Standard Operating Procedure

Title: Retention Sample Management

Department	Quality Management		Document no	QMS-195	
Title: Retention Sample Management					
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Purpose

This procedure describes the collection, storage, and management of retention samples at a GMP site.

Scope

This procedure applies to biological and pharmaceutical products; raw materials used in the manufacturing processes; Third party manufactured products Purchased products; Packaging and Components.

Responsibilities

QA Associate(s) is responsible for the maintenance of the retention sample program, the disposal of expired retention samples and the collection of raw material, packaging retention samples, Third party and Purchased Finished product retention samples.

Production Line Supervisors/Team Leaders are responsible for the collection and labeling of retention samples of products manufactured at the Penrith and Crookwell facilities.

General

The retention sample system is divided into separate areas, with specific procedures outlined in this SOP. It is the QA Departments' responsibility to oversee the program, with the assistance of the Production Areas Supervisors.

Retention samples need to be stored under the registered storage conditions with access to these samples by QA only. Once a sample has reached the allocated destruction date, it must be disposed of appropriately.

Retention sample storage areas are described in Table 1.

Retention sample sizes are described in Table 2.

Retention sample logs are maintained for each area and type.

In the event of a product complaint, or if further investigation/testing is required, the retention sample is located, removed and tested. Any removal is documented on the appropriate log.

When retention samples are transferred to an external warehouse, the details are recorded in the appropriate log.

'Drop boxes' have been set up in certain locations where the line supervisors are to leave the retention samples collected during a packing job. Once notified that the samples have been collected, the QA Associate will retrieve the samples and proceed as per this procedure.

Retention logs are to remain with QA until ALL items recorded in the log have reached the destruction date, been disposed of and the date of disposal recorded. Once a log book is complete, it is forwarded to Documentation for archiving.

Safety and Process Specific Information

All safety requirements for relevant areas at the GMP facilities must be followed at all times.

Retention Samples may not be required for Semi-Finished Purchased product; the sample will be taken once the final packing is complete. Refer to the relevant Finished Product Specification for requirements.

Destruction date is 1 year past expiry date.

Secondary Packed Finished Products

Retention Samples are taken as per the relevant packing paperwork and labeled with an in-house label.

The samples are placed in the relevant 'drop box' and the QA Associate notified that the samples are ready for collection.

The QA Associate checks that the details are correct.

The samples are then placed in the appropriate storage area; refer to Table 1, and the details recorded on the Retention Sample Log (**Form-965 or Form-975**),

Destruction date is 1 year past expiry date.

Antigens

Upon containment of antigen into a mobile vessel, a production technician takes 2 x 500mL samples of that antigen and labels with the relevant information:

The details are recorded in the Production Sample log **Form 1000**, by the production technician and the sample and log forwarded to a QA Associate. QA checks that the sample details and appearance are correct and signs the production log to confirm that the samples have been received.

The samples are then placed in the box labeled for the year the antigen is to be destroyed in the appropriate storage location, refer to Table 1, and the details recorded on the Retention Sample Log (**Form 970**).

Destruction date of antigen samples is 5 years from date of containment. (Maximum shelf life of any antigen produced is typically 36 months. Antigens are kept ≥ 2 years past their shelf life).

Registered Secondary Packaging (For EU Market)

Retention samples are retained from every delivery of registered secondary packaging used to package European product. The sample may be taken from the 'Inspection' samples **provided** that no destructive testing has been conducted (refer to QMS-190 Inspection, Sampling and Disposition of Incoming Goods).

Each sample is labeled with the blue 'Retention' label, as per WAR-095 Status Labels, with the 'QIS number'; QA Associate shall sign and date the label.

The sample/s are then placed in the appropriate storage location, refer to table 1 and the details recorded in the Packaging Retention Sample Log (**Form-990**)

Destruction date is 3 years past the allocated expiry date.

Labels/ Instruction Leaflets

Retention samples are retained from every delivery (refer to Table 2) and are attached to the QIS once dispositioned. These will remain with the QIS in the relevant folder.

Primary Components

A sample is to be retained from every delivery (refer to Table 2). This applies to containers, caps, taps and dosing guns **(excluding non-printed pails and lids).** The sample may be taken from the 'Inspection' samples (refer to QMS-190 Inspection, Sampling and Disposition of Incoming Goods) provided that no destructive testing has been conducted.

Each component is to be labeled using the blue 'Retention' label, as per WAR-095 Status Labels, with the 'QIS number'. QA Associate shall sign and date the label.

Table 2 - Retention Sample Requirements

Product Type	Item	Retention Sample Size
Purchased Products	All	Refer to Finished Product Specification
Third Party Manufactured Products	All	Refer to Finished Product Specification
Biological Finished Products	All	2 x finished units from each packing run
Biological Filled Products	(For EU markets)	Sufficient to permit the carrying out, on, at least, two occasions, of the full analytical controls on the batch in accordance with the Marketing Authorisation.
Manufactured Pharmaceuticals	All	1 x fully labeled filled container
Secondary Packed Finished Products	All	Refer to Finished Product Specification and Packing Document
Third Party Manufactured Finished products	All	Refer to Finished Product Specification
Antigens	All	2 x 500mL samples
Raw Materials	Liquids	Refer Raw Material Specification
	Solids	Refer Raw Material Specification
	Peptones	Refer Raw Material Specification
Components	Primary Containers, Caps, Taps, Dosing guns, Draw Off tubes	Refer to Component Specification
Registered Secondary Packaging	All	Refer to Packaging Specification
Labels	All	Refer to Packaging Specification
Leaflets	All	Refer to Packaging Specification

