GAIKER

STUDY TITLE

"External validation of a medical devices cytotoxicity testing method: IOBA_CYTOTEST"

--- FINAL REPORT ---

4465

14 november 2019

SPONSOR: **Instituto Universitario de Oftalmobiología Aplicada (IOBA)**
Universidad de Valladolid, Campus Miguel Delibes, Paseo de Belén, 14
47011 Valladolid, Spain
Teléfono: 983185085
Contactos:
By the Sponsor: Girish Kumar Srivastava (girish@ioba.med.uva.es)
Study Monitor: Iván Fernández Bueno (ifernandezb@ioba.med.uva.es)
Sponsor's Quality Assurance: Miguel Ángel Garcia Hontoria (mgarciah@ioba.med.uva.es)

CONCLUSIONS:

This study was carried out in accordance with the Principles of Good Laboratory Practice published by the OECD (OECD Principles of Good Laboratory Practice), adopted by the EU according to Directive 2004/10/EC and in Spain by Royal Decree 822/1993 of 28th May, modified by Royal Decree 1369/2000, of 19th July.

IOBA requested a study to externally validate a cytotoxicity testing method (IOBA_CYTOTEST) for medical devices. In order to validate this method, four different test items were evaluated, following the procedure described by IOBA and named IOBA_CYTOTEST. This method follows the ISO Guideline 10993-5.
A total of 5 assays were performed. Assays E1, E2 and E3 included two exposure times and two post-exposure times. Assay E4 included two exposure times and 24h post-exposure and E5 evaluated only one test item.
According to the results obtained, the cytotoxicity protocol IOBA_CYTOTEST correctly evaluated the cytotoxic or non-cytotoxic nature of the test item assayed.

Study Director: Amaia García

Quality Assurance Unit: Fco. J. Ereño Aldecoa