

Standard Operating Procedure

Title: Product Complaint Procedure

To be read in conjunction with [Appendix 2](#).

- 2.3.1. The process for Imported or Contract Manufactured complaints is very similar to locally manufactured complaints. The difference is that the responsibility for investigation is for the contract manufacturer.
- 2.3.2. For Investigation by Contract Manufacturer, forward sample with covering letter detailing the complaint and results of initial evaluation to designated contact.
- 2.3.3. Keep track of complaints with the contract manufacturer so that they will be analysed and reported within the specified time frames.

3. Storage of Samples

The QA Staff is responsible for the storage of samples using the following process:

- 3.1. Disposal of samples takes place as set out in **SOP LAB-045**. Samples are to be kept for one (1) year past their expiry date. Boxes are kept in designated Complaint Storage area in the retention Sample Room.
- 3.2. The system in place allows for samples to be stored in numbered boxes that can be easily discarded at the end of the storage period.
- 3.3. The boxes are numbered and clearly labelled "Complaints, Box Number ---, "To be discarded in December XXXX" (the appropriate year for sample disposal). Details and allocation of Box numbers are recorded in the table QA Complaint Spreadsheet:

4. Trending of Product Complaints

- 4.1. The Quality Assurance staff reviews the data entered into an Excel **Spreadsheet for Customer Complaint**, periodically to determine if there are any unfavourable trends in the Complaints Data.
- 4.2. The data is analysed based on the following criteria:
 - 4.2.1. Process Line (for In-house manufactured goods)
 - 4.2.2. Product Code
 - 4.2.3. Date of Manufacture
- 4.3. The data will be sent to management for review and copy of the data will be held in QA files under "Quarterly Complaints Trend Review".
- 4.4. Any unfavourable trends will be discussed in the Quality Meeting with the view to generate Continuous Improvement Plans and Preventive Action Plans to reduce the level of complaints received for the issue identified.

5. Handling of Suspect Counterfeit Samples and Product Diversions

- 5.1. **A sample will be suspect if there is reason to believe that:**
 - A counterfeit product and/or pack
 - Product that has been tampered with
 - Product that has been diverted from the normal supply chain.
- 5.2. A written and documented record (Chain of Custody) of the history and movements of the suspect sample to support any legal prosecutions has to be initiated and maintained with sample by the designated QA Staff if a suspect sample is received and should include the following information: