Aim: Preparation of Piperazine Citrate Elixir

References

1. British Pharmacopoeia Codex 1968.
2. Ansel, H. C., Allen, L. V., & Popovich, N. G. *Pharmaceutical Dosage Forms and Drug Delivery Systems.*
3. Lachman, L., Lieberman, H. A., & Kanig, J. L. *The Theory and Practice of Industrial Pharmacy.*

Objective

To prepare Piperazine Citrate Elixir, a pharmaceutical liquid formulation, and understand the procedure, properties, and quality control tests associated with its preparation.

Introduction

Elixirs are clear, sweetened, and flavored hydro-alcoholic solutions designed to deliver active pharmaceutical ingredients (APIs) in a palatable form. Piperazine Citrate Elixir is an anthelmintic preparation used for the treatment of parasitic worm infections, especially ascariasis and enterobiasis.

Principle

The formulation involves the dissolution of Piperazine Citrate in a hydro-alcoholic base containing a sweetener and flavoring agents to ensure solubility, stability, and patient compliance.

Materials and Equipment

Chemicals Required:

- **Piperazine Citrate:** 12 g
- **Ethanol (95%):** 50 mL
- **Sucrose:** 60 g
- **Purified Water:** Quantity Sufficient (QS) to 1000 mL
- **Glycerin:** 10 mL
- **Flavoring agent (e.g., Lemon essence):** 5 mL

Apparatus Required:

- Beaker (1000 mL)
- Measuring cylinder
- Glass rod
- Funnel
- Filtration assembly

Procedure

1. **Dissolution of Piperazine Citrate:**
    - Dissolve 12 g of Piperazine Citrate in approximately 800 mL of purified water. Stir until completely dissolved.
2. **Preparation of Sweetening Solution:**
    - Dissolve 60 g of sucrose in the above solution with continuous stirring.
3. **Addition of Co-solvents:**
    - Add 10 mL of glycerin to the solution.
    - Gradually add 50 mL of ethanol (95%) while stirring.
4. **Flavoring:**
    - Incorporate 5 mL of the chosen flavoring agent (e.g., lemon essence) into the solution.
5. **Adjusting Volume:**
    - Make up the final volume to 1000 mL with purified water. Mix thoroughly.
6. **Filtration:**
    - Filter the solution using a filtration assembly to ensure clarity.
7. **Packaging and Storage:**
    - Transfer the prepared elixir into clean, amber-colored bottles with airtight caps.
    - Store in a cool, dry place away from direct sunlight.

Observation and Results

- **Appearance:** Clear, colorless liquid.
- **Taste:** Sweet with a hint of flavor (e.g., lemon).
- **Odor:** Pleasant, depending on the flavoring agent used.

Quality Control Tests

1. **Clarity Test:** The elixir should appear clear and free from particulate matter.
2. **pH Test:** Measure the pH of the elixir. It should be within the range of 5 to 7.
3. **Assay of Piperazine Citrate:** Perform an assay to determine the concentration of Piperazine Citrate using titrimetric or spectrophotometric methods.
4. **Specific Gravity:** Measure using a hydrometer. It should meet the pharmacopoeial standards.
5. **Alcohol Content:** Verify the ethanol content using distillation or gas chromatography.

Discussion

Role of Ethanol and Glycerin: Ethanol acts as a solvent for the active ingredient, while glycerin improves sweetness and viscosity.

Importance of Filtration: Filtration ensures the elixir is clear, enhancing its aesthetic appeal and patient compliance.

Flavoring Agents: Adding flavoring agents masks any unpleasant taste of Piperazine Citrate, making it suitable for pediatric use.

Applications

- Used in the treatment of roundworm (ascariasis) and pinworm (enterobiasis) infections.
- Suitable for administration in children and adults due to its palatability.

Precautions

1. Ensure accurate weighing of all ingredients to maintain therapeutic efficacy.
2. Store the elixir properly to prevent degradation or microbial growth.
3. Use purified water to avoid impurities that may affect clarity.