Determination of Extractable Species - IOL

Overview:

For a wide range of applications, it is important to quantify the amount of material that can be easily extracted from a polymer. This is especially true for any materials that come into contact with the human body including contact lenses and more importantly implantable devices such as intraocular lenses. It is vital that such devices are essentially free of extractable substances, which will ensure their safe and effective use. The polymerisation process used to produce such polymers will always result in the potential for extractable species in the form of unreacted monomer. Since hydrogel materials become swollen in water, unreacted monomer is usually eluted from the material and the finished device is rendered free of extractable material. In the case of PMMA the material is hard and glassy which effectively stops the migration of unreacted monomer to the surface of the material.

The amount of extractable species present in finished intraocular lenses can be determined by extraction as detailed in the following standard.

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

Specifically this corresponds with Annex A – Exhaustive extraction test. Soxhlet extraction with different solvents is a standard method for quantitative determination of substances extractable from intraocular lenses. The intraocular lenses are dried to constant mass and the difference between the original dry mass of the lenses and the extracted dry mass determines the quantity of extractable substances.

Knowledge of the quantity and identity of extractable substances is helpful in evaluating new materials and in determining the subsequent pre-clinical examination programme. The material extracted from the intraocular lenses may be examined by appropriate chromatographic methods to identify residual monomers, cross-linking agents and catalysts that were employed in the polymerization process.

Procedure:

The method uses a normal Soxhlet extraction apparatus. Water and another suitable organic solvent are used for extraction. In selecting the organic solvent, consideration should be given to the effect of the solvent upon the matrix of the material. Ideally a solvent should not degrade the lens material. However, in the development of new intraocular lens materials, a solvent that causes reversible swelling may give valuable information relating to the possibility for extraction over extended periods of time.

Test samples should be representative of the finished product and be in finished intraocular lens form. The method of preparing and finishing the lenses shall reflect as far as possible the normal production processes including sterilization.

Hydrophilic lenses are usually packaged in a solution containing inorganic salts. An adjustment in the calculation should be made for the contribution of the inorganic salt of the packaging solution. The water content of the lenses will be required in order to accurately calculate the contribution of the inorganic salt to the extractables. Alternatively, the lenses may be equilibrated in at least two changes of water each for 24 hours at room temperature prior to the beginning of the test.

Lenses are dried in an oven and are then allowed to cool to room temperature in a closed container over active desiccant. When constant weight has been achieved the weight of the lenses is recorded to ± 0.1mg (W_1). Ensure that at least 200mg of dry intraocular lenses are available for the extraction step. The lenses are placed into the extraction thimble and the flask is filled to approximately 70% of its capacity with the appropriate solvent. The lenses are extracted for a minimum of 4 hours and the solvent is then allowed to cool before removing the lenses from the extraction thimble. The lenses are dried to constant weight as described above and again the weight is recorded to ± 0.1mg (W_2)

The quantity of extracted material ($W_{extracted}$) is expressed as a percentage of the initial dry mass.

$$(W_{extracted}) = \frac{(W_1 - W_2)}{W_1} \times 100$$

where

W_1 is the mass of lenses prior to extraction

W_2 is the mass of extracted lenses

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