

Unit - 5

Microbial Spoilage : The term spoilage means sub-standarded quality.

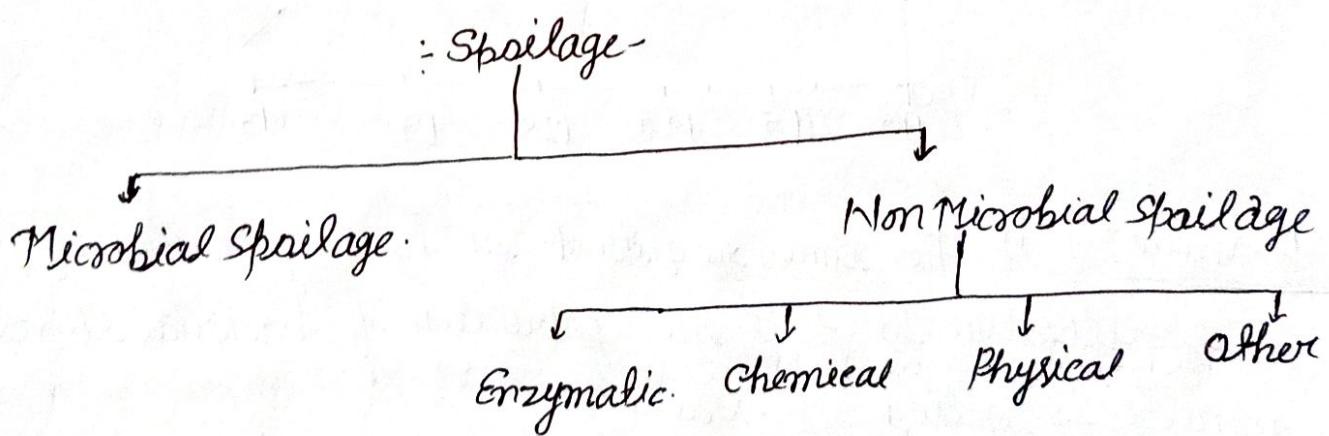
When the quality of any food products is not up to standard or their some quantity of material is wasted by micro organisms then those product is called spoilage.

→ These spoilage product can affect the health and their quality is reduced.

Ex. Rancid meat, Sour Milk, Moldy cheese etc.

→ The spoilage of food material can be identified by their characteristic like, color, odour, & taste.

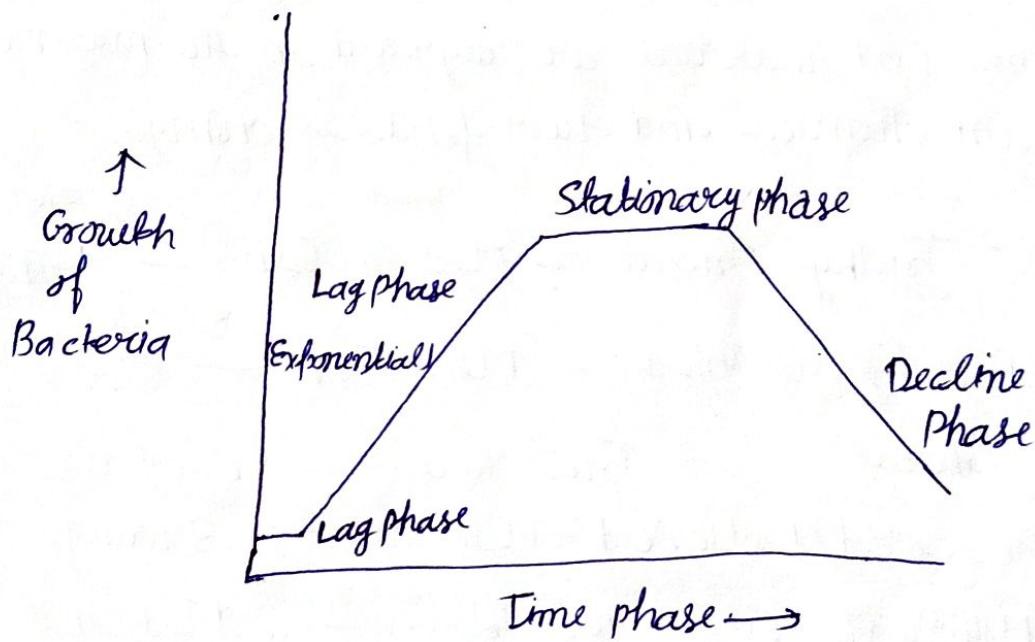
⇒ Types of spoilage:



