GALENIC PROPERTIES OF PLASMA RICH IN GROWTH FACTORS EYE DROPS

A.C. Riestra[1], S. Berisa[1], F. Muruzabal[2], G. Orive[2], E. Anitua[2], J. Merayo[1]
1 Instituto Oftalmológico Fernández-Vega, Fundación de Investigación Oftalmológica, U niversidad de Oviedo (Spain)
2 Biotechnology Insitute, Vitoria (Spain)

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PURPOSE

Assess the **galenic properties** of the **plasma rich in growth factors (PRGF) eye drops** and its compliance with European Pharmacopeia requirements.

METHODS

Eye drops were obtained using the PRGF-Endoret Ophthalmology kit (BTI, Vitoria, Spain). Briefly, blood was collected into 9 mL tubes, centrifuged at 580g, plasma column was drawn off avoiding the buffy coat, and incubated at 37 ºC with $CaCl_2$, finally, supernatants were collected, filtered and aliquoted in single-dose containers. Eye-drops were kept fresh or stored at -20 ºC for 3 months.

Aseptic process simulations (Media Fill) were performed using tryptic soy broth (TSB) to 6 batches. The samples were incubated for 14 days and inspected for microbial growth. A growth promotion test was done.

Deliverable volume test was applied to 5 single-dose containers.

Oat-Water tightness test was done in two batches in duplicate with a toluidine solution and applying vacuum for 10 minutes.

pH and **osmolarity** were assessed in fresh and after 3 months frozen.

Image 1: Oat-water tightness test.

RESULTS

In the media fill all units were negative for growth. In the growth promotion test clearly growth of all the microorganisms was seen. The volume of each container filled within the range of 95-110%. In the first batch no toluidine was detected inside the vials or the caps. In the second batch only one vial has a shadow of toluidine inside the cap.

Image 2: Vials after oat-water tightness test.

Image 3: Vial with a shadow of toluidine inside the cap.

pH and osmolarity values were slightly modified after freezing. Eye drops were clear and free from particles.

DISCUSSION

Plasma rich in growth factors (PRGF-Endoret) is an autologous platelet-enriched plasma that has been standardized for ophthalmic application. In the recent years, PRGF-Endoret has been successfully used like an eye drop for the treatment of a wide range of ocular surface diseases, including dry eye, persistent corneal epithelial defects and ulcers. Current classification of autologous plasma derivate as human medicines implies that it have to meet all the recruitments of ophthalmic preparations.

Previous studies have established its biological stability during 6 months. In the present work the galenic properties of PRGF eye drops have been assessed confirming that it meets the ophthalmic preparations recruitments of aseptic obtaining, deliverable volume, oat-water tightness, pH and osmolarity.

CONCLUSIONS

The PRGF-Endoret® obtained method is aseptic.

The waterthigness of the vials is correct, and the deliverable volume corresponds with the nominal volume. pH and osmolarity remain constants during all the using period.

We can affirm that PRGF-Endoret ® has fulfilled the European Pharmacopeia requirements and their galenic properties.