5.2.1 **Lot Numbers and Identification**
Must contain the producer's lot numbers and the name of the source of the material or in house materials so that they can be identified. As much as possible of the supplied identification for the material is to be recorded to enable tracking of the details of the material. A batch number based on the format “8SBXX” where XX is a 2 digit sequential number is issued to the trial. This also separates the trial product from the batch numbers used for release for sale products.

5.2.2 **Safety**
Must contain the appropriate safety instructions; this can include MSDS information that could accompany the material.

5.2.3 **Instructions**
Must contain detailed instructions of how the material is to be handled and in what machinery and equipment it will be used.

5.2.4 **Protocols**
If a Process Qualification or Trial Protocol is involved with the work it is to be referenced

5.2.5 **Cleaning**
Procedures for recording machine cleanliness and readiness are to be followed, so there is a record of machine usage that can be related to the next product the machinery is used for.

5.2.6 **Disposal**
Once the trial is complete the disposal of the material should be recorded, for example "Moved to reject area of warehouse".

5.2.7 **Document Storage**
Completed documents are to be stored with all other Manufacturing Instruction (MI's) and PIs in the Quality Assurance Department filing system from where it can be retrieved if needed later.

5.2.8 **Bulk/Placebo Trial Materials and Bulk Capsules**
All bulk quantities of trial material must be stored in Quarantine Hold.

5.2.9 **Notification of Planning / Commercial**
Production and Commercial should be notified of the impending trial so that they can allow for its impact on production capacity.

5.2.10 **Impact on Cleaning Validation Status**
Any new excipients or API's need to be evaluated for their impact on the cleaning validation status of equipment or process trains in the plant. Consultation with Technical Services or a specialist in cleaning validation will enable evaluation of the new materials against the Cleaning Validation Plan to determine if the new materials are a worst case for the equipment involved. A brief assessment report of this can be the documentation to show that this has been taken into account.

5.2.11 **Non Standard Testing in QC Laboratory**
Trial process will often result in samples to be tested by the QC Laboratory. A *QC Laboratory Analytical Testing Report for Non Standard Testing* form (**Form-715**)

