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UNIT – 5

Microbiology :→

Spoilage :→ It refers to a form of substandard or process of spoiling, especially the deterioration of food and others perishable goods.

OR

Spoilage is referred as change in physical and chemical properties of P'ceutical and drug products in such a way that they are not suitable for use.

Types of spoilage

Microbial spoilage

→ Spoilage due to contamination of any microbial cell (microorganism)
eg→ Bacteria, fungi etc

Non microbial spoilage

- Physical spoilage
- Chemical spoilage
- Enzymatic spoilage
- other

Non-microbial spoilage :→ Spoilage due to other factors –

① Physical → spoilage due to any physical factor like pressure, temp^{r}
eg→ spoilage of salt due to water

② Chemical :→ Spoilage due to any chemical reaction
eg→ Oxidation, reduction etc

③ Enzymatic :→ Spoilage due to any enzyme like lipase
eg :→ protease, maltose etc

Microbial spoilage :→

It is spoilage of any p'ceutical product or drug due to contaminating M.O and their products which further not intended for use.

Types of Microbial Assay :→

Physiochemical	chemical	Biological
→ Viable growth	→ Hydrolysis	→ Release of toxins
→ Gas production	→ Acetylation	→ Microbial metabolites
→ olfactory	→ Depolymerisation	
→ Coloration	→ Degradational Metabolisation	

Physiochemical :→ chemical changes caused by MO

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Due to which physical properties get altered

1. Viable growth :→ Visible layer formed over the surface of p'ceutical formulations.
   eg→ layer of mould over syrups.
2. Gas production :→ formulation containing carbohydrate or starchy material are more succeptible for gas production.
   eg→ Klebsiella produces gas (CO_2) in creams and ointment containing Vit and protein

— appear as broth / foam over the formulation

(3) Coloration :→ Color change occur in formulation
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due to change in pH, redox, production of some other metabolites.
eg→ Surface decoloration of tablet containing biological products by some mould.

(4) Olfactory spoilage :→ results in unpleasant smell from the product.
→ mainly caused by microbial cells that produce sulphur containing gases [SO_2, H_2S] and fishy smell.

Chemical spoilage → Due to chemical rxn mediated by MO

(1) hydrolysis :→ some bacterial cells contains enzymes that catalyse hydrolysis of P' ceuticals.
eg → Aspirin hydrolysis by estrase producing bacteria

2- Acetylation :→ Some M.O cellular enzymes causes acetylation of drugs and causes loss of activity

eg→ Chloramphenicol —acetylation→ (chloramphenicol acyl transferase)
Staphylococci & Streptococci
gram +ve bacteria

③ Depolymerisation :→ Polymers are degraded to monomers
eg→ Starch depolymerize by bacterial pectinase

③ Degradation :→ Due to the microbial contamination the API or formulation ingredients can be degraded or metabolized
eg→ Penicillin → degrade by batalactamase containing bacterial cells

Biological spoilage :→

Some bacterial cells contaminate the p'ceuticals and utilize various compounds present in the formulation to perform the metabolic activities

Due to these metabolic activities, the microbial cells produces certain chemicals which they release in p'ceutical preparations. This is called biological spoilage

2 types of chemicals are mainly released by MO
→ Microbial toxins
→ Microbial metabolites

Microbial toxins

→ Some MO produces toxic molecules that may cause spoilage of p'ceutical formulations such as endotoxin produced by some gram -ve bacterias like E-coli

microbial metabolites

Bacterial metabolites are biosynthetic products from microbial cells.
Bacterial cell produces various metabolites that causes product spoilage.

eg → different amines and organic acids from bacterial cells.
Metabolites from fungi and mould.

Factors Affecting spoilage of pharmaceutical products

(1)