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FORMULATION AND STABILITY TESTING OF FORTIFIED GENTAMICIN EYE DROPS

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BACKGROUND & IMPORTANCE

- Bacterial eye infections at tertiary hospitals pose serious health challenges and require prompt treatment.
- Since commercial products are not available, fortified antibiotic eye drops must be prepared in a hospital pharmacy unit.

AIM & OBJECTIVES

To evaluate and compare the stability of fortified gentamicin eye drops during four weeks of storage at room temperature and in the refrigerator in relation to the method of preparation and type of solvent.

MATERIALS & METHODS

Preparation of Fortified Gentamicin Eye Drops (1.36%)

Two preparation methods were evaluated:

Method A: Addition of IV Gentamicin
- Intravenous gentamicin 80 mg/2 mL
- Added to gentamicin ophthalmic solution 0.3% (5 mL)
- Solutions prepared in:
  - 1.92% boric acid solution
  - Citrate buffer

Method B: Dissolution of Gentamicin Sulphate
- Gentamicin sulphate powder
- Directly dissolved in:
  - 1.92% boric acid solution
  - Citrate buffer

Storage Conditions

Room temperature: 25 °C
Refrigerated: 2–8 °C
Duration: 4 weeks

Stability Evaluation Parameters

Measurements were performed weekly and included:
- pH → *pH meter*
- Gentamicin concentration → *Assay*
- Absorbance values → *Spectrophotometer*

Key Takeaway
Citrate buffer → superior long-term stability when dissolving gentamicin sulfate
Boric acid → rapid loss of gentamicin content in fortified formulations

RESULTS

pH Stability

- **pH remained within stability limits** (<10% change from initial value)
- Consistent across all formulations
- **Independent of preparation method, solvent type, and storage temperature**

Gentamicin Content

Fortified eye drops prepared from gentamicin sulfate

Boric acid (1.92%)
- Gentamicin content decreased to 57.2% by Day 7
- **Degradation occurred regardless of storage temperature**

Day 0 → Day 7↓↓↓ ~57% loss

Citrate buffer
- Only a slight loss (≤10%) observed
- **Stable for up to 28 days regardless of storage temperature**

Day 0 → Day 28↓ slight decline

Formulations prepared by adding IV gentamicin to 0.3% ophthalmic solution

Boric acid (1.92%)
- **Absorbance values remained stable for 21 days**

Day 0 → Day 21 — stable

Citrate buffer
- **Stability limited to ≤14 days**

Day 0 → Day 14— then decline

CONCLUSION & RELEVANCE

- **Significant differences** were observed among gentamicin ophthalmic formulations based on **preparation method and solvent type.**
- **Temperature had no significant effect** on physicochemical properties.
- The optimal gentamicin ophthalmic formulation (1.36%) was prepared by **dissolving gentamicin sulphate in citrate buffer.**