Standard Operating Procedure

Title: Inspection, Sampling and Disposition of Incoming Goods

Department	**Quality Management**		**Document no**	**QMS-190**	
Title: **Inspection, Sampling and Disposition of Incoming Goods**					
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1. PURPOSE

This procedure defines the inspection, sampling and disposition of incoming (purchased) goods.

2. SCOPE

This procedure is applicable to all inventory goods and consumable items at any GMP site including contract manufacturing processes.

3. RESPONSIBILITIES

3.1 **QA Personnel**

- Responsible for inspection, organization of sampling and disposition of all inventory goods and critical consumables as per this procedure.

3.2 **Warehouse Personnel**

- Responsible for the receipt of all items delivered to Virbac Penrith and Crookwell facilities.

3.3 **Logistics / Purchasing Personnel**

- Responsible for the ordering of items from the appropriate approved supplier/manufacturer.

3.4 **QC Personnel**

- Responsible for the testing of raw materials as per the relevant specification.

4. SAFETY AND PROCESS SPECIFIC INFORMATION

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

5. DEFINITIONS

5.1. Inventory goods – Goods that are inventory controlled by the ERP system.

5.2. Critical Consumables – goods that are directly related to the manufacture of product but not present in the finished product and any items that have the potential for product contact or may directly influence the product quality.

5.3. Non-Critical Consumables – Goods that are not directly related to the manufacture of product.

5.4. Expiry date – date the material is at the end of its shelf life and a retest and/or re-evaluation of material is not permitted.

5.5. Retest date – date by which material requires a retest and/or re-evaluation for continued use.

5.6. QIS – Quarantine Inspection Sheet

5.7. PPE – Personnel Protective Equipment

5.8. C of A – Certificate of Analysis

5.9. C of C – Certificate of Compliance

- QC and ASD chemicals.

7.3. **Inspection of Goods**

7.3.1. Upon receipt of the QIS from the Warehouse Receival store, or a requirement for re-evaluation of material, QA Personnel will select the appropriate specification file and relevant checklist.

- Form 945 - QA Inspection and Disposition of Raw Materials Checklist
- Form 950 - QA Inspection and Disposition of Incoming Goods Checklist
- Form 955 – QA Inspection and Disposition of Raw Materials Pre-Purchase Samples Checklist.

7.3.2. The relevant information on the QIS, Specification and Checklist shall then be checked by QA Personnel:

- Name of material.
- Quantity received.
- Supplier name.
- Manufacturer's name.
- Test sample requirements.
- Manufacturer's code/batch number/lot number.

7.3.3. The Purchasing Department shall be notified if required documentation has not been received with the delivery (e.g. C of A; Sterility Certification).

7.3.4. For raw material deliveries received directly into the warehouse, trained personnel will be responsible for the visual inspection of goods. Once the material inspection is complete the checklist is returned to QA. Disposition of the material will be finalised in ERP system and the required number of status labels printed and sent to warehouse for application to the goods.

7.3.5. All goods shall be inspected and dispositioned within cycle times.

7.3.6. **Raw Materials**

Using Checklist Form 945 - QA Inspection and Disposition of Raw Materials Checklist, QA personnel shall confirm and document the following where applicable:

- Presence of all relevant documentation (as appropriate):
  - Certificate of Analysis.
  - Certificate of Conformance.
  - Certificate of Sterility/Irradiation.
  - Any Import Permit (if applicable).
  - Supplier and Manufacturer.

- Visual inspection of containers:
  - ID of product checked and confirmed against QIS.
  - Containers clean, undamaged, sealed.
  - Sterility/irradiation labels applied to each container (as appropriate).
  - Each container is labeled with supplier/manufacturer ID / Batch No.

- Supplier and Manufacturer

- Visual inspection:
  - ID of product checked and confirmed against QIS
  - Item is clean and undamaged
  - Sterility/irradiation labels applied to each carton (as appropriate)
  - Fluorination labels applied to each carton (as appropriate)
  - Each pallet/carton labeled with supplier/manufacturer ID and Batch Number
  - Each individual carton and/or pallet has an “under inspection” label applied by Warehouse personnel.

7.3.9. **Advanced Samples** (Pre-batch - New Supplier/Manufacturer).

Advanced samples of Raw Materials received by Warehouse Receival store are forwarded to QA Personnel with the QIS.

Using checklist **Form-955**, QA Inspection and Disposition of Raw Materials Pre Purchase Samples Checklist, QA personnel shall confirm and document the following where applicable:

- Presence of all relevant documentation (as appropriate):
  - Confirm sample type (pre-batch test sample; change control sample; other)
  - Certificate of Analysis
  - Certificate of Conformance
  - Certificate of Sterility/Irradiation
  - AQIS Import Permit
  - Supplier and Manufacturer

- Visual inspection:
  - ID of product checked and confirmed against QIS
  - Containers clean, undamaged, sealed
  - Each container identified with supplier/manufacturer ID / Batch No.
  - Sterility/irradiation labels applied to each carton

- Testing:
  - QA personnel shall complete **Form-960** Quality Control Test Request and Results and forward together with the test sample, QIS and Certificate of Analysis to QC.

Once testing is completed and disposition determined, the original documentation shall be filed by QA and Purchasing informed by email of the results. In the case of evaluation of a new supplier, another copy of the test results, QIS and checklist, shall be attached to the relevant Change Control documentation.

