

**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.