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SINGLE-USE BIOPROCESS CONTAINERS: RAW MATERIAL CONTROL STRATEGY FOR OPTIMAL CELL GROWTH

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There is an upward trend in the use of disposable containers for manufacturing biopharmaceuticals. Single-use systems offer several advantages such as increased flexibility, the elimination of cleaning procedures, and reduced capital expenditure. However, due to the plastic nature of these disposable bags, the materials of construction can be more complex than traditional stainless steel vessels. They are often made of films containing multiple layers of polymers with various additives for processing. There have been scientific reports of the inhibition of biopharmaceutical cell culture growth attributed to a leachate originating from an antioxidant commonly used in the plastic films of single-use bioprocess containers. In the current study, extractions were carried out at the different stages throughout the production of a single-use container from raw materials through to finished product in order to establish a comprehensive understanding of the origin of the leachate and the factors that influence its formation. The processing conditions used to manufacture the film were also assessed in the study. Both chemical analysis of extracts and cell culture growth performance were evaluated. The extraction profile of the single-use bioprocess container was found to be influenced by the raw materials, the film processing parameters, and container sterilization. The cell culture growth performance correlated to changes in the extraction profile throughout the production of the bioprocess containers. This comprehensive study demonstrates that the extraction profile of single-use bioprocess containers and the subsequent impact of the potential leachates on cell culture growth can be effectively controlled through implementation of risk management from raw material selection to container production.