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CHEMICAL STABILITY AND PHYSICAL COMPATIBILITY OF INSULIN EYE DROPS USED IN CLINICAL PRACTICE

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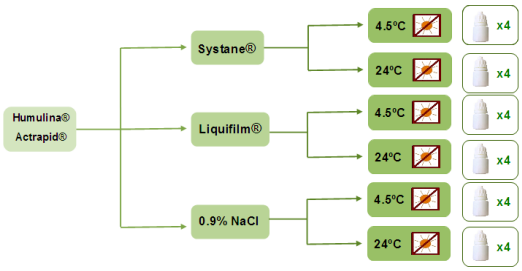
BACKGROUND AND IMPORTANCE

Insulin eye drops are an effective treatment for corneal neurotrophic ulcers. The current information available about the physico-quemical stability is limited to a maximum period of 7 days. By conducting this study, the intention is to assess whether the stability could be increased using different vehicles or conservation conditions.

AIM AND OBJECTIVES

To study, during 30 days, the chemical stability and physical compatibility of eye drops of human insulin (Humulina® or Actrapid®) at 1 UI/mL, diluted in different vehicles (Systane Ultra®, Liquifilm® or 0.9% sodium chloride), at different temperatures (24 or 4.5ºC), in polyethylene bottles and protected from light.

MATERIAL AND METHODS



Chemical stability → analysed by high performance liquid chromatography → **T90** (Time at which human insulin retained the 90% of the initial concentration)

Physical compatibility → visual inspection, gravimetric analysis and measures of pH

RESULTS

T90 (HUMULINA®)

	Systane ®	Liquifilm ®	0.9% NaCl
4.5 ºC	9 days	9 hours	1 day
24 ºC	7 days	10 hours	15 hours

T90 (ACTRAPID®)

	Systane ®	Liquifilm ®	0.9% NaCl
4.5 ºC	10 days	17 hours	4 days
24 ºC	10 days	6 hours	3 days

VARIATION OF pH > 5% from day 2 → Humulina® in 0.9% NaCl; Actrapid® in 0.9% NaCl

NO variation of pH with Systane® and Liquifilm®

NO changes in color

NO lost of weight

CONCLUSION AND RELEVANCE

Eye drops of human insuline (1 UI/mL) diluted in Systane®, in polyethylene bottles and protected from light, provides the greatest physico-quemical stability, either at 24ºC (7-10 days) or at 4.5ºC (9-10 days), and regardless of the commercial insuline (Humulina ® or Actrapid ®).