

# Standard Operating Procedure

## Title: Reconciliation of Component and Product

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- 1.2. The purpose of reconciliation is to ensure that all materials have been accounted for and no mix-up occurred. Reconciliation is carried out on printed and/or coded components and the finished product. The limits outlined in this procedure should help detect errors at the time of manufacture and avoid release of a non-conforming product.
  - 1.3. Reconciliation should be performed at the end of each stage, especially if the goods are moved from one location to another. Final reconciliation should cover the whole process.
  - 1.4. The reconciliation calculation should be based on real figures. Estimate is allowed in relation to materials that can be lost during the process,
  - 1.5. It is of prime importance that all products are correctly identified (labelled). A series of systems - defined by batch documents and SOP's - exist to ensure components are correctly labelled, e.g.
    - Unique component Material and version number
    - Bar code checks
    - Reconciliations after pre-coding
    - Line Clearance/Opening/Cleaning Procedures
    - Security storage
    - Sampling of all printed and/or coded materials

### 2. Procedure

- 2.1. At the end of each specific packing of a batch or part-batch, the printed components and product will be tallied by the Machine Operator, e.g. labels, cartons, leaflets, tablets, etc.
- 2.2. These components will be reconciled as a % yield, comparing the number at the start with the number at the end of the process including all waste that occurred during the process.
- 2.3. % yield =  
$$\frac{\text{No. of Goods produced at the end of process} + \text{Rejects} + \text{Samples} + \text{Returned}}{\text{No. of goods received at the start of process}} \times 100$$
- 2.4. All components and products should reconcile 100%, however, allowances are made (Tolerance limits) to allow for counting error and/or minor inconsistencies.  
  
ANY UNUSUAL situation and out-of-tolerance tally must be investigated immediately on checking the reconciliation.  
  
In the case of the out of the range result a recount must be done and the entries corrected. If the % yield is still outside the allowable limits a thorough investigation must take place to ensure the cause of such a deviation to establish that no mix up has occurred.
- 2.5. Yields outside the set tolerances must be explained in a Deviation Report (DR). See SOP QMS-035.

### 3. Example-Allowable Tolerances for Printed Components

Batch Size (Packs)	0 50,000 Packs	Over 50,000 Packs
Cartons used on packs	99 -101%	99.5 - 100.5%
Leaflets used on units	99 -101%	99.5 - 100.5%
Labels used on units	99 - 101%	99.5 - 100.5%

**Note:**

The number of leaflets received on the line should be taken as the amount specified on the manufacturer s label, or in the case of partial boxes, the number written on the partial sticker.