The Value of USP Class VI Testing

for Plastics Used in Medical Devices

Performance failure in medical devices can have catastrophic and even life-threatening consequences for patients. To mitigate the risk, it is critical to evaluate the compliance of each element of a medical device with the relevant requirements. USP Class VI Testing is among the commonly recognized certification schemes for medical devices and integrated plastics in the United States.

USP Classification of Plastics

Plastics tested according to the appropriate In Vivo Biological Reactivity tests specified in the General Chapters of United States Pharmacopeia and National Formulary (USP-NF) will be assigned a specific USP Plastic Class designation between Class I and Class VI. The purpose of the tests is to determine a plastic article's biocompatibility, and its suitability for use in medical devices, implants and other systems.

USP Classification of Plastics (USP Biological Reactivity Tests, In Vivo) :

Test To Be Conducted	Extracts	USP Class					
		I	II	III	IV	V	VI
Systemic injection test (injection in mouse)	Sodium chloride (intravenous)	X	X	X	X	X	X
	Alcohol saline (intravenous)		X	X	X	X	X
	Polyethylene glycol (intraperitoneal)			X		X	X
	Vegetable oil (intraperitoneal)			X	X	X	X
Intracutaneous test (injection in rabbit)	Sodium chloride (intravenous)	X	X	X	X	X	X
	Alcohol saline (intravenous)		X	X	X	X	X
	Polyethylene glycol (intraperitoneal)					X	X
	Vegetable oil (intraperitoneal)				X	X	X
Implantation test (strips implanted in rabbit)	None				X		X



What tests are to be done?

Plastics to obtain USP Class VI designation must successfully undergo all the three in vivo biological reactivity evaluations, generally performed on mice or rabbits to mimic use in humans.

Systemic Injection Test:

Extracts of the test material are prepared in appropriate extracting medium (saline, vegetable oil, alcohol saline, and polyethylene glycol) and injected into test animal intravenously or intraperitoneally, according to the medium type. Test animal is observed for three days for signs of toxicity or death. The test material is rated as passing or failing depending on whether any test models died or showed significant reaction to the extracts during the observation period. Systemic injection test is designed to evaluate general toxicity of the extract—whether it will cause abnormal behavior such as convulsions or prostration, weight loss, or other whole-body problems.

Intracutaneous Test:

Extracts of the test material are prepared in the same four extracting medium (saline, vegetable oil, alcohol saline, and polyethylene glycol) and injected into five sites on each of two test models. Examine and rate the test models at 24, 48, and 72 hours for evidence of any tissue reaction by comparing the test and control sites. Intracutaneous test is designed to assess toxicity and localized irritation when the test material is in contact with live subdermal tissue.

Implantation Test:

The test article is implanted in the muscle tissue of two test models. After a period of not less than 120 hours, the implantation and control sites are examined macroscopically to determine whether a significant reaction, such as hemorrhage, necrosis, discolorations and infections, occurred. Implantation test is designed to measure toxicity, infection, and irritation of an intramuscular implantation of plastic materials into a test animal over several days.

Why needs USP Class VI designation?

Plastics with USP Class VI designation demonstrates that it has passed the most comprehensive and stringent evaluation, encompassing implantation and extract tests which include not only the standard polar and nonpolar extracts required in ISO 10993-12 for finished medical devices, but also two additional extracts to mimic possible drug carriers. Class VI designation is the gold standard for medical-grade plastic materials and a prudent choice for medical device manufacturers, hence an excellent option for plastic manufacturers to enhance the marketability of their product.

STC can provide USP Class VI Testing service. With advanced equipment and a professional team, STC can assist you in meeting the ever-changing standards and regulations, and making your products more competitive.

Contact STC

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