Procedure: Status Labelling

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| Prepared by: | Job title: | Signature: | Date: |
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# Purpose

To ensure that equipment, raw materials, labelling, packaging and pharmaceutical product at [Company] is appropriately status labelled in accordance with current Good Manufacturing Practice required in the identification and labelling of materials.

# Scope

The scope of this procedure includes all materials and equipment used in the manufacture of pharmaceutical product.

# Responsibilities

Amend to reflect organisational structure.

|  |  |
| --- | --- |
| Role | Responsibility |
| Quality Manager | * Initiates and maintains this procedure. * Ensures staff are trained in this procedure. |
| Production Manager | * Initiates and maintains this procedure. * Ensures staff are trained in this procedure. |
| All staff | Correctly label raw materials, products and samples receipted and used within the company. |

# Procedure

## General requirements for labelling

All materials within the facility are to be correctly and adequately labelled. Labels include:

* quarantine label
* released label
* dispensing label
* product label
* sample label
* reject label
* container sample label.

Only suitably qualified and trained staff are to complete and apply labels.

Only Quality Control (QC) staff can change the status of a product, for example from Quarantine to Approved/Released.

## Quarantine labels

Quarantine labels are applied by Inwards Goods staff immediately when receiving raw materials and are orange in colour.

|  |  |  |
| --- | --- | --- |
| QUARANTINE | | |
| DO NOT USE | | |
| SAMPLED   By:……….Date:….   Sample of | PRODUCT: |  |
| Product Code: |  |
| Control Number: |  |
| Date received : |  |
| Container | of |

Amend label colours if unsuitable for your company’s QMS document system.

## Released labels

Released labels are applied (over the quarantine label) by QC staff when raw materials and finished products have passed their test requirements. Passed labels are green in colour.

|  |  |  |
| --- | --- | --- |
| RELEASED | | |
|  | PRODUCT: |  |
|  | Product Code: |  |
|  | Control Number: |  |
|  | Released by: |  |
|  | Release date: |  |
|  | Container | of |

## Sample labels

Sample labels are applied by QC staff when sampling raw materials or by manufacturing staff when taking In-process samples. Sample labels are white in colour.

|  |  |  |
| --- | --- | --- |
| SAMPLE | | |
|  | PRODUCT: |  |
|  | Product Code: |  |
|  | Storage conditions: |  |
|  | Control Number: |  |
|  | Suppliers Batch No: |  |
|  | Sampled by: |  |
|  | Date sampled: |  |
|  | Sample | of |

## 

## Reject labels

Reject labels are applied by QC staff or by manufacturing staff when rejecting materials. Reject labels are red in colour.

|  |  |  |
| --- | --- | --- |
| REJECT | | |
|  | PRODUCT: |  |
|  | Product Code: |  |
|  | Control Number: |  |
|  | Process Stage: |  |
|  | Rejected by: |  |
|  | Date: |  |
|  | Container | of |

## Dispensing tags

Dispensing tags are applied by Dispensary staff when dispensing raw materials for manufacturing. Dispensing tag labels are white in colour.

Dispensing Tags are removed from the packaging of the raw materials and attached to the Batch Instructions as a permanent record of the materials used in the batch.

Raw Material code: …………………...……………..…..

Raw Material name: …………………...……………..…..

Date dispensed: ………….….…By:. …………………..

Control Number: ……...…….……....……..

DISPENSED FOR:

PRODUCT:

Product Code:

Batch No.:

Batch number - ……………….………….…..

Quantity Dispensed: ……….……………....

## Cleaning tags

Cleaning tags are applied by manufacturing and cleaning staff when equipment or rooms are to be cleaned. Cleaning tags are white in colour.

Cleaning Tags are removed from the equipment that has been cleaned when the next batch is started and attached to the Batch Instructions as a permanent record.

Batch Number:……….….......…………..

Batch Number:……….….......…………..

Batch Number:……….….......…………..



Previous Material/Product:……………...……………

Cleaning Method: ………….….……………..

Cleaned by and Date: ……...………………

ATTACH TO BATCH INSTRUCTIONS:

Batch Number:……….….......…………..

Code Number - ……...……...……..………..

EQUIPMENT/ROOM: ……………….……………....

Batch Number:……….….......…………..

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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| Associated forms and procedures | |
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| Doc. No. | Document Title |
|  |  |

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

| Associated records | |
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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.

DOCUMENT END