⇒ Microbial spoilage:

When the quality of standard of any pharmaceutical and food products is affected by the microorganism like bacteria, virus, fungi, then this is called microbial spoilage.

- The growth of microbes in food material depends on diff. factor like temp., climatic condition, and the type of material.
- Microbial spoilage can be prevented by using preservative
- The growth of microorganism in food products follow following growth curve.



Non microbial spoilage:

- If the food material is spoil by other factor than microorganism this is called non microbial spoilage.
- It is of following type.

- i) Enzymatic Spoilage: Many food material are hydrolyse by in the presence of enzyme.
- Enzyme caused rancidity by two reactions hydrolysis & oxydation.

Ex: Lipase — Milk, oil.

Thiaminase — Meat, fish.

Peroxidase — Fruits.

Protease — Egg, pulse.

Lipoxygenase — Vegetable.

Chemical Spoilage

→ Some food material are degraded in the presence of certain chemical and their性质 is change

Enzyme Product Odour
Ex → Triethyl Amine — Meat, Egg, Fish. — Fishy.

Dimethyl Disulphide — Meat, Fish — Garlic.

Ethanol — Fruit, Juice. — Alcoholic.

Acetic Acid / Lactic Acid — Milk, Wine — Souring.

2-Methoxy Phenol — Juice, Wine — Medicinal.

Physical Spoilage

It occurs due to temp, light, RH (Relative Humidity) medicinally change the nature of food and drug.

→ Oxidation of food is caused by light.

→ Greenish of potato in light.

→

Other spoilage

When the food material is spoil due to insect, Rodent, and birds results in the changes into color odour and chemical changes is called other spoilage.

→ On the basis of rate of spoilage it is can be classified into other three types -

i) High perishable :-

Meat, fish, poultry, eggs, milk, fruits and vegetable.

ii) Semi Perishable : Potato's apples.

3) Stable or Not Perishable : Sugar, Flour, Doy beans.

Factors affecting microbial Spoilage

In any pharmaceutical drugs various kinds of excipients are mixed with drug so the chances of spoilage is high due to presence of excipients.

→ The spoilages of pharmaceutical is depends upon following factors.

1) Types and size of contaminant :-

Some of the contaminants such as the bacteria and virus have high replication power and they can increase their number in very less time.

- but some contaminants like fungi and protozoa have less replication property.

The size of contaminants depends upon the types of raw material is used.

2) Nutritional Factor :-

Bacteria requires water, oxygen, sugar, Nitrogen etc. for their growth in liquid dosage form. These all are present in high amount so the chances of contamination is high.

3) Water:-

Water is the basic requirement for growth and reproduction of bacteria. So in those pharmaceutical water content is high. The chances of contamination is high.

4) Storage temperature.

The contaminant grow in the range of temp 12°C to 60°C if we kept the temp of pharmaceuticals low up to 1 to 12°C then the chances of spoilage is very less.

5) pH

Bacteria grow maximum at pH 5.5 and most of the liquid dosage form are stable at pH 4-6 so chances of contamination of product in this pH range is very high.
→ Some gram -ve bacteria grow in acidic pH range

b) Packaging design :-

It has major influences on microbial stability of some formulations in controlling the excess the contaminant in storage and use.

→ The parenteral dosage form are directly goes into the blood so the chances of their contamination is very risky so they are packed in well design container.

7) RH - Relative Humidity :-

That dry air which contains 0% of water is called saturated air.

→ At normal temp. the ratio of moisture present in air to the saturated air is called relative humidity.

