

Standard Operating Procedure

Title: Archiving Laboratory Documentation

results were printed on the Certificate of Analysis. Trend cards were filled in prior to the Certificate of Analysis being filed (all chemicals and components except printed materials which had a sample attached to the Certificate of Analysis). All of these certificates of analysis have been archived into numbered well boxes for long-term storage. If results are required from any of these certificates of analysis, check the Trend cards first before retrieving the actual document.

5.5. Raw Material Register

All incoming Raw Materials are entered into the Raw Material Register (Form-255). These registers recorded the following information: Lab. batch No., Item Description, Code, Quantity, No. of Labels, Manufacturer's Batch No., Supplier, Order No., GRS (Goods Receipt Slip), QA signature and Date when product was passed.

5.6. Trend Cards

Trend cards are a good way to look back at results for specific products/codes.

There are two lots of manually recorded Trend cards: Finished Goods and Raw Materials.

5.6.1. Finished Goods Trend Card (Form-260)

5.6.2. Raw Material Trend Card (Form-265)

6. Procedure for Archiving Documentation Long Term

6.1. This is to be applied to all documentation that is to be kept for a set period of time, but not referred to on a regular basis. All archived documentation is to be packed into well boxes and clearly labelled with contents, disposal dates and must be stored on site.

6.2. Each well box is to be given a number that is unique and distinguishes it from all other well boxes. It must contain the letters 'QA', with a prefix L (Laboratory) and followed by either 2 or 3 digits e.g.

LQA017 is Laboratory Quality System Documents box number 17

6.3. Well number must be issued sequentially.

6.4. Documents are to be packed into smaller boxes of same size collected from warehouse and the contents filled out on the Laboratory and QA Documents Log Sheet and Box labels form (Form-270). After the boxes are registered in the form place them in the well box until there will be no spaces left.

6.5. Each smaller box is given a letter that distinguishes it from all other smaller boxes within the larger well box, e.g. H. The labels are printed from the Form-270 and stuck on the outside.

6.6. Once a smaller box is filled, the completed Laboratory and QA Documents Log Sheet is photocopied, with the copy being inserted into a plastic invoice slip and stuck on the outside of the corresponding box. The original copy of the completed Form-270 is kept in the designated Laboratory Cabinets. These completed forms are to be used for retrieving information at any time during the retention period.

6.7. Once a well box is full of smaller boxes, the front panel is inserted and the lid put on. The front panel must have the well box number e.g. LQA017 and Date to be Discarded. These are to be written as large and legible as possible.

6.8. Example of what should be written on the front panel of the well box: