A-10 DRUGS USE IN DIABETES

3PC-032

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OPTIMIZATION OF AN INSULIN 1 IU/ML EYE DROP FORMULATION FOR THE TREATMENT OF CORNEAL ULCERS

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BACKGROUND AND IMPORTANCE

According to the literature…

CORNEAL ULCERS TREATMENT

A formulation of regular human insulin (Actrapid®) 1 IU/mL eye drops was elaborated using a solution of **artificial tears (Systane Ultra®)** in **sterile ambar glass dropper bottles**

30-day galenic validation

Day 0 **turbidity**

It was decided to formulate it in **0.9% NaCl** (**normal saline**)

AIM AND OBJECTIVES

Optimize and study the stability through galenic validation of 1 IU/mL insulin eye drops formulated using normal saline in sterile amber glass dropper bottles and in low density polyethylene (LDPE) dropper bottles.

MATERIALS AND METHODS

All samples were prepared in a horizontal laminar-flow cabinet following the Good Practice Guidelines for sterile drug preparation

Eye drop	Composition per 5 mL	Storage conditions	Packaged
IN1	Insulina regular 100 UI/mL vial (Actrapid®) ..... 0,05 ml Cloruro sódico 0,9%...c.s.p 5 ml	Refrigeration 2-8ºC	Sterile ambar glass dropper bottles
IN2			Sterile low density polyethylene (LDPE) dropper bottles

30-day galenic validation:

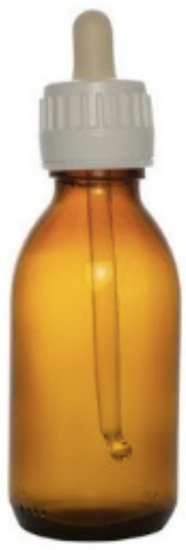
Days 0,1,2,7,15,22,30

- ✓ Clarity
- ✓ Colour
- ✓ pH
- ✓ Osmolality
- ✓ Sterility

3 **U**nits per sampling point and analyzed property

NOTE: pH value at which insulin commercial presentations are buffered 6.9-7.8; pH value of normal saline 6.0.

RESULTS



IN1

Day 0: all samples **pH** around **8,5**

Analyzing this pH value

It was due to the **sterilization process of the amber glass dropper bottles**, which uses **buffered formol**.

The formulation **IN1** was **rejected**.

IN2

Tested property	Outcome Days 0,1,2,7,15,22,30
Clarity	Transparent and homogeneus. Absence of particulates.
Colour	Uncolored
pH	6-6,3
Osmolality	282-286 mOsm/kg
Sterility	Absence of microbiological growth

All samples maintained the characteristics described during the 30 days of galenic validation.

CONCLUSION AND RELEVANCE

The 1 IU/mL insulin eye drops packaged in LPDE dropper bottles showed no changes in the parameters studied throughout the 30-day galenic validation. They also remained within the eye pH range of maximum tolerability (3.5–10.5). It is required more physicochemical and microbiological stability studies to confirm the stability of the formulation.

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