Different Sources of Contamination in an Aseptic Area

There are various contamination sources in an aseptic area, which are discussed below:

1) Personnel: Those supervising, performing, or controlling drug manufacturing are a potential source of microbial contamination, due to the following reasons:

i) Inadequate training,

ii) Direct contact between the hands and starting materials, primary packaging materials, and intermediate or bulk products,

iii) Improper hygiene,

iv) Unauthorised personnel entering the production, storage, and product control areas,

V) Insufficient gowning and protective equipment, and

vi) Eating, drinking, or smoking within the storage and processing areas.

2) Buildings and Facilities: These are also important contributors to microbial contamination due to the following reasons:

i) Inadequate size and organisation of the space, which lead to selection errors (such as mix- ups or cross-contamination between consumables, raw materials, in-process materials, and finished products),

ii) Poor filth and pest controls,

ii) Rough floors, walls, and ceilings,

iv) Absence of air filtration systems,

v) Inadequate lighting and ventilation systems,

vi) Poorly located vents, ledges, and drains, and improper washing, cleaning, toilet, locker facilities, sanitary operation, and personal cleanliness.

3) Equipment and Utensils: These are used during processing, holding, transferring and packaging. They are the common sources of microbial contamination due to the following reasons

i) Unsuitable design, size, corrosion-causing materials, static material accumulation, and/or adulteration with lubricants, coolants, dirt, and sanitising agents,

ii) Inadequate cleaning and sanitisation,

iii) Inefficient cleaning and maintenance due to their designing

iv) Inappropriate calibration and irregular service, and

v) Using defective equipment.

4) Raw Materials: These are used during production and are considered a potential source of contamination due to the following reasons:

i) Improper storage and handling, which leads to mix-ups or selection errors,

ii) Microbial or chemical contamination,

ii) Degradation due to extreme environmental conditions (like heat, cold, sunlight, moisture, etc.),

iv) Wrong labelling.

v) Incorrect sampling and testing, and

vi) Using materials not meeting the acceptance criteria.

5)Manufacturing Process: During the manufacturing process, microbial contamination of raw materials, intermediates or packaging materials can widely occur due to the following reasons:

i) Absence of facilities required for manufacturing of a single product,

ii) Improper cleaning between batches for minimising the amount of product changeovers,

ii) Use of an open manufacturing system for exposing the product to the room environment,

iv) Improper zoning,

v) Lacking an area line clearance (as per the approved procedures) after each cleaning process and between each batch, and

vi) Lack of cleaning status labelling on all equipment and materials used within the manufacturing facility.

AHVAC (Heating, Ventilation, and Air Conditioning) System: An inappropriate HVACsystem is a possible source of microbial growth and also disperses the contaminants throughoutthe manufacturing unit. This occurs due to the follow1ng reasons:

i) Organic materials accumulate in or near HVAC air intakes,

ii) Inadequate air filtration system,

iii) Inadequate magnitude of pressure differentials, which causes flow of reversal,

iv) Incorrect ratio of fresh air to re-circulated air,

v)Incapability of accessing ventilation dampers and filtering from outside the manufacturing areas, and non-directional airflow within production or primary packing areas