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

Subpart J		
Records and Record Keeping - General	**Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:**	**Conforms to Requirements**
All documents related to the quality system are prepared, reviewed, approved and distributed according to written procedure.		☐ Yes ☐ No
The issuance, revision, superseding and withdrawal of all documents are controlled and records of these activities are maintained in revision histories or equivalent.		☐ Yes ☐ No
Procedures exist describing cGMP-recordkeeping practices. E.g. permanent ink, identification of "who" and "when" for all entries and procedures for correcting entries (sign, date, explain and not obliterate original entry).		☐ Yes ☐ No
Procedures have been established that describe the requirements for record retention.		☐ Yes ☐ No
Records will be maintained for 1 year after the expiration date or 3 years beyond the date of distribution of the last batch associated with those records.		☐ Yes ☐ No
All records are maintained as original record, as true copies or electronic records.		☐ Yes ☐ No
Annual Product Review and Inspection of Reserve Samples	**Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:**	**Conforms to Requirements**
The Quality Unit performs an Annual Product Review [21 CFR 211.180(e)].		☐ Yes ☐ No
The Quality Unit perform an annual physical inspection of a representative number of reserve samples [21 CFR 211.170(b)].		☐ Yes ☐ No

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Product Complaints and Complaint Files: 21 CFR 211.198	**Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:**	**Conforms to Requirements**
Procedures have been established describing how product complaints will be received, investigated and documented.		☐ Yes ☐ No
All product complaints have been reviewed to determine if the complaint was the result of a product specification failure or quality.		☐ Yes ☐ No
The decision to investigate a complaint as well as the final decision as a result of the investigation, including corrective action, has been approved by the Quality Unit.		☐ Yes ☐ No
The investigation for a product complaint was approximately extended to other batches, products, processes, etc.		☐ Yes ☐ No
Product complaint information has included adequate information.		☐ Yes ☐ No
Procedures for handling complaints include provisions for investigation and, if necessary, reporting of serious adverse events as outlined in 21 CFR 310.305.		☐ Yes ☐ No
Procedures have been established to define the recall of a product and a mock recall exercise is conducted at least annually.		☐ Yes ☐ No
Control of Documents and Records – Electronic Records and Electronic Signatures	**Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:**	**Conforms to Requirements**
Any GMP related computerized systems have been validated.		☐ Yes ☐ No
Procedures and controls have been established for electronic closed systems used to create, modify, maintain or transmit electronic records in order to ensure the authenticity, integrity and confidentiality of the records [Closed System] (21 CFR Part 11).		☐ Yes ☐ No

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Procedures and controls have been established for use of open electronic systems. Areas of control have been identified, as necessary, per the requirements of 21 CFR Part 11.		☐ Yes ☐ No
Electronic signatures conform to requirements.		☐ Yes ☐ No
Passwords and codes have been established.		☐ Yes ☐ No
Backup electronic files have been maintained of the following: current software programs, outdated software programs that may be necessary to retrieve past records and data that was entered.		☐ Yes ☐ No
Backup files are an exact and complete record and are secure from alterations, erasures or loss and damage.		☐ Yes ☐ No

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