Procedure: Product Batch Release

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# Purpose

The purpose of this procedure is to ensure the appropriate control of the release process for finished pharmaceutical products at [Company].

# Scope

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

# Responsibilities

Amend to reflect company structure.

|  |  |
| --- | --- |
| Role | Responsibility |
| Quality Manager or delegate | Reviews batch manufacturing and associated documents and releases finished product. |
| Production Manager or delegate | Completes and collates all batch related manufacturing documents and delivers to the Quality Manager in a timely manner. |
| QC Manager or delegate | Completes and collates all test results relating to product release. |

# Procedure

## General requirements

### Batch record masters

The Quality Assurance Department maintains a file of master Batch Processing Instructions (BPI). There is usually one BPI for every product, including different dosages and presentations.

Whenever a change is made to a product specification, the change control record must include a review of the BPI master for impact on the content.

Whenever a batch of product is scheduled for manufacture, a copy is made of the master for use in the manufacture of the batch.

### Batch record issue

The production department usually receives notification for batch manufacture from the planning group. The BPIs for upcoming batches are made by photocopying the master records, marking each page with an authorisation signature and issuing to production. Record the issue on a BPI register.

The BPI records the sign-off of typical key production activities, such as:

* Equipment cleaning
* Line clearance
* Assembling raw materials and components for manufacture
* Samples taken for testing
* Packaging samples
* Rejects
* Production records
* Product, component reconciliation, including packaging
* Laboratory test results
* Final batch QA disposition

### Batch record QA review

Quality Assurance (QA) receives the completed BPIs from production and assembles it with other batch related documentation, forming the entire batch record.

The BPI is reviewed along with the associated documents including information from measuring and monitoring devices and test results from Quality Control (QC) testing laboratories.

### Batch review checklist

The QA review of each batch must be performed using a checklist as a guiding document. This ensures a consistent approach between QA associates and in time. The checklist should be a controlled document.

The documents are reviewed for the following which should be included in the checklist.:

|  |  |
| --- | --- |
| * Verify that the BPI is properly authorised and issued * issue correct batch number * correct product name * correct product strength * packaging size (if applicable) * correct product code * correct date of manufacture * correct components and quantities have been issued * Sample packaging label matches expected * theoretical, expected and actual yields calculated and correct * yield satisfactory – comparable to expected and theoretical * packaging components reconciled properly * correct expiry/ retest date assigned * deviations from the instructions * signed off by the operator and supervisor | * in process testing carried out and completed * in process testing passed * any issues have been documented and resolved * document is completed correctly * Perform a page count and verify that all required pages are present and in order * Verify that all entries and marks on the BPI conform to good documentation practices * BPI signed by production management * Verify all expected charts and graphs are present * changes under change control * CAPAs initiated * deviations closed * issues resolved * sampled and tested by QC * QC testing appropriate and passes. |

### Batch review corrections

If the batch reviewer finds that information is missing or incorrect, these errors must be highlighted and the BPI returned to production or QC for corrections to be made or an explanation justifying the entries made.

### Deviations

If the batch reviewer finds that the batch manufacturing process has deviated from the expected process or that QC results are not within specification, then a deviation must be raised to investigate the anomalous results.

## Status labels

QA controls all quality status labels.

The following status labels are used as per Procedure QP711: Status Labelling.

|  |  |
| --- | --- |
| For finished product, intermediate product or materials that… | use label… |
| is awaiting testing | Quarantine |
| has been tested and meets required specification | Released |
| has been tested and does not meet the required specification | Reject |

## 

## Acceptance criteria

Acceptance criteria for the sampling and testing conducted by the quality control unit must be clearly stated on the BPI. In this way QA reviewer can ensure results are appropriate and adequate to assure that each batch meets the appropriate specifications.

Documentation recording the manufacture, testing and results must conform to Procedure QP401: Document Control and fully reflect the manufacturing process and any deviations used to manufacture the batch.

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.

## Assignment of verdict

If all acceptance criteria have been met, all documentation is present and any deviations approved, the product may be reassigned to ‘Released’ status and the batch labelled accordingly. This process must be recorded in the batch documentation. If it fails, it must be assigned to ‘Reject’ status and the batch labelled accordingly.

## BPI record archival

The QA department must file all BPIs in a secure, fireproof area and retain in accordance with the documentation requirements specified in Section 5.1 of Procedure QP403: Control of Records.

## Review of BPI review process

The QA department must periodically audit the review process to ensure the effectiveness in maintaining the level of BPI documentation to the expected standards.

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. |
| BPI | Batch Processing Instruction |
| QA | Quality Assurance |
| QC | Quality Control |
|  |  |

Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
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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 |
| QP711 | Status Labelling |

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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