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LAB RESEARCH PRODUCTS

Rabbit Pyrogen Study-Material Mediated

Purpose: To determine whether an extract of the test article induced a pyrogenic response following intravenous injection in rabbits.

Method: Body temperature after injection of sample material is used to indicate presence of chemically mediated pyrogens (fever-inducing substances) in accordance with the guidelines of the current USP.

Result: non-pyrogenic

USP Intracutaneous Toxicity Study in the Rabbit (Extracts)

Purpose: To determine whether leachables extracted from the material would cause local dermal irritant or toxic effects following injection into rabbit skin.

Method: Tissue at the site intracutaneous injection of sample material extracts is evaluated for erythema (redness) and edema (swelling) or other evidence of tissue irritation.

Result: non-irritating / non-toxic

USP Systemic Toxicity in the Mouse (Extracts)

Purpose: To determine whether leachables extracted from the material would cause acute systemic toxicity following injection into mice.

Method: In accordance with the current USP, observation is made for adverse effects occurring after intravenous and intraperitoneal administration of sample material extract.

Result: non-systemically toxic

Ames Salmonella/Mammalian Microsome Mutagenicity Assay

Purpose: Evaluates the ability of sample material extracts to cause gene mutations in specific histodine-dependent strains of Salmonella typhimurium.

Method: Five (5) specially constructed strains of Salmonella typhimurium have an increased ability to detect mutagens. In the absence of histidine, these genetically altered strains are unable to grow. When placed in a histidine-free medium, only those cells which mutate spontaneously back to their wild type state are able to form colonies.

Result: non-mutagenic

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Biological Testing

Direct Hemolysis

Purpose: To evaluate the effects on blood or blood components from contact with test material and/or its extracts as required by ISO 10993-4, 1992.

Method: Test article was added to a test vial of USP Sodium Chloride for Injection. Control and test vials were incubated in waterbath, then fresh diluted rabbit blood was added to all vials. All vials were incubated and centrifuged and absorbance of each supernatant was determined. Hemolysis is expressed as a percentage.

Result: non-hemolytic

USP Elution Test

Purpose: To determine what effects are caused by addition of test article and/or it's extracts to a cell culture. Cultures are evaluated for cell lysis/cell death, inhibition of cell growth or abnormal cellular morphology.

Method: Extracts were prepared in a humidified atmosphere containing carbon dioxide. The extracts were used to replace the maintenance medium o the cell culture then incubated. Biological reactivity was examined and given a rating from Grade 0 (No reactivity) to Grade 4 (Severe reactivity).

Result: non-cytotoxic

USP Heavy Metals (Method 1)

Purpose: Determines the absence of potentially toxic trace metals.

Method: Sample was extracted in USP water for injection, placed into a test tube and pH adjusted to 3.0-4.0. Samples were diluted with water, mixed and hydrogen sulfide added. Reactions observed after 5 minutes.

Result: meets requirement

USP Muscle Implantation Study in the Rabbit with Histopathology
(26 weeks or 5 days)

Purpose: To evaluate the potential for a local irritant or toxic response to material being implanted in direct contact with muscle tissue.

Method: The sample material is implanted into the muscle tissue of a rabbit and evaluated for evidence of irritation or toxicity in accordance with the guidelines of the current USP.

Result: non-irritating

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