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SubjectName	: Pharmaceutics
Topic Name	: Preservative

3.2 PRESERVATIVE

PRESERVATIVES

A preservative is a natural or synthetic chemical that is added to pharmaceutical products to prevent decomposition by microbial growth or by undesirable chemical changes. Preservative is a substance commonly added to pharmaceutical product in order to prolong its shelf life.

Preservatives are added in pharmaceutical preparation to inhibit growth of bacteria, yeasts, or molds that can cause disease. Chemical preservation cannot totally keep products away from spoiling, but they slow down the spoiling process caused by microorganisms.

Ideal Properties of Preservatives:

- It should be non - irritant, non - toxic and physico - chemically stable.
- It should be compatible with other ingredients used in formulation.
- It should act as antimicrobial agent and exert wide spectrum of activity.
- It should be potent and act effectively in small concentrations.
- It should maintain activity throughout product manufacturing, shelf life and usage.

Types of Preservative:

A. Based on mechanism of action:

1. Antioxidants: The agents that prevent oxidation of drugs which otherwise undergo degradation due to oxidation as they are sensitive to oxygen.

Examples: Vitamin E, vitamin C, butylated hydroxyanisole, butylated hydroxytoluene, etc.

2. Antimicrobial agents: These are agent that acts against gram positive and gram negative microorganism responsible for causing degradation of pharmaceutical preparation.

Examples: Sodium benzoate, sorbates, methyl paraben, propyl paraben, etc.

3. Chelating agents: These are agents which form the complex with the pharmaceutical ingredient and prevent degradation of pharmaceutical formulation.

Examples: Disodium ethylenediamine tetraacetic acid (EDTA), polyphosphates, citric acid, etc.

B. Based on source:

1. Natural preservatives: These are substances obtained from natural sources such as plant , mineral sources and animals which act as antimicrobial agents .

Examples: Neem oil, sodium chloride, lemon, honey, etc.

2. Artificial preservatives: These are agents prepared by chemical synthesis which acts against various micro - organisms in small concentrations.

Examples: Benzoates, sodium benzoate, sorbates, propionates, nitrites, etc.

(i) Tocopherols:

- Alpha tocopherol is a source of vitamin E and is a commercially available preservative.
- Amongst tocopherols the beta, delta and gamma tocopherols are considered to be more effective as antioxidants.
- Alpha - tocopherol is a highly lipophilic compound, and is an excellent solvent for many poorly soluble drugs of wide spread regulatory acceptability.
- Tocopherols are of value in oil- or fat - based pharmaceutical products and are normally used in the concentration range 0.001-0.05 % v / v.
- Its antioxidant effectiveness can be increased by the addition of oil - soluble synergists such as lecithin and ascorbyl palmitate.

(ii) Sodium benzoate:

- Sodium benzoate is used as preservative that becomes effective at concentrations of 0.02- 0.5 % in oral medicines, 0.5 % in parenteral products and 0.1-0.5 % in cosmetics.
- It is effective over a narrow pH range and is used in preference to benzoic acid due to its greater solubility.
- It may impart an unpleasant flavour to a product.

(iii) Potassium benzoate:

- Potassium benzoate's preservative efficacy increases with decreasing pH and is most effective below pH 4.5 However, at very low pH undissociated benzoic acid may produce a perceptible taste in products.
- It is used as an alternative to sodium benzoate in applications where low sodium content is desirable.

(iv) Methyl paraben:

- Methyl paraben is used in almost all types of pharmaceutical formulations.
- Methyl paraben is most effective against yeasts and molds over a wide range of pH and have a broad spectrum of antimicrobial activity.
- It may be used either alone or in combination with other parabens or with other antimicrobial agents.
- Its preservative efficacy can also be improved by the addition of propylene glycol (2-5 %) , or by using parabens in combination .

(v) Propyl paraben:

- Propyl paraben is a benzoate ester (propyl ester) of 4 - hydroxybenzoic acid.
- It can also be used as a food additive.

- It acts as an antifungal agent and an antimicrobial agent.
- It is typically used in many water - based cosmetics, such as creams, lotions, shampoos and bath products.

(vi) Ethyl alcohol:

- Ethanol is bactericidal in aqueous mixtures at concentrations between 60 % and 95 % v / v;
- the optimum concentration is generally considered to be 70 % v / v.
- Antimicrobial activity is enhanced in the presence of edetic acid or edentate salts.
- Ethanol is inactivated in the presence of nonionic surfactants and is ineffective against bacterial spores.