Regulatory Basis:
FDA Quality Systems Regulations

Reference: FDA CFR - Code of Federal Regulations Title 21

1 Purpose

The purpose of this procedure is to describe the minimum requirements for the retention of samples and documents under GMP and Medical Device regulations/legislation. Local legislative and regulatory requirements which may require retention of increased sample quantities or longer retention periods, take precedence over this procedure.

2 Scope

This procedure covers GMP and Medical Device documentation and Reference/Reserve samples for Active Pharmaceutical Ingredients (API's), Intermediates, Formulated Products, Starting Materials Packaging Materials and Finished Products. (**Note:** No reference/reserve samples of Medical Devices are required)

This procedure does not include GMP documentation and Reference/Reserve samples related to Clinical Trials.

3 Definitions

3.1 GMP Documentation

GMP documentation is any procedure, control, record, distribution or related record, or electronic file that is required to be retained as evidence of compliance with GMP.

3.2 Medical Device

Any instrument, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purposes of diagnosis, prevention, monitoring, treatment or alleviation of disease.

3.3 Medical Device Documentation

Medical Device Documentation is any procedure, control record, distribution or related record, or electronic file that is required to be retained as evidence of compliance to Medical Device Legislation.

3.4 Reference Samples

Is the term used in the GMP of the European Community for samples taken for retention.

3.5 Reserve Samples

5.5.1 Raw Materials, Excipients, API's, Intermediates, Formulated Products and Finished Products.

The Reference/Reserve sample shall consist of at least twice the quantity necessary for all tests required to determine its compliance with specification, except for sterility and pyrogen testing; where the quantity required to repeat these tests only once shall be retained.

The Reference/Reserve sample shall be retained and stored under conditions consistent with the product labelling and/or specification requirements.In the case that there are no conditions given on the label and/or in the specification the samples shall be stored in controlled room temperature. The Reference/Reserve sample shall be stored in the same primary container enclosure system in which the product is marketed or shipped, or in one that has essentially the same characteristics, (i.e. mimics the container-closure system); it is acceptable to use smaller packs.

Reference/reserve samples of APIs shall be retained as described in the Appendix A3.

Reference/reserve samples need not be taken for intermediates. However, intermediate samples are typically taken and retained until stock is consumed and API released.

Reference/reserve samples need not be taken from Raw Materials. However, individual sites may take the decision to keep some materials for investigative purposes. Typically this will be the case for New Product Introduction/Technology Transfer materials or changes in suppliers. Consideration should be given to the criticality of the material in the production process.

Reference/Reserve samples need not to be taken from water, gases or starting materials that are highly corrosive or very inflammable unless stated specifically.

Reference/Reserve samples should be retained in accordance with the retention stated in Appendix A2, if the stability of the product permits.

For product marketed in the USA or starting material used for USA marketed product, as a minimum, representative sample lots or batches of Finished Products shall be selected by acceptable statistical procedures. The samples for Finished Products should be examined visually at least once a year for evidence of deterioration unless visual examination could affect the integrity of the samples. The results of the examination should be documented and maintained with other stability data on the Finished Product.

5.5.2 Packaging Material

Reference/Reserve Samples need only be taken from primary and printed packaging materials. For printed and primary packaging material one unit must be retained, unless retained as Finished Product. Any overprinting such as batch code and/or expiry date must be included. This can be included as a sample retained in the associated packaging documentation.

5.6 Sampling

Reference/Reserve Samples shall be taken by personnel and by methods approved by Quality

fire and flood etc and their salvage in the event of such a disaster.

5.11 Disposal of Documentation and Samples

Documents and samples should be destroyed at the end of their appropriate retention period. Disposal of samples must be in accordance with relevant EHS principles. A record of the disposal should be retained. Documents must be disposed of by shredding or incineration.

In the event of a third party contractor being used to dispose of documents and/or samples, this contractor's activities should have been inspected by site QA personnel in order to determine suitability and to ensure that systems are in place to ensure that confidential information/proprietary material is adequately safeguarded before, during and after disposal.

6. Appendix A : A1 GMP Documentation
A2 Medical Device Documentation
A3 Samples

A1 GMP DOCUMENTATION

WHAT	RETENTION PERIOD YRS	COMMENTS
REGULATORY DOCUMENTATION - SMF - DMF - Regulatory Authority inspection reports/documentation	Indefinite	
MANUFACTURING DOCUMENTATION - Raw Mat. Receipts - Dispensing information - Batch Prod. Record - Packaging Prod. Record - In process controls (+ raw data) - Deviation reports/investigations - Hygiene controls - Distribution records - Returns information - Equipment usage + cleaning logs. - Cleaning records - Temperature/humidity records (inc. Transit) - Master batch production records - Master packaging production records		Full change history Full change history
APIs	Retest/Expiry life + one year or three years after final distribution whichever is the longer	
FORMULATED PRODUCTS	Shelf life + one year or at least five years	

A2 MEDICAL DEVICE DOCUMENTATION

WHAT	RETENTION PERIOD YRS	COMMENTS
QUALITY MANAGEMENT SYSTEM DOCUMENTS	5 years	
PRODUCT SPECIFYING DATA	Active life + 5 years	i.e. 5 years after manufacture of the product ceases.
BATCH HISTORY RECORDS	5years	
OTHER QUALITY RECORDS	5years	
RAW MATERIALS	N/A	
INTERMEDIATES	N/A	Typically until stock consumed and API released
APIs	Expiry date + one year or three years after the final distribution	
EXCIPIENTS	10	If stability permits. Exclude water, gases, highly corrosive or inflammable
FORMULATED PRODUCTS - Finished tablets/capsules - Dry powders (unlabelled final containers) - Bulk liquid - Semi solids (eg creams/ointment/suppositories - Placebos	Expiry date + one year	
FINISHED PRODUCTS - Tablets/capsules - Powders and inhalers - Liquids (sterile and non-sterile) - Semi solids - Parenterals - Medical devices - Aerosols	Expiry date + one year	
PACKAGING MATERIALS - Primary and printed	Expiry date + one year	
CUSTOMER COMPLAINTS	2	3 yrs for medical