Thermoplastic elastomers

Thermoplastic elastomers (TPE) are synthetic materials that are used in many fields including the medical field. One of the chief reasons for using synthetic materials is their property of not harming the patient, which is called biocompatibility. The properties of these synthetic materials when used in biological environments may not be affected. TPEs are very pure and contain low levels of compounds that can leach from the TPE into the surrounding environment. Other advantages of TPEs include their cost effectiveness and recyclability. Apart from being United States Pharmacopoeia (UPS) VI certified several TPEs have United States Food and Drug Administration compliance (GLS Corporation 2007). The Medicines Control Council (MCC) of South Africa aligns itself with the FDA. In the case of drug registration in South Africa when a drug is registered with a body that the MCC aligns itself with in another country, the drug to be registered in South Africa does not undergo the lengthy application process that new drugs undergo. Rather the drug undergoes an abbreviated medicine review process (Medicines Control Council 2012)

Safety of TPEs

Tests conducted on TPE

Name of test	Implications of test	Result obtained by TPE
USP 661	Determines extent to which material under consideration maintains integrity and releases its constituents (ingredients) into the surrounding environment.	Passed
ISO 10993-5 (Cytotoxicity)	The test method evaluates the material for being toxic to cells	Passed
United States Pharmacopoeia Class VI test (USP is a non-governmental organisation that is based in the United States and establishes standards to safeguard the quality of medicines and health technologies. The standards it sets are in terms of product quality, purity, strength and consistency.)	Tests biological reactivity of material. Consists of animal tests to determine: Whether the material under consideration irritates the test animal and causes unwanted side effects (acute systemic toxicity test). How the animal tissue responds to the material under consideration when the material is implanted in the live animal (intracutaneous test; Implantation test).	Passed as Class VI (Strictest standard used, therefore the TPE is likely to not cause problems in a human system)
ISO 10993-4 (Haemolysis, indirect in human blood)	Test determines the ability of the material under consideration to cause red blood cell destruction.	Passed
ISO 10993-10 (Intracutaneous irritation)	Test determines how the animal tissue responds to the material under consideration when the material is implanted in the live animal	Passed
ISO 10993-11 (Acute system toxicity)	Test determines whether the material under consideration causes unwanted side effects in the test animal.	Passed

Ugandan case study

Thirty one females used the menstrual cup in a study in Uganda over a five month period aimed at determining the hygienic safety as well as the acceptability and safety of the menstrual cup. The study came to the conclusion that menstrual cup use did not result in, or increase the chances of reproductive tract infections, or urinary tract infections (Tellier, Hyttel et al. 2012).

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