Sources of Contaminant

→ The main cause of spoilage of pharmaceutical is due to mixing of contaminants :-

These contaminants are mixed in pharmaceutical by following reason

(1) Air Carrying dust :-

- When air enters into the ^(clean area) aseptic area then if looks to lot of microbial contaminants enters into the pharmaceutical.
- It should be avoided by using HEPA Filter at the entrance

2) Skin of the operator :-

If any microbial contaminants is stick with the operator skins then it will makes our product.

3) Movement of person inside the Aseptic Room :-

By the continuous movement of person into aseptic Area from outside to inside brings a lot of contaminants.

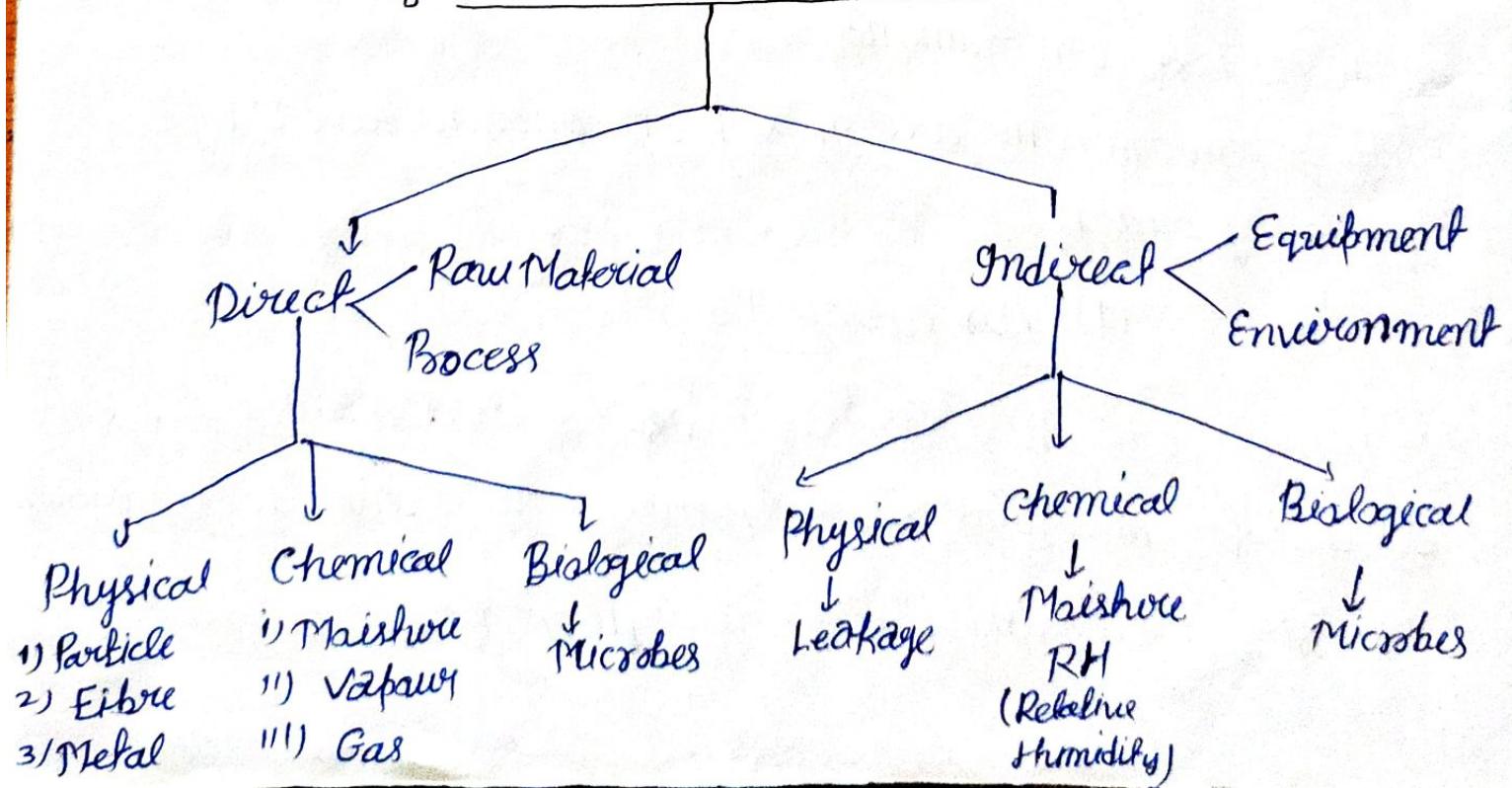
4) Operators Health :-

If operator or worker is suffered with any communicable disease then the microbes from their body can be mixed into product.

5) Manufacturing Process :-

In the batch size of product is large then the chances of contamination is high.

6) Microbial contamination :-



⇒ Direct contamination :

When the chances of microbial contamination due to the use of drawn steel material and by using the wrong process it is called direct contamination.

⇒ Physical :

If contamination occurs due to the help of particle, Fibre and metal then it is called physical contamination.

⇒ Chemical :

