PHYSICOCHEMICAL STABILITY STUDY OF TWO ACETYLCYSTEINE 10% EYE DROP FORMULATIONS

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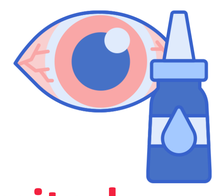
Background and Importance

Acetylcysteine

- **Used in ophthalmology in eye drop formulations as in Spain there are not marked drugs available**
- **Considered high-risk formulations and the stability available information is limited**



Aim and Objectives

To determine the physicochemical stability of two acetylcysteine 10% eye drop formulations prepared in two hospitals

Materials and Methods

Eye Drop-M

Acetylcysteine 10% eye drop formulation at Complejo Hospitalario Universitario Insular Materno Infantil, 6 mL: Flumil® 100 mg/mL injectable solution 600 mg/6 mL. Sterile amber glass. Expiration: 9 days

Eye Drop-C

Acetylcysteine 10% eye drop formulation at Complejo Hospitalario Universitario Nuestra Señora de la Candelaria, 7.5 mL: Flumil® 5 g/25 mL, 3.75 mL, and artificial tears (BSS®) q.s. to 7.5 mL. Sterile eye dropper. Expiration: 14 days

Both hospitals provided **6 samples**. Stability was assessed under storage **at 5 °C, protected from light**

Chemical stability of the formulations stored at 5 ± 0.1 ºC in 3 unopened samples on days 0, 21, and 30, and in 3 opened samples on days 0, 2, 4, 7, 9, 11, 21, and 30	**Ultra High Performance Liquid Chromatography** Stationary phase Acquity UPLC® BEH column (C18, 2.1 × 100 mm, 1.7 µm), mobile phase 0.1 M phosphate buffer adjusted to pH 3.0 with phosphoric acid, flow rate 0.5 mL/min, injection volume 10 µL, detection wavelength 214 nm and run time 10 minutes
pH of the formulations on days 0 and 30	**Crison GLP21 pH Meter**

Results were expressed as a percentage of declared value of acetylcysteine

Results

Acetylcysteine concentrations remained above 90%

Eye Drop-M

Up to day 11

Eye Drop-C

Up to day 30

No relevant pH variations were observed

Eye Drop-M

Day 0 pH 6.51
Day 30 pH 6.42

Eye Drop-C

Day 0 pH 6.16
Day 30 pH 6.07

Conclusion and relevance

- ✓ **Eye Drop-C maintained its stability for 30 days, extending its original expiration date**. Eye Drop-M showed an increase in stability from 9 to 11 days
- ✓ **Microbiological stability studies will be conducted** to ensure their long-term safety and efficacy

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eahp european association of hospital pharmacists

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