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

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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 is an ethical, scientific and economic discussion worldwide in relation to the reliability of the application of the General Safety Test and the Rabbit Pyrogenic 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 pharmacopeia's 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.

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