Procedure: Sampling

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# Purpose

The purpose of this procedure is to ensure the correct, safe and hygienic sampling of all incoming materials and manufactured product at [Company].

# Scope

The scope of this procedure includes all incoming raw materials, finished products, and product contact packaging materials.

# Responsibilities

Amend this to reflect company structure.

|  |  |
| --- | --- |
| Role | Responsibility |
| Production Manager