



Hydrolytic Stability

Overview:

It is important to determine the long-term stability of an intraocular lens when it is exposed to an aqueous environment. After implantation a lens is exposed to the aqueous environment within the eye and therefore must not degrade or be subject to physical change. The purpose of this testing is the detection and quantification of possible degradation products from hydrolysis and also changes in physical appearance, optical properties and chromatographic characteristics.

The hydrolytic stability of finished intraocular lenses can be determined as detailed in the following standard.

ISO 11979-5:2006 Ophthalmic Implants - Intraocular lenses - Part 5: Biocompatibility.

Specifically this corresponds with Annex C - Hydrolytic stability. The intraocular lenses or representative samples are exposed to a suitable aqueous medium and incubated at an appropriate temperature for the test material.

The study will evaluate the stability of the material in an aqueous environment at $35^{\circ}\text{C} \pm 2^{\circ}\text{C}$ for a period of at least five years or at an elevated temperature for a simulated exposure time of at least five years. The simulated exposure time is to be determined by multiplying the actual study time with the following factor F .

$$F = 2.0^{(T_a - T_o)/10}$$

where

T_a is the accelerated temperature
 T_o is the temperature of the inside of the eye (35°C)

This gives the following temperature and duration combinations

<u>Temperature</u>	<u>Study Duration</u>
35	5yrs
45	2.5yrs
55	1.25yrs
65	228days
75	114days
85	57days
95	28days



Procedure:

The test material is placed into glass vials containing sufficient volume of a suitable aqueous medium to achieve a ratio of 10g of test material per 100ml of medium. These are incubated at a temperature appropriate for the test material for a specific duration as calculated by the previous equation. At least two vials of each combination of temperature and duration are prepared to ensure confidence in the results obtained. After the required testing duration the vials are allowed to equilibrate to room temperature before the test samples are removed and subject to testing.

Before testing, the test material is rinsed in pure water. The optical transmittance spectra of the test material in the ultraviolet and visible spectral regions shall be recorded before and after testing. By comparison of the spectra it can be determined if there are any significant changes in the spectral transmittance. The refractive index should also be measured before and after testing to ensure there is no significant change. The test material is examined by light microscopy at 10x magnification or higher before and after testing. The test material is compared to untreated material and there should be no significant difference in surface appearance (e.g. bubbles, dendrites, breaks and fissures).

Qualitative and quantitative analysis is performed on the supernatant from each individual vial by gas chromatography and UV/Vis spectrophotometry as appropriate. This process is also performed on the solvent blanks that have undergone the same incubation procedures. The results of the samples are compared to the solvent blank and the findings interpreted in the context of possible material changes.