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2D Single-use Storage Bags Technical Manual

Guangzhou Jet Bio-Filtration Co.,Ltd.

Abstract

China's biopharmaceutical industry has entered a stage of rapid development. The approval policies for biopharmaceuticals are gradually in line with international standards, and the relevant policies, regulations, and guidelines are being quickly complemented, encompassing functional applicability study, biosafety study and compatibility study between drugs and packaging materials. The quality requirements for drugs and consumables related to drug manufacturing will be subject to more rigorous regulation. Biopharmaceutical products include antibodies, vaccines, blood products, cell therapies, recombinant proteins and more. All these biopharmaceuticals rely on large-scale production. Traditionally, large-scale production has mostly used stainless steel equipment. In recent years, single-use storage bags have been widely adopted as substitutes for stainless steel containers and integrated into various steps of bioproduct production for liquid storage and transfer due to their lower risk of contamination and high process flexibility.

In recent years, Chinese biological drug regulatory authorities have issued several policies, regulations and guidelines in the field of biopharmaceuticals to establish requirements and specifications for production equipment, packaging and container closure systems, so as to ensure the safety and effectiveness of biopharmaceuticals in clinical use. Article 74, Chapter 5 of China's Good Manufacturing Practice (GMP) stipulates that "Manufacturing equipment should not present any hazard to drug quality. The surface of the equipment that come into direct contact with the drug should be smooth, spotless, and easy to clean, disinfect and anti-corrosive. It must not be reactive, additive or absorptive to affect product quality." On January 4, 2022, the National Medical Products Administration issued Good Manufacturing Practice - Appendix for Cell Therapy Products (Draft for Comments) to standardize the production and quality control of cell therapy products. The document specifies that "sterile consumables in direct contact with cell products should use disposable materials as much as possible".

Single-use storage bags have been extensively used in the pharmaceutical industry, including vaccine production, monoclonal antibody manufacturing, and more. As production materials that directly or indirectly contact the product or intermediates during the drug manufacturing process, these bags need to undergo suitability and biosafety assessments. In particular, a compatibility study of extractables/leachables is necessary to evaluate the safety of storage bags for the preparation of bioproducts.

The 2D Single-Use Storage Bags newly developed by JET BIOFIL have shown excellent biosafety, chemical compatibility and physical properties. Having passed quality tests and validation, they are safe and reliable single-use system products for users of biopharmaceutical manufacturers. The Technical Manual describes the physicochemical characteristics, critical controls in the manufacturing process, specifications, critical quality parameters, and other relevant information of the 2D Single-Use Storage Bags of JET BIOFIL, providing its customers with foundational information for evaluating and testing this product before use.

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