Aim: Preparation of Paracetamol Pediatric Elixir

References

- 1. Pharmaceutical Formulation Design and Preparation Aulton, M.E.
- 2. British Pharmacopoeia (2023) Monograph on Oral Liquid Preparations.
- 3. Articles from PubMed on "Paracetamol Elixir Stability."

Objective: To prepare 100 mL of Paracetamol Pediatric Elixir, ensuring accurate formulation and compliance with pharmaceutical standards.

Materials Required

Chemicals:

- Paracetamol (Active Ingredient): 2.4 g
- Sucrose (Sweetening Agent): 40 g
- Glycerin (Cosolvent): 10 mL
- Sorbitol Solution (70% w/v, Sweetening Agent): 5 mL
- Methyl Paraben (Preservative): 0.1 g
- Propyl Paraben (Preservative): 0.02 g
- Propylene Glycol (Cosolvent): 10 mL
- Citric Acid (pH Adjuster): q.s.
- Sodium Benzoate (Preservative): 0.1 g
- Flavor (e.g., Raspberry, Orange): q.s.
- **Distilled Water:** q.s. to 100 mL

Equipment:

- Analytical balance
- Beakers (100 mL, 250 mL)
- Stirring rod
- Measuring cylinders (10 mL, 100 mL)

- Water bath
- pH meter or pH indicator paper
- Funnel
- Storage bottles (Amber-colored)

Principle

Paracetamol pediatric elixir is a liquid oral formulation designed for children. It combines the therapeutic effects of paracetamol with a sweetened, palatable base. Cosolvents enhance the solubility of paracetamol, while preservatives ensure microbial stability. The pH is adjusted to maintain drug stability.

Procedure

1. Dissolution of Paracetamol:

- Weigh 2.4 g of paracetamol and transfer it into a 100 mL beaker.
- Add 10 mL of propylene glycol and stir until paracetamol dissolves completely.

2. Preparation of the Base:

- In another 250 mL beaker, dissolve 40 g of sucrose in 30 mL of distilled water by gentle heating.
- Add 10 mL of glycerin and 5 mL of sorbitol solution to the sucrose solution. Stir to mix well.

3. Incorporation of Preservatives:

• Dissolve 0.1 g of methyl paraben and 0.02 g of propyl paraben in 10 mL of propylene glycol using gentle heating. Add this mixture to the sucrose base with continuous stirring.

4. pH Adjustment:

Measure the pH of the solution. Add citric acid solution dropwise to adjust the pH to
4.5-6.0, suitable for paracetamol stability and pediatric use.

5. Addition of Flavor:

• Add the desired amount of flavor to mask the bitter taste of paracetamol. Mix thoroughly.

6. Combining Solutions:

• Gradually add the paracetamol solution to the prepared base while stirring continuously.

7. Final Dilution:

• Add distilled water q.s. to make up the volume to 100 mL. Stir the mixture until homogeneous.

8. Filtration and Packaging:

- Filter the final elixir through a fine filter or muslin cloth to remove any undissolved particles.
- Transfer the elixir into amber-colored bottles to protect from light. Label the bottles appropriately.

Label

- Product Name: Paracetamol Pediatric Elixir
- **Dosage**: Each 5 mL contains 120 mg of Paracetamol.
- Storage: Store at room temperature, away from direct sunlight.
- Shake well before use.
- · Keep out of reach of children.

Precautions

- 1. Ensure all equipment is clean and sterilized.
- 2. Avoid overheating to prevent degradation of the active ingredient and other excipients.
- 3. Maintain proper pH to ensure stability and palatability.
- 4. Perform quality checks for uniformity and clarity.