3.3.8. **ALL** trial documentation is kept. Documentation must be completed to GMP requirements and treated as per a routine batch unless the trial documents specifically instruct otherwise.

3.3.9. **ALL** Laboratory samples, waste, product, reconciliations, in-process testing must be taken/performed as per a routine batch unless the trial documents specifically instruct otherwise.

3.4. Trial Completion

Once the actual trial has been executed, the documentation and results must be collated, the trial reported on, the batch disposition established, (where applicable) and the documents affected by the trial updated.

3.4.1. The area Manager, (or delegate) must collect the trial documentation generated and perform a review, using the checklist provided with the protocol, to ensure all documentation is present and complete.

3.4.2. The Trial Coordinator, (or delegate) is responsible for:

3.4.2.1. Performing a review of the documentation and collecting any additional data required, (including Laboratory reports).

3.4.2.2. Processing the results.

3.4.2.3. Drawing up a trial conclusion with a clear outcome of the trial.

3.4.2.4. Organising for the destruction of any non-saleable trial material.

3.4.2.5. Communicating the trial outcome to all affected parties.

3.4.3. Alterations to documents/processes as a result of the trial are to be carried out using the Change Control system.

4. Trial Preparation Checklist

The following lists some of the most common considerations that should be discussed at the Pre-Trial meeting:

4.1. How much the cost involved?

4.2. Does this trial have any impact on the product registration?

4.3. Are all trial components available? If not, what is the lead-time required to order these? Will this interfere with supply of routine production components?

4.4. Is this the most cost efficient way of achieving the trial outcome?

4.5. Are MI (Manufacturing Instruction) sheets required / are MI sheet amendments required?

4.6. What testing is required? Are test methods available for all required testing?

4.7. Does each department have the resources (equipment and personnel) to support the trial?

a) Production – Review trial Protocol to ensure it can be fully understood by ALL production staff and it complies with the process. Review trial report and provide sufficient trained personnel to support the trial.

b) Technical Service– Provide sufficient resources to create manufacturing instruction update technical documents and stability cards as necessary.

c) Validation/Engineering/QA – Provide sufficient resources to write trial Protocols, execute and support trial protocols and write trial reports.

d) Logistics – schedule trials and order/allocate components.

e) QA – Review documents for GMP compliance.

