


	GILES CHEMICAL ~ PREMIER MAGNESIA		
	Company Form		
	Title: Internal Audit Checklist – Building and Facilities	Number: Q12-PR-100-F008e	
	Owner: Deborah Durbin	Revision: 0	
	Effective Date: 12/19/12	Page: 1 of 3	

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?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the waste treatment and disposal adequate and prohibit a source of potential contamination?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the production facility maintained in a clean and sanitary condition and in a proper state of repair?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Are the entrances to the facilities controlled and maintained to prevent contamination?		<input type="checkbox"/> Yes <input type="checkbox"/> 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?		<input type="checkbox"/> Yes <input type="checkbox"/> 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?		<input type="checkbox"/> Yes <input type="checkbox"/> 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)?		<input type="checkbox"/> Yes <input type="checkbox"/> No

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Are there established procedures for pest control regarding appropriate use of insecticides, fungicides, fumigants, rodenticides, etc?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the water supply safe and sanitary and under suitable temperature and pressure requirements and is the water system validated?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Does water that may contact a product surface met US Federal, State, and Local requirements for drinking water?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the water used as a component of non-parenteral drug product meet USP purified water standards?		<input type="checkbox"/> Yes <input type="checkbox"/> 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?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the floor drainage system adequate with immediate and continuous drainage, no pooling, and proper drain covers?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Are the bathrooms and wash facilities kept clean and not a potential source of contamination to components, products, and contact surfaces?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Are hand-washing facilities constructed in appropriate areas to ensure proper hand-washing of personnel?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the solid waste and trash disposed of properly and not allowed to accumulate?		<input type="checkbox"/> Yes <input type="checkbox"/> 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?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Are there areas provided for quarantine and release of materials to be used in the manufacturing, packaging, or labeling of product?		<input type="checkbox"/> Yes <input type="checkbox"/> No

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

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