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

Subpart C		
Buildings and Facilities	**Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:**	**Conforms to Requirements**
Have the grounds been properly maintained with removal of litter and waste, cutting of grass and weeds adjacent to the plant, maintenance of roads and parking lots, and providing adequate drainage, etc?		☐ Yes ☐ No
Is the waste treatment and disposal adequate and prohibit a source of potential contamination?		☐ Yes ☐ No
Is the production facility maintained in a clean and sanitary condition and in a proper state of repair?		☐ Yes ☐ No
Are the entrances to the facilities controlled and maintained to prevent contamination?		☐ Yes ☐ No
Have cleaning and sanitizing compounds been established for the cleaning of the facility and are these agents safe and adequate under the conditions of use?		☐ Yes ☐ No
Are the cleaning/sanitizing agents, pesticide chemicals, and fungicides identified, used, held, and stored in a manner that protects against adulteration of raw materials and in-process or finished products and free from the possibility of contaminating processing equipment, utensils, and packaging materials?		☐ Yes ☐ No
Have procedures been established to prevent entry into the facility by pests and animals (including screens/barriers, rodent traps, insect traps, light traps, etc)?		☐ Yes ☐ No

Are there established procedures for pest control regarding appropriate use of insecticides, fungicides, fumigants, rodenticides, etc?		☐ Yes ☐ No
Is the water supply safe and sanitary and under suitable temperature and pressure requirements and is the water system validated?		☐ Yes ☐ No
Does water that may contact a product surface met US Federal, State, and Local requirements for drinking water?		☐ Yes ☐ No
Does the water used as a component of non-parenteral drug product meet USP purified water standards?		☐ Yes ☐ No
Do water sources act as a potential source of contamination, due either to the water purity or the configuration and construction of the water delivery system?		☐ Yes ☐ No
Is the floor drainage system adequate with immediate and continuous drainage, no pooling, and proper drain covers?		☐ Yes ☐ No
Are the bathrooms and wash facilities kept clean and not a potential source of contamination to components, products, and contact surfaces?		☐ Yes ☐ No
Are hand-washing facilities constructed in appropriate areas to ensure proper hand-washing of personnel?		☐ Yes ☐ No
Is the solid waste and trash disposed of properly and not allowed to accumulate?		☐ Yes ☐ No
Are the areas clearly defined or separated for receiving, inspecting, and identifying, holding and withholding from use components, packaging, and labels to be used?		☐ Yes ☐ No
Are there areas provided for quarantine and release of materials to be used in the manufacturing, packaging, or labeling of product?		☐ Yes ☐ No

Do the working areas have adequate access and space?		☐ Yes ☐ No
Are the aisles clear to allow for persons to perform their duties and to protect against contamination?		☐ Yes ☐ No
In areas where open vessels are used; is there adequate protection against contamination such as protective coverings, physical location, use of screening,etc?		☐ Yes ☐ No