Audit #: _____ Auditor(s): _____ Date: _____

Subpart C		
Buildings and Facilities	**Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:**	**Conforms to Requirements**
Grounds have been properly maintained through the removal of litter and waste, cutting of grass and weeds adjacent to the plant, maintenance of roads and parking lots, providing adequate drainage, etc.		☐ Yes ☐ No
Waste treatment and disposal is adequate and does not provide a source of potential contamination.		☐ Yes ☐ No
Production Facility is maintained in a clean and sanitary condition and in a proper state of repair.		☐ Yes ☐ No
Entrances to the facilities are controlled and maintained to prevent contamination.		☐ Yes ☐ No
Cleaning and sanitizing compounds have been established for cleaning the facility. These agents are safe and adequate under the conditions of use.		☐ Yes ☐ No
Cleaning and sanitizing agents, pesticide chemicals and fungicides have been identified, used, held and stored in a manner that protects against adulteration of raw materials and in-process or finished products, and against contamination of processing equipment, utensils and packaging materials.		☐ Yes ☐ No
Procedures have been established to prevent entrance to the facility by pests and animals, including screens and barriers, rodent traps, insect traps or light traps, etc.		☐ Yes ☐ No
Pest control procedures have been established for the appropriate use of insecticides, fungicides, fumigants, rodenticides, etc.		☐ Yes ☐ No

The water supply is safe and sanitary and under suitable temperature and pressure. Water that may contact a product contact surface must meet US Federal, State and Local requirements for drinking water. Water used as a component of a non-parenteral drug product must meet USP purified water standards, and the water system must be validated.		☐ Yes ☐ No
Water sources do not act as a potential source of contamination, either due to water purity or due to the configuration and construction of the water delivery system.		☐ Yes ☐ No
Floor drainage is adequate (immediate and continuous drainage, no pooling, proper drain covers, etc.).		☐ Yes ☐ No
Bathrooms and wash facilities are kept clean and are not a potential source of contamination to components, products, contact surfaces, etc.		☐ Yes ☐ No
Hand washing facilities are constructed in appropriate areas to ensure proper hand washing of personnel.		☐ Yes ☐ No
Solid waste and trash are disposed of appropriately and not allowed to accumulate.		☐ Yes ☐ No
Areas have been clearly defined or separated for receiving, inspecting and identifying, holding and withholding from use components, packaging and labels to be used.		☐ Yes ☐ No
Areas have been provided for quarantine and release of materials to be used in the manufacturing, packaging or labeling of product.		☐ Yes ☐ No
Working areas have adequate access and space, aisles are clear, etc. to allow for persons to perform their duties and protect against contamination.		☐ Yes ☐ No
In areas where open vessels are used, there is adequate protection against contamination, e.g. use of protective coverings, physical location, use of screening, etc.		☐ Yes ☐ No