

General Safety Test and the Rabbit Pyrogen Test in the Quality Control of Biopharmaceuticals

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Abstract

The use of alternative methods to animal testing has been encouraged, thus during the last decade an increasing number of alternative approaches in the biopharmaceutical industry have been formally adopted. In this context, there are an ethical, scientific and economic discussion worldwide in relation to the reliability of the application of the General Safety Test and the Rabbit Pyrogen Test in the quality control of biopharmaceuticals. The application of the former has been questioned because no reliable conclusions can be drawn from this test. For this reason, this assay has been removed from some pharmacopeias and it is no longer mandatory for several Regulatory Agencies, especially after the introduction of Good Manufacturing Practices and the use of other stringent methods. In addition, in vitro alternatives for pyrogens control, such as the Monocyte Activation Test, have been developed. This alternative method mimics the human fever reactions and detects the enhancing pro-inflammatory effect of substances that are commonly found in the biopharmaceutical industry, increasing the product safety. It is known that the position of a Regulatory Authority is focused in the assurance on the safety of products; however, Cuban regulations have not yet specifically ruled on the usefulness of both tests. This work offers a scientific basis on the reliability of these tests and their role to increase or not the safety of biological products. In addition, the position of the Cuban Regulatory Authority with respect to its application in the quality control of biological products is exposed.



Biography:

Zenia Pardo-Ruiz has expertise in the development and application of alternative methods in the quality control of vaccines and other biopharmaceuticals as part of the Biochemistry team at the Center for Pharmaceuticals Research and Development, where she reach her PhD degree. Currently, she is a reviewer of biological products, specialized in vaccines, at the Cuban Regulatory Authority (Center for State Control of Drugs, Equipment and Medical Devices).

Speaker Publications:

- 1 Perdomo-Morales, R., Pardo-Ruiz, Z., Spreitzer, I., Lagarto, A., Montag, T. Monocyte Activation Test (MAT) Reliably Detects Pyrogens in Parenteral Formulations of Human Serum Albumin. ALTEX 28, 3/ 2011.
2. Perdomo-Morales, R., Pardo-Ruiz, Z., Spreitzer, I., Lagarto, A., Montag, T. Monocyte Activation Test (MAT) Reliably Detects Pyrogens in Parenteral Formulations of Human Serum Albumin. ALTEX 28, 3/ 2011.
3. Muñoz-Cernada, A., Pardo-Ruiz, Z., Montero-Alejo, V., Fernández-Cervera, M., Sosa- Testé, I., García-Rodríguez, J. Effect of Nonionic Surfactants and HPMC F4M on the Development of Formulations of Neuro-EPO as a Neuroprotective Agent. Advanced Pharmaceutical Science and Technology (2014) 1(2).
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