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.		☐ Yes ☐ No
Complete traceability of active pharmaceutical ingredients (API's) is available.		☐ Yes ☐ 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.		☐ Yes ☐ No
Supplier Qualification Procedures are established and include initial qualification, periodic examination (requalification) and procedures for disqualification. This includes supplier COA verification requirements.		☐ Yes ☐ No
Rejected components, packaging, labeling and products are appropriately quarantined and dispositioned.		☐ Yes ☐ 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.		☐ Yes ☐ No
In-process materials requiring specific holding conditions (temperature, humidity etc.) are stored appropriately.		☐ Yes ☐ No
Distribution of product must occur under conditions that will protect against contamination and deterioration.		☐ Yes ☐ No

Procedures have been established for holding and distribution operations, including distribution of the oldest approved materials first.		☐ Yes ☐ 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]		☐ Yes ☐ No