If contamination occurs due to help of moisture, Vapour and gas then it is called chemical contamination.

⇒ Biological :

If contamination occurs due to the help of microbes like bacteria, virus, Fungi etc. then it is called biological contamination.

⇒ Indirect contamination :

When the chances of contamination is increase by the using of improper equipment or non calibrated equipment by environment it is called indirect contamination.

⇒ Physical :

If contamination occurs due to the help of moisture, or Relative humidity then it is called contamination.

⇒ Chemical ⇒

If contamination occurs due to the help of moisture or Relative humidity then it is called chemical contamination.

Biological

If contamination occurs due the help of microbes then it is called biological contamination.

⇒ Preservative ⇒

⇒ Preservation of pharmaceutical by using Antimicrobial ⇒

After using sterilization and aseptic preparation if any microbes is remain alive in the product then it will spoil the all product in few days. so there is a need of preservative and antimicrobial to save the product.

⇒ Preservative increase the stability of Product till there expiry by inhibiting growth of microbes, by oxidation and by mixing of foreign particles.

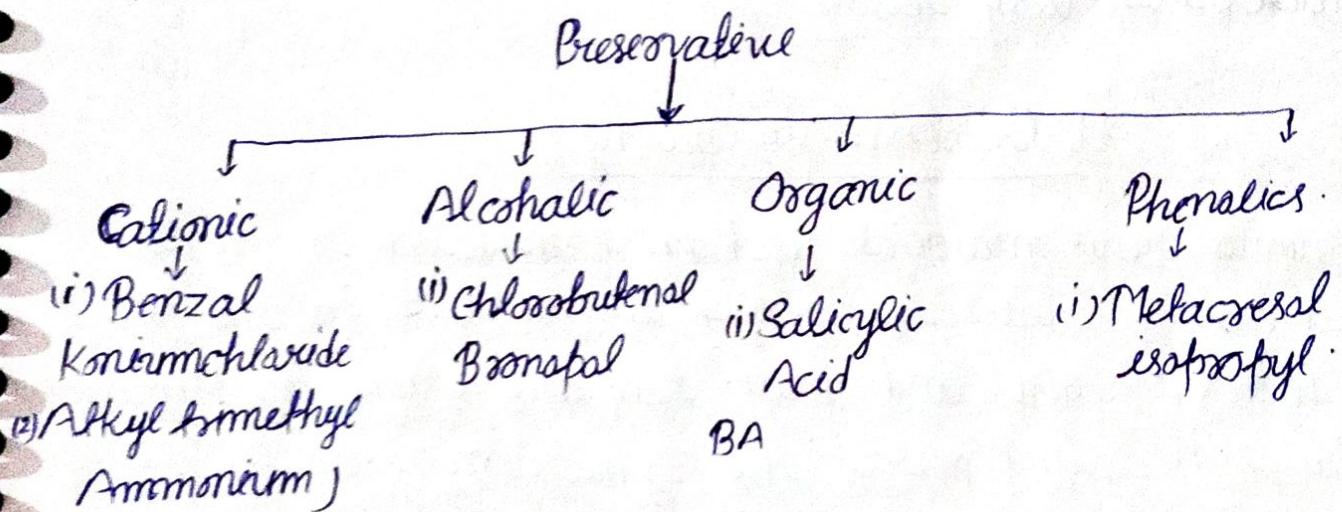
⇒ Characteristics of Preservative ⇒

- 1) Non toxic or non irritant.
- 2) Kill Microbes.
- 3) Soluble.
- 4) Stable.
- 5) Compatible.

