check by a colleague. The results are verified by signing the "Read and Understood By" page containing calculations and results.

1.8. A periodic review of the Workbook is carried out by a Laboratory colleague using form **Form-275**. This person then signs the "Read and Understood By" section of the Workbook pages to indicate they have reviewed the Workbook pages against the checklist. The completed checklists are filed in the "Laboratory Workbook – Review Folder".

1.9. The Laboratory Manager randomly reviews Workbooks, and the logical flow of an experiment should be assessed against the checklist. Internal or external auditors may also randomly audit Workbooks.

1.10. There should be a link between any analytical work, and any internal reports or reports to the Regulatory authorities.

The key point is that all data can be traced to an original raw data or collection source.

2. Format of Laboratory Workbooks for Daily Testing

2.1. Information required in the workbook:

- Name, Batch Number (and/or Inspection Lot Number), Trial Number (if applicable) of product tested.
- Testing date and all raw data, e.g. weights, volume.
- Equipment system, where applicable, (e.g. if several instruments of the same type are available in the one Laboratory and a choice is possible).
- Control Method number or protocol (if applicable).
- Column serial number for HPLC and GC.

2.2. It is not necessary to write all the testing steps/methods in the workbook only those tests that require measurements that affect a calculation (see **SOP LAB-060 & LAB-065**).

2.3. Record in the Workbook the following information for chemicals used to make up testing reagents: Manufacturer, Lot No., Expiry Date, date when container opened.

2.4. Qualitative and quantitative test results can be directly entered onto the Raw Material / Finished Product Specification and Test Report (see SOP QMS-030, TEM-005, TEM-060). Terms such as "negative", "positive" or "conforms" are used to describe limit and identity test results. All entries on the specification reports must signed and dated.

2.5. All calculations for raw materials/finished products must be entered in the Analyst's workbook and Raw Material / Finished Product Specification and Test Report are to given the book page reference number of the work book . All entries on the workbooks and the Specification and Test Reports must signed and dated.

2.6. Corrections or modifications of data entry must not obscure the original entry. Correction Fluid (Liquid Paper) is not permitted. The correct procedure (see **SOP QMS-020**) is to put a single line through the incorrect entry, write in the new entry next to it and initial and date it. The reason for making the new entry must also be recorded. The abbreviation, EE, for entry error may be used. Entry error is the most common reason for making corrections or modifications.

2.7. No pages are to be removed from the workbook. If any page are to remain blank cross through the page and write "Void" and date and sign the page.

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