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.		☐ Yes ☐ 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).		☐ Yes ☐ No
A system has been established to determine if all specifications that are established have been met.		☐ Yes ☐ 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])).		☐ Yes ☐ No

Procedures have been established for the handling of unexpected events, including any deviations from written procedures.		☐ Yes ☐ 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.		☐ Yes ☐ 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).		☐ Yes ☐ 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.		☐ Yes ☐ No
Precautions have been taken to prevent contamination, such as micro, filth, chemical, foreign material, etc., throughout the manufacturing and repackaging process.		☐ Yes ☐ No
Manufacturing operations have included controls in manufacturing steps to prevent contamination, including metal detection.		☐ Yes ☐ No
Production and Process Controls: Requirements for the Master Manufacturing Record	**Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:**	**Conforms to Requirements**
Master Manufacturing Records have been prepared for each unique formulation and batch size of the drug products.		☐ Yes ☐ No

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.		☐ Yes ☐ No
Subpart G		
Packaging and Labeling Controls	**Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:**	**Conforms to Requirements**
Procedures have been established for all packaging and labeling operations, including controls for any subcontracted packaging and/or labeling operations.		☐ Yes ☐ 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.		☐ Yes ☐ No
Packaging and labeling materials are examined before usage to determine that they conform to the Master Manufacturing Record.		☐ Yes ☐ 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.		☐ Yes ☐ No
Physical separation is implemented to prevent mix-ups with other components or drug products.		☐ Yes ☐ No
Filling and packaging operations are appropriately protected from contamination sources.		☐ Yes ☐ No
Procedures have been established to identify unlabeled materials that will be held for future labeling operations.		☐ Yes ☐ No
Procedures have been established for assigning a lot or batch number for each lot of packaged and labeled drug product.		☐ Yes ☐ No

All OTC products are packaged with tamper-evident packaging, and labels include the required wording regarding the tamper-evident feature(s).		☐ Yes ☐ 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.		☐ Yes ☐ No
An appropriate quarantine system has been established for holding any rejected packaged and labeled drug product.		☐ Yes ☐ No
Storage areas have been demonstrated to meet the necessary requirements.		☐ Yes ☐ No