



Title:
ATTACHMENT A – RECORD SCHEDULE

Effective Date:
10-01-03
Revised: 05/02/14

Laboratory and related records, with their storage locations, retention periods and disposal, are maintained as follows:

Record	Retention	Disposal	Schedule #
LIMS Database Records (includes sample data, laboratory results, comments)	End of fiscal year after final action	10 years after cutoff	ORA 3230
Output Records (includes data extracted periodically For reports)	Temporary	When no longer needed	ORA 3240
System Documentation (includes system and user manuals, data dictionary, Requirements)	Temporary	When superseded or obsolete	ORA 3250
Laboratory Test Records, Reg. (includes analytical work- sheets, lab test results Summary report, attachments For lab control documents)	End of fiscal year after final action or analysis	5 years after cutoff	ORA 6220
Non-Violative Lab worksheets (Imports)	End of fiscal year upon release	2 years after cutoff	ORA 4110
Non-Violative Lab worksheets (Domestic);(includes labeling, Seal integrity & other documentation)	End of fiscal year after reg. decision	2 years after cutoff	ORA 6110
Violative Lab worksheets (Imports)	End of fiscal year after re-exportation	5 years after cutoff	ORA 4130
Violative Lab worksheets (Domestic)	End of fiscal year after reg. decision	5 years after cutoff	ORA 6120
Pre-Market/PreApproval Lab Test Records (includes analytical worksheets, lab test results summary report, attachment for lab control documents for NDA, ANDA, NADA)	End of fiscal year after final action or analysis	10 years after cutoff	ORA 6210
Shelf Life Extension Program Records (analytical worksheets)	End of calendar year when entire lot testing complete	10 years after cutoff	ORA 2422
Lab QA Records (includes lab notebooks, instrument calibration, validation, growth media, lab procedures, QC charts)	End of fiscal year after final action	3 years after cutoff	FDA 4300

NDA – New Drug Application; ANDA – Abbreviated New Drug Application;NADA – New Animal Drug Application;
QA/QC - Quality Assurance/Quality Control