in pharmaceutical industries for extracted products from microorganisms like natural antibiotics. Another track that use of microorganisms to check for effectiveness &Validity of some antibiotics or disinfectants, the third track is to keep microorganisms under control through

- Inputs, like raw materials & water
- Microbiological Environmental control, like hygiene practice and Heating & Ventilation Air Conditioning system 'HVAC'.

Mesophiles is our scope in pharmaceutical industries in other wards pharmaceutical products have the susceptibility to mesophilic microorganisms to be existed.

- For sterile pharmaceutical manufacturing, like injectable products, presence of any microorganism in consumable products is prohibited even if only one colony.
- For Non-sterile pharmaceutical manufacturing, like manufacturing of oral dosage forms '' Solids, syrups, Powder Sachets'' or Semisolid products like '' Ointments, Creams & Lotions'', microorganisms shall be kept under control & each item is subjected to specific specification according to its nature and formula.

➢ To achieve the microbiological attribute for consumable pharmaceutical products, the following equation to be realized

Inputs (Complies to the specifications) + **Good Environmental condition** ⟶ **Output** (Finished product complies to the required microbiological specification)

Inputs, we shall check raw materials and confirm its compliance to its specific specification in the global guidelines "like Pharmacopoeias, WHO, FDA", as each material has its specific concerns according to its nature and probability for microorganisms to grow in its culture.

Water used for manufacturing processes have a high concern as it is a source of contamination, So we shall check for quality of water station output (Purified Water, Highly Purified Water). We shall confirm that the treatment stages done without biofilm formation on SS Walls or inside filters with more specific consideration to carbon filter '' has hyper susceptibility for formation of biofilm'', Also P& ID shall demonstrate zero dead legs.

Environmental Condition, we shall confirm that the area where product is exposed is restricted classified area & have authorization for limited number of qualified personnel (to reduce microbiological risk).

HVAC system shall minimize microorganisms present in the manufacturing area and this can be subjected to many concerns like Air change rate, Air velocity, Differential pressure between different manufacturing areas, Air flow turbulence & integrity of HEPA filter "effectiveness more than 99.99 %

Also, Layout and premises shall comply to Good manufacturing practice ''GMP'', Material & product flow shall be unidirectional and doesn't interfere with personnel flow.

Equipment shall achieve hygienic design through absence of dead legs, smooth surfaces 'limited roughness degree'', without sharp edges or screw connections & with hygienic valves.

In addition to cleaning and sanitization program.

Also, personnel shall be qualified & aware enough to manufacturing process and GMP concerns to reduce the microbiological risk also follow Good hygienic practice 'GHP' especially who deals with exposed products.