


	<b>GILES CHEMICAL ~ PREMIER MAGNESIA</b>		
	<b>Company Form</b>		
	Title: <b>Internal Audit Checklist – Production and Process Controls</b>	Number: <b>Q12-PR-100-F008i</b>	
	Owner: <b>Deborah Durbin</b>	Revision: <b>0</b>	
	Effective Date: <b>12/19/12</b>	Page: <b>1 of 4</b>	

Audit #: \_\_\_\_\_ Auditor(s): \_\_\_\_\_ Date: \_\_\_\_\_

Subpart F		
Production and Process Controls	Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:	Conforms to Requirements
Production and processes have been designed to ensure the quality of the product and the Quality Unit has approved the control systems.		<input type="checkbox"/> Yes <input type="checkbox"/> No
A documented policy has been established to manage any change associated with the production of a drug product, such as changes to specifications, formulations, raw material suppliers, equipment, computer systems, process, Manufacturing, etc. The policy should describe how to document and effectively communicate changes to all applicable parties in order to secure the necessary approvals prior to implementation of the change, as well as evaluation of the need for any re-validation activities. Pre- and post-change activities are approved by the Quality Unit. Appropriate risk management principles and tools have been incorporated into this process (ICH Q10).		<input type="checkbox"/> Yes <input type="checkbox"/> No
A system has been established to determine if all specifications that are established have been met.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Procedures and controls have been established for investigation and handling of materials that do not meet specification requirements (i.e., Out-Of-Specification [OOS] procedures meeting FDA requirements [in the lab], as well as procedures for investigation and handling of material once an OOS condition is confirmed [in production])).		<input type="checkbox"/> Yes <input type="checkbox"/> No

### Controlled Document



Only those quality documents viewed through the Giles Chemical electronic Documentation System are officially controlled. All other copies, whether viewed through another computer program or a printed version, are not controlled and, therefore, the Quality Unit at Giles assumes no responsibility for accuracy of the document.

	<b>GILES CHEMICAL ~ PREMIER MAGNESIA</b>		
	<b>Company Form</b>		
	Title: <b>Internal Audit Checklist – Production and Process Controls</b>	Number: <b>Q12-PR-100-F008i</b>	
	Owner: <b>Deborah Durbin</b>	Revision: <b>0</b>	
	Effective Date: <b>12/19/12</b>	Page: <b>2 of 4</b>	

Procedures have been established for the handling of unexpected events, including any deviations from written procedures.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Reprocessing controls have been established and meet all requirements and have been approved by the Quality Unit. These controls prevent the blending of out-of-specification batches with other batches for the purpose of meeting specifications.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Manufacturing processes have been designed to produce a product that consistently meets specifications. This has been verified by appropriate process validation (including any relevant automated / computer equipment).		<input type="checkbox"/> Yes <input type="checkbox"/> No
Manufacturing Operations are conducted using adequate sanitation principles. Appropriate cleaning validation studies have been performed to validate the effectiveness of cleaning procedures with respect to material carryover (i.e., cleaning / sanitizing agents as well as components, in-process materials, or products) as well as prevention of microbial contamination.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Precautions have been taken to prevent contamination, such as micro, filth, chemical, foreign material, etc., throughout the manufacturing and repackaging process.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Manufacturing operations have included controls in manufacturing steps to prevent contamination, including metal detection.		<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Production and Process Controls: Requirements for the Master Manufacturing Record</b>	<b>Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:</b>	<b>Conforms to Requirements</b>
Master Manufacturing Records have been prepared for each unique formulation and batch size of the drug products.		<input type="checkbox"/> Yes <input type="checkbox"/> No

**Controlled Document**



Only those quality documents viewed through the Giles Chemical electronic Documentation System are officially controlled. All other copies, whether viewed through another computer program or a printed version, are not controlled and, therefore, the Quality Unit at Giles assumes no responsibility for accuracy of the document.

	<b>GILES CHEMICAL ~ PREMIER MAGNESIA</b>		
	<b>Company Form</b>		
	Title: <b>Internal Audit Checklist – Production and Process Controls</b>	Number: <b>Q12-PR-100-F008i</b>	
	Owner: <b>Deborah Durbin</b>	Revision: <b>0</b>	
	Effective Date: <b>12/19/12</b>	Page: <b>3 of 4</b>	

The Master Record identifies specifications for the control points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the drug products. MMR's contain all of the required elements.		<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Subpart G</b>		
<b>Packaging and Labeling Controls</b>	<b>Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:</b>	<b>Conforms to Requirements</b>
Procedures have been established for all packaging and labeling operations, including controls for any subcontracted packaging and/or labeling operations.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Packaging and labels are controlled for issuance and are reconciled after use. Note: Reconciliation is not necessary for cut or rolled labels when 100% examination is performed by appropriate electronic or electromechanical equipment during or after completion of operations.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Packaging and labeling materials are examined before usage to determine that they conform to the Master Manufacturing Record.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Packaging and labeling of the finished packaged and labeled products are visually examined, at a minimum, to determine that the correct packaging and labeling has been used.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Physical separation is implemented to prevent mix-ups with other components or drug products.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Filling and packaging operations are appropriately protected from contamination sources.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Procedures have been established to identify unlabeled materials that will be held for future labeling operations.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Procedures have been established for assigning a lot or batch number for each lot of packaged and labeled drug product.		<input type="checkbox"/> Yes <input type="checkbox"/> No

**Controlled Document**

Only those quality documents viewed through the Giles Chemical electronic Documentation System are officially controlled. All other copies, whether viewed through another computer program or a printed version, are not controlled and, therefore, the Quality Unit at Giles assumes no responsibility for accuracy of the document.

	<b>GILES CHEMICAL ~ PREMIER MAGNESIA</b>		
	<b>Company Form</b>		
	Title: <b>Internal Audit Checklist – Production and Process Controls</b>	Number: <b>Q12-PR-100-F008i</b>	
	Owner: <b>Deborah Durbin</b>	Revision: <b>0</b>	
	Effective Date: <b>12/19/12</b>	Page: <b>4 of 4</b>	

All OTC products are packaged with tamper-evident packaging, and labels include the required wording regarding the tamper-evident feature(s).		<input type="checkbox"/> Yes <input type="checkbox"/> No
Disposal procedures have been established for disposing of labels or packaging materials that are obsolete or incorrect to ensure that they are not used.		<input type="checkbox"/> Yes <input type="checkbox"/> No
An appropriate quarantine system has been established for holding any rejected packaged and labeled drug product.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Storage areas have been demonstrated to meet the necessary requirements.		<input type="checkbox"/> Yes <input type="checkbox"/> No

### Controlled Document

Only those quality documents viewed through the Giles Chemical electronic Documentation System are officially controlled. All other copies, whether viewed through another computer program or a printed version, are not controlled and, therefore, the Quality Unit at Giles assumes no responsibility for accuracy of the document.