

Morimatsu | Quality control elements for Single Use Systems

A Single Use System (SUS) is a process equipment solution that is typically assembled from polymeric material components to form a system or unit of operation for a single or one-stage pharmaceutical production activity. SUS should be considered for the following elements in quality control:

SUS compatibility assessment

SUS compatibility assessment involves the safety of the materials used throughout the life cycle of the SUS application, including chemical compatibility, biocompatibility, animal components, extractables and leachables, non-specific adsorption, etc.

SUS physical properties

Primarily tests for robustness and system integrity (material thickness, smoothness, flexibility and ductility, etc.), material strength, puncture resistance, and component and system integrity.

SUS raw material controls

Compliance and stability of raw material quality standards to ensure product lot-to-lot consistency.

The supply of raw materials shall ensure the continuity of SUS production, and critical quality attributes should be identified with upstream suppliers.

SUS production process control

Processes and key process parameters should be established on the basis of comprehensive validation and sound production operation specifications.

During the production process, the production process parameters are strictly enforced, the risks that may be introduced in the production are vigorously controlled, and the corresponding monitoring items and limit indicators are established.

SUS aseptic guarantee

SUS is mainly made of plastic, with complex structure, different materials and different shapes, so the evaluation of the sterilization process, verification of the sterilization process, post-sterilization evaluation, and the determination of the relevant process parameters are particularly important for the sterilization process guarantee. Factors affecting the sterilization process include the bioburden of the sterilized product, the type of microorganisms, the material, quantity, size and shape of the product, and the complexity of the SUS system.

With the rapid development of pharmaceutical process equipment and the increasing maturity of single use technology, single use systems are more and more widely used in the pharmaceutical field, especially in the production of vaccines, genetically engineered products, monoclonal antibodies and other biopharmaceuticals.

Morimatsu is committed to meeting the different needs of customers in the biopharmaceutical industry at home and abroad with high-quality and reliable single use system solutions. Our product process and quality are sound and reliable. With verification tests that meet USP and other international standards, we can provide customers with abundant verification document support.

Morimatsu's Total Disposable System Solution

