

# Standard Operating Procedure

## Title: In-House Trial Procedure

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- f) Laboratories - test products within allowed timeframes, draw up test methods if required, release batches.
- g) Warehouse – Pick components specific to the trial, dispose of reject material after the trial, and ship finished goods.

### 5. Protocol for Trials

All documentation and data generated during the trial is considered GMP documentation for retention and archiving purposes. It must be retained in a manner that permits traceability and ensures that it is readily retrievable.

The protocol must describe how the trial activities are to be executed and define the acceptance criteria. It must be approved by QA, issued in advance of the work and be version controlled. Where deemed appropriate, the rationale, justification, scope, and strategy should be documented.

Trial Protocols and documentation must be flexible and tailored to the proposed trial. The following checklist will assist protocol and documentation preparation:

The protocol should include the following, as appropriate:

1. Detailed objectives
2. Process description
3. List of products
4. List of process, facilities, systems and equipment to use
5. Summary of critical parameters and activities to evaluate
6. Number and identity of runs / batches
7. Release specification/s and list of analytical methods
8. Acceptance criteria
9. Proposed in-process controls
10. List of forms that are required to be filled by production
11. Additional testing to be carried out
12. Sampling plan and testing procedures
13. Methods for recording and evaluating results
14. Functions and responsibilities
15. Proposed timetable
16. Checklists to include all important steps
17. Log sheets for all data to be recorded.
18. Checklist listing equipment settings prior to alteration and confirming these have been returned to original setting on completion of trial. Entries need to be confirmed by a second person.

### 6. Trial Conclusion

The Trial Conclusion includes, but is not limited to:

- 6.1. The summary of the raw data and evaluation of the work against the acceptance criteria.
- 6.2. A clear conclusion, stating whether the trial has been completed and if successful or not.
- 6.3. Any recommendations for future implementations.