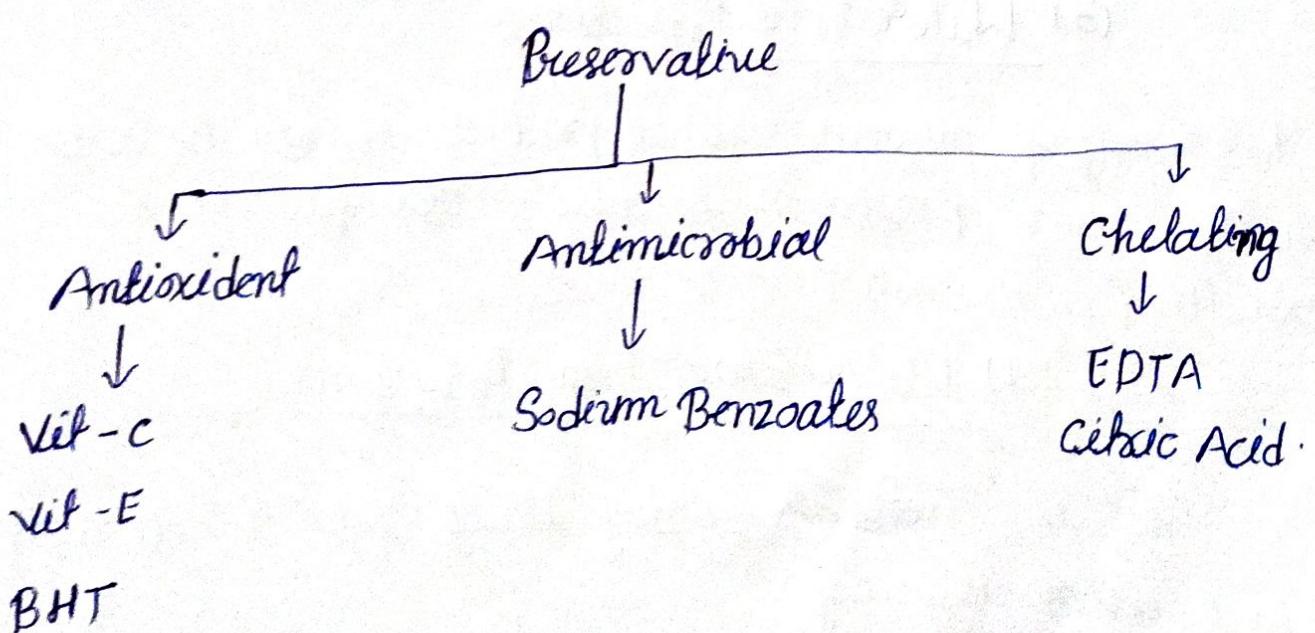
- i) It should be non toxic or Non irritant.
- ii) It should have Property to kill microbes.
- iii) It should be soluble.
- iv) It should be stable.
- v) It should be compatible.

Types of Preservative

(i) On the basis of chemical Nature



(iii) On the basis of Mechanism



Method of Preservation

The pharmaceutical product and food products can be preserved by using preservative and there are various method of use of preservative.

(1) Physical Protection

By the use of proper packaging and aseptic condition the pharmaceutical can be preserved physically.
→ Under the aseptic condition the chances of growth of bacteria is very less.

(2) Preservative Coating

Aqueous raw material used in formulation in paints and coating create the perfect environment for the growth of bacteria, fungi and yeast. They can destroy the pharmaceutical formulation coating protect the formulations from the entry of microbes.

→ And it increase the shelf of product.

(3) Water Proof Protection

Packaging of pharmaceutical product should be under water proof protection because water favours the growth of micro organism.

(4) Water Vapour Proof Protection

This is essential for dry dosage form with very low water activity.

(5) Water Proof Protection with dessicant :-

Dessicant are those material which absorb the moisture and protect the pharmaceutical from moisture.

⇒ Evaluation of Microbial stability of Formulations

After the manufacturing of pharmaceuticals it should remain stable till their shelf life.

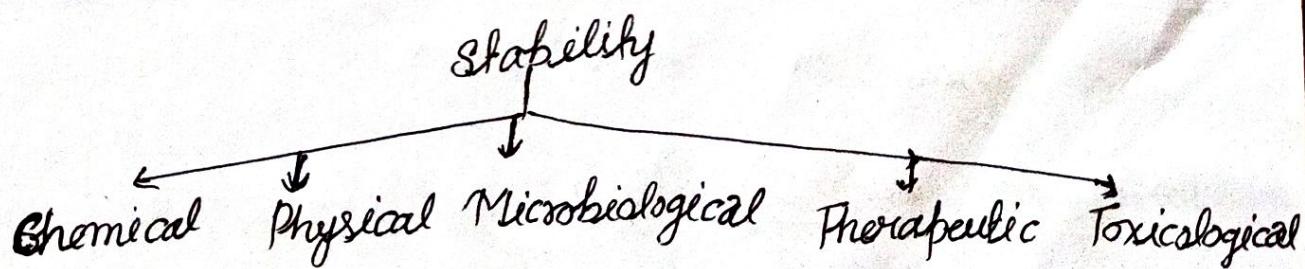
→ The term stability means the remaining of drug as some physical chemical and therapeutical action till the expiry of drug.

⇒ Types of stability study :-

On the basis of duration :- On the basis of duration it is of three types.

- (1) Long term — 1 - 5 years.
- (2) Medium — 6 - 12 months.
- (3) Accelerated — 6 Month.

⇒ On the basis of nature :-



On the basis of duration

(i) Long term stability: In this stability test we check the product in 1 to 5 years.

(ii) Medium Stability: In this stability test we check the product in 6 to 12 months.

(iii) Accelerated Stability: In this stability test we check the product in 6 months.

On the basis of nature

Chemical Stability: In this stability test we check the chemical nature of drug like, pH, taste, etc.

Physical Stability: In this stability test we check the external appearance of the drug.

Microbiological stability: In this stability test we check the presence of microbes like bacteria, virus etc.

Therapeutic Stability: In this stability test we check the drug action in response.

Toxicological stability test: In this stability test we check the adverse effect, side effect and toxicity of the drug.

Microbiological stability test :-

- To check the microbial contamination in product during and after the manufacturing is called microbiological stability test.
- The main potential pathogens in cosmetic is pseudomonas aeruginosa, candida albicans, staphylococcus aureus. These pathogens must not be detected more than 0.1 gram.
- The microbiological testing can be performed by three methods.

1) Screening Test :-

- 2) Quantitative Test.
- 3) Antimicrobial effectiveness Test.

(i) Screening Test :-

It is also known as plate count or dip slide method

- This method is used to detect aerobic bacteria in aqueous sample.
- A small quantity of T.T.C (tri phenyl tetra jonium chloride) is added to detect the aerobic bacteria in the sample.
- The slide is dipped into aqueous solution for 10 second and excess liquid is removed from the slide. And then it is inoculated at 35° to 37° C for 18 to 48 hours.

→ If the bacterial colonies is present red spot will appear.

⇒ (2) Quantitative test ⇒

Quantitative test is determine actual count of bacteria, molds and yeast in cosmetic product this method is used for isolation of microorganism from cosmetic products. include enrichment culturing

(3) Antimicrobial Effectiveness test :

The main function of preservative and antimicrobial is to protect the product from microbes and the testing of effectiveness of Antimicrobial is very important