Procedure: Batch Processing Instruction and Recording

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# Purpose

The purpose of this procedure is to ensure that the correct batch processing instructions are used in the manufacture of product, and completed and stored correctly.

# Scope

The scope of this procedure includes all products manufactured by [Company].

# Responsibilities

Amend this section to reflect company structure.

|  |  |
| --- | --- |
| Role | Responsibility |
| Quality Manager | * Approval of batch processing instructions. * Approval of completed batch processing records. |
| Production Manager | Approval of batch processing instructions. |
| Production Associates | * Verifiy batch processing instructions before batch is manufactured * Complete batch processing record during manufacture, including deviations * File and store batch processing records after manufacture. |

# Procedure

## General

Each batch of finished goods must be accompanied by a batch processing instruction.

Batch processing instructions must be approved before batch manufacture can commence. Batch processing documents are controlled documents and managed under Procedure QP401: Document Control once initiated.

Deviations made from the batch processing instructions must be recorded at the time they are made.

## Master batch processing instruction

As master batch documents assure continuity of product from batch to batch, control and management of these documents is to be carefully controlled.

A master batch processing instruction is required for each product manufactured. This must reflect the formulation and processing instructions required to successfully manufacture the product. Master batch processing instructions are managed as controlled documents, see Procedure QP401: Document Control.

Vary the template to suit the type of product manufactured.

Master batch processing instructions must contain:

* product name and strength and description of the dosage form
* name, weight or other measure of each active ingredient per dosage unit or weight or measure of the product
* statement of the total weight or measure of the dosage unit
* complete list of all components, each clearly and unambiguously described with name, code, quality as appropriate, with the weight or measure required using the same units (e.g. gram, mL)
* details of any calculated excess of component
* details of weights or other measures at appropriate phases of processing
* statement of theoretical maximum and minimum yields outside of which investigation is required
* full description of product containers, closures, packaging materials
* specimen copy of all labels
* complete manufacturing/processing instructions for each stage of manufacture
* details of sampling or other in-process checks to be carried out.

## During manufacture

The batch processing instructions are to be completed at the time the batch is processed and must include:

* results of pre-use checks to ensure the area is clear, clean and suitable for use
* a record of all equipment and facilities used and dates and times they were used
* records of actual weights or measures of active ingredients and all other components used during processing or manufacture. Batch numbers must be recorded. Each entry must be completed, signed and dated by one operator and checked, signed and dated by another operator.
* a record of all equipment and facilities used and dates and times they were used
* detail of any deviations to instructions, weights or measures required, together with explanations as to why these deviations are acceptable
* results of sampling or other in-process checks undertaken
* post-use checks to ensure all materials, labels, documents are accounted for
* identification of all personnel performing, supervising or checking during manufacture.

## At completion of manufacture

When batch processing instructions have been carried out and product manufactured, the batch processing instructions become the batch processing record and are treated as controlled records and managed under Procedure QP403: Control of Records.

As soon as possible after the completion of the batch, the batch processing record must be checked for completeness, and include associated documents such as in-process results, Quality Control (QC) testing results and deviations.

The completed batch processing record and associated documents must together form a complete record of manufacture. They must be sufficient, without requirement to refer to other data, to enable a full quality control review to be undertaken and quality verdict given according to Procedure QP804: Product Batch Release.

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
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Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
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Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP401 | Document Control |
| QP403 | Control of Records. |
| QP804 | Product Batch Release |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
|  |  |

List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

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