


	GILES CHEMICAL ~ PREMIER MAGNESIA		
	Company Form		
	Title: Internal Audit Checklist – Requirements for Components, Packaging and Labels Number: Q12-PR-100-F008h		
	Owner: Deborah Durbin	Revision: 0	
	Effective Date: 05/04/16	Page: 1 of 2	

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

Subpart E		
Requirements for Components, Packaging and Labels	Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:	Conforms to Requirements
Specifications have been established for components, packaging and labels.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Complete traceability of active pharmaceutical ingredients (API's) is available.		<input type="checkbox"/> Yes <input type="checkbox"/> No
If a Certificate of Analysis (COA) is used to confirm the components, the supplier must be qualified and documentation must be maintained for this qualification.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Supplier Qualification Procedures are established and include initial qualification, periodic examination (requalification) and procedures for disqualification. This includes supplier COA verification requirements.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Rejected components, packaging, labeling and products are appropriately quarantined and dispositioned.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Subpart H		
Holding and Distribution	Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:	Conforms to Requirements
Drug products, components, labeling, and packaging are held under the appropriate conditions of temperature, humidity, and light and do not lead to mix-up, contamination, or deterioration.		<input type="checkbox"/> Yes <input type="checkbox"/> No
In-process materials requiring specific holding conditions (temperature, humidity etc.) are stored appropriately.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Distribution of product must occur under conditions that will		<input type="checkbox"/> Yes <input type="checkbox"/> No

Controlled Document

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protect against contamination and deterioration.		
Procedures have been established for holding and distribution operations, including distribution of the oldest approved materials first.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Product distribution records have been retained. Records shall be maintained for a period of 3 years beyond the date of distribution of the last batch of drug products associated with those records or 1 year past the expiration date. [21CFR 211.196]		<input type="checkbox"/> Yes <input type="checkbox"/> No