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

Subpart I		
Laboratory Controls	**Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:**	**Conforms to Requirements**
Procedures have been established for laboratory operations. These procedures include Out-of-Specification (OOS) procedures meeting FDA requirements.		☐ Yes ☐ No
Laboratory testing facilities are adequate for testing of components, in-process materials and product. This includes contracted laboratories.		☐ Yes ☐ No
Laboratory controls have been established and have been approved by the Quality Unit. Controls include reagents and standards, calibration of instruments and equipment, sample receipt, handling and traceability, test method validation and use and raw data handling and storage.		☐ Yes ☐ No
Procedures have been established for the collection of representative samples for analysis.		☐ Yes ☐ No
Procedures have been established for the collection of reserve samples for each lot of active pharmaceutical ingredient (API) and for all finished material.		☐ Yes ☐ No
Parameters have been set for laboratory controls for sampling plans, criteria for examination and test methods.		☐ Yes ☐ No
Scientifically valid test methods are used for all testing of components, packaging materials, in-process materials and final products. Method validation procedures are defined and followed and validation test method data is available for all test methods.		☐ Yes ☐ No
The impurity profile of API's has been determined and is compared to historical data at regular intervals.		☐ Yes ☐ No

All products bear an expiration date that is supported by stability data generated under GMP/ICH requirements.		☐ Yes ☐ No