

IZZ-AL-DIEN.H



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01

Define microbial
spoilage

02

Identify microbial
spoilage in
pharmaceuticals

03

Classify types of
microbial spoilage
In pharmaceuticals

04

Outline factors affecting
microbial spoilage of
pharmaceutical products



➤ **Microbial spoilage:**

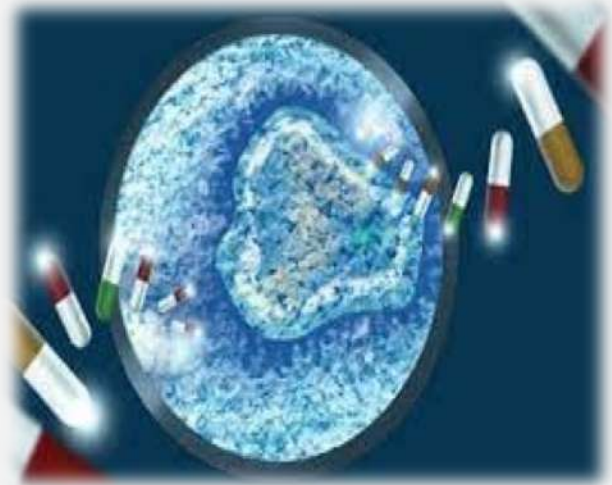
This refers to damage to food pharmaceutical products that is caused by microorganisms (bacteria, moulds and yeasts), micro-organisms occur everywhere around us, there is always a risk of microbial spoilage.



➤ MICROBIAL SPOILAGE OF PHARMACEUTICALS:

Microbial spoilage includes the microbial contamination of pharmaceutical products with the microbes which lead to spoilage of product affecting the drug safety and quality and is not intended for use.

Shortly, microbial spoilage of pharmaceutical products is the deterioration of pharmaceuticals with contaminant microbes.



➤ TYPES OF MICROBIAL SPOILAGE:

1. PHYSIO-CHEMICAL: In this kind of spoilage, there are some chemical changes are caused by microbial species and due to these changes the physical properties.

EX: Gas production , Physical spoilage .

2. CHEMICAL: There are various types of chemical spoilage in spoilage pharmaceutical compound, these occurs due to various types of chemical reactions

Ex : Hydrolysis.



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3. **BIOLOGICAL:** Some bacterial cells contaminated the pharmaceuticals and utilize the various compounds present in that formulation to perform their metabolic activities.

EX: Release of toxins.

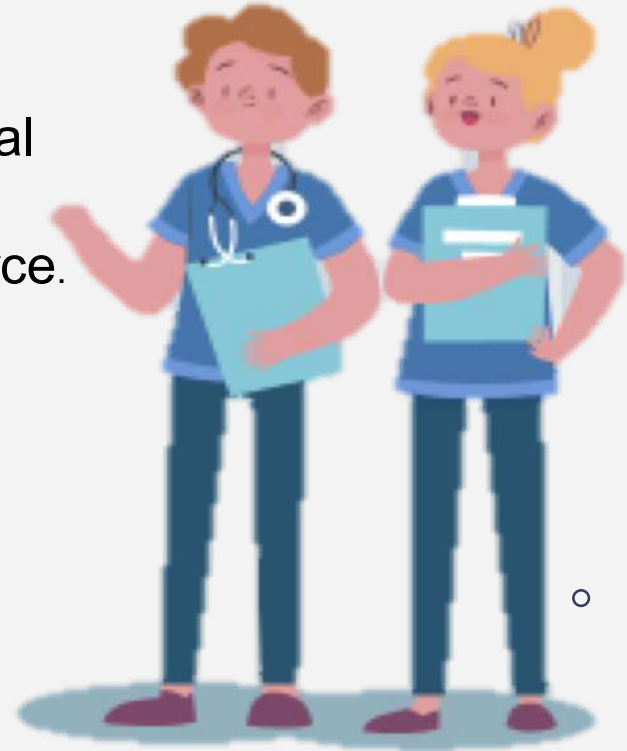


➤ FACTORS AFFECTING SPOILAGE OF PHARMACEUTICAL PRODUCTS:

1. NUTRITIONAL FACTOR: Presence of nutritional material enable or favours microorganisms to utilize these nutritional material as energy source.

2. MOISTURE CONTENT [Water Activity]: Microorganisms readily need water or moisture to grow.

3. REDOX POTENTIAL: If the oxygen is present in any formulation, then this condition favours microbial growth.





4. PACKAGING MATERIAL AND DESIGN: Packaging can have major influence on microbial spoilage pharmaceuticals because they are exposed to environment when the drug is withdrawn from container.

- **5. STORAGE TEMPERATURE:** The pharmaceutical formulation can be affected by microbial cell between the temperature range of -20°C – 60°C .



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6. PH: Some bacterial cells are grown better in Acidic medium and some are in basic medium, this happens because in their favourable pH the enzymes of bacterial cells are more active to perform their metabolic activities.

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REFERENCE

<http://www.jiwaji.edu/pdf/ecourse/pharmaceutical/Microbial%20Spoilage%20B%20Pharma%20%20305%20%20T.pdf>



THANKS FOR LISTENING!

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