

PREPARATION OF AN EXPERIMENTAL CORD BLOOD SERUM EYE DROPS FOR TOPICAL USE IN SEVERE CORNEAL EPITHELIOPTHY

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BACKGROUND

The use of cord blood (CB) serum as a tear substitute has been recently proposed to heal severe corneal epithelial damages due to its high concentration of epithelial growth factors. No branded CB serum based eye drops are currently available on the market.

PURPOSE

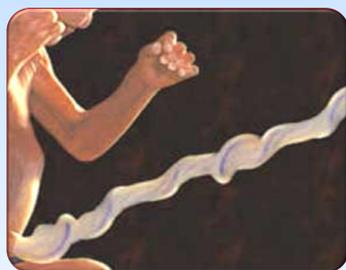
The aim of this study was to optimize the preparation of experimental galenic CB serum based eye drops for topical use by ensuring product high quality, safety and effectiveness.

MATERIALS AND METHODS

In S.Orsola-Malpighi University Hospital of Bologna, Italy, galenic CB serum based eye drops were prepared in collaboration between the Transfusion Centre and the Pharmacy Laboratory in the context of an open clinical trial which enrolls thirty patients a year suffering from severe corneal epithelial damages. The whole procedure was performed under vertical laminar flow hood with aseptic technique and chain of custody monitoring process.

Transfusion Centre

- In Transfusion Centre CB serum was collected from CB units, centrifuged for 10 minutes, aliquoted into 15 mL sterile tubes and frozen at -80°C for six months as a quarantine period.
- Serological and molecular tests for HIV1, HIV2, HCV, HBV, TOXO, CMV and TPHA were performed on each CB serum sample according to the Italian regulations.
- CB serum levels of EGF (Epithelial Growth Factor), TGF-β1 (Transforming Growth Factor-β1) and IL-10 (Interleukin-10) were tested in the Hospital Analysis Laboratory by automated immunoassay in different step points, specifically: freshly collected, thawed after quarantine, after filtration, after dilution and after one or two months storage at -20°C, respectively.



Umbilical cord



Cord blood stem cells



CB serum bag



Aliquoted CB serum sterile tubes

Pharmacy Laboratory

- Thawed CB serum was sent to the Pharmacy Laboratory where it was diluted 1:5 with refrigerated sterile physiological saline, filtered (Millex HV 0.45 μm) and aliquoted into 1 mL single-dose syringes. Filled syringes were sealed with a luer-lock cap and packed in sealed labelled envelopes. Finally, they were stored at -20°C for 30 days before delivery to patients who had to keep the eye drops refrigerated and use them within twelve days.
- Sterility was validated by BacT/Alert test on each batch of eye drops.
- Certification of sterility, molecular and serological tests was retained in the pharmacy.



CB serum eye drop preparation under vertical laminar flow hood with aseptic technique



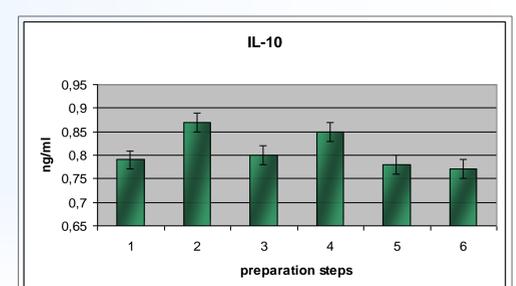
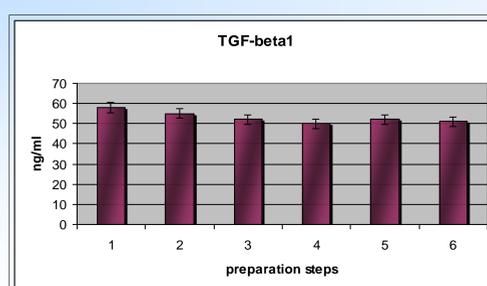
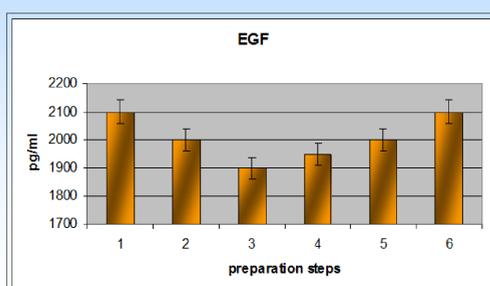
Single-dose eye drop syringe, package and label

S.Orsola-Malpighi University Hospital, Bologna, Italy
Clinical Pharmacy
Clinical Trial OFTACAMPOS-08-01
Sterile eye drop UCS (Umbilical Cord Serum)
20% diluted in physiological saline 1 mL
Batch n. - Preparation date
Store under -20°C
Expiry: 30 days
Experimental drug

RESULTS

Sterility tests confirmed that all batches of eye drops remained sterile after handling and storage. Immunological tests showed that CB serum levels of EGF, TGF-β1 and IL-10 were maintained over the whole process. All treated patients showed an improvement in symptoms and signs.

Concentration of growth factors in cord blood serum



Legend: 1. freshly collected CB serum; 2. thawed after quarantine; 3. after filtration; 4. after dilution; 5. after one month storage at -20°C; 6. after two months storage at -20°C.

CONCLUSIONS

The collaboration among interdisciplinary professional figures overcome preparation critical points, providing patients with a high quality, safe and effective product.