Formulation of an Oral Pediatric Suspension of Amlodipine 1 mg/mL

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3PC-003

Background and Importance

- **Amlodipine** is a calcium channel blocker used to treat hypertension.
- In **pediatrics**, the recommended dose is **2.5** to **5** mg daily as a single dose.

Objective

-Formulate a readily **redispersible oral suspension of amlodipine 1 mg/mL** and assess its quality and stability, due to the difficulty of redisperging the existing suspension.

Materials and Methods

Adaptation of the National Formulary (NF):

1. **Methylcellulose replacement** with **preservative water** free of propylene glycol.
2. **Reduction** of simple **syrup** content.
3. Use of Amlodipine **tablets** (10 mg) due to the unavailability of the pure active ingredient.

CHEKLIST:

- **Concentration**: Adjusted to 1 mg/mL (instead of 0.5 mg/mL in the NF).
- Weekly evaluation of parameters:
  - **Redispersion** time.
  - **Color** and **odor.**
  - **pH** (NF range: 5.5-6.5).
- **Shelf Life**: Determined according to the Guide to Good Practice in the Preparation of Medicines in Hospital Pharmacy Services.

Results

- **Shelf Life**: 30 days under refrigeration (2-8°C).
- Physicochemical **Stability**: **Immediate redispersion** time after gentle agitation.
- **No changes** in **color** or **odor**.
- **pH** remained **stable** between 5.5 and 6.5.

Conclusions

1. **Successful** adaptation: Meets NF standards and maintains the original concentration.
2. **Stability** confirmed: Safe and effective for 30 days.
3. Practical **advantages**: Improved redispersion facilitates administration and reduces the workload for nursing staff.