



GALENIC VALIDATION OF A 5% AND 20% ACETYLCYSTEINE EYE DROP FORMULATION FOR THE TREATMENT OF DRY KERATOCONJUNCTIVITIS



5PSQ-073

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BACKGROUND AND IMPORTANCE

A 30-day galenic validation study was conducted to evaluate the stability of two acetylcysteine eye drops (5% and 20%) made with artificial tears in low-density polyethylene (LDPE) dropper bottles and stored under refrigeration for the treatment of dry keratoconjunctivitis

AIM AND OBJETIVES

Optimize and study the stability through galenic validation of 5% and 20% acetylcysteine eye drops formulated with a solution of artificial tears in LDPE dropper bottles

MATERIALS AND METHODS

Eye drop	Composition per 5ml	Storage conditions	Packaged
5% Acetylcysteine	Acetylcysteine 20% (Hidonac®).....250 mg (1,25 ml) Liquifilm tears®.....c.s.p. 5 ml	Refrigeration 2-8°C	LDPE
20% Acetylcysteine	Acetylcysteine 20% (Hidonac®).....1.000 mg (5ml)		



30-day galenic validation
Days 0, 1, 2, 7, 15, 22, 30

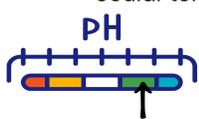
- ✓ Clarity
- ✓ Color
- ✓ pH
- ✓ Osmolality
- ✓ Sterility

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Units were tested per sampling point

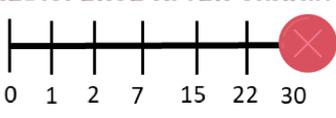
ACETYLCYSTEINE EYE DROPS 5%

pH stable within the ocular tolerance range
6.83-7.32



No microbiological growth was detected throughout the galenic validation period
The samples remained sterile for 30 days

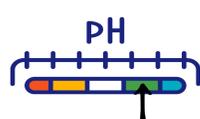
ON DAY 30, A PRECIPITATE WAS OBSERVED THAT DID NOT REDISPERSE AFTER SHAKING



RESULTS

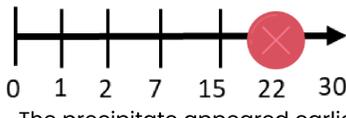
ACETYLCYSTEINE EYE DROPS 20%

pH stable within the ocular tolerance range
6.48-6.84



No microbiological growth was detected throughout the galenic validation period
The samples remained sterile for 30 days

ON DAY 22, A PRECIPITATE WAS OBSERVED THAT DID NOT REDISPERSE AFTER SHAKING



The precipitate appeared earlier than the lowest concentration

CONCLUSION AND RELEVANCE

Although both concentrations remained within the ocular pH tolerance range (3.5-10.5), precipitates were observed during galenic validation

VALIDITY PERIOD: 14 DAYS

Galenic validation is essential to ensure the properties of a compounding, as well as to detect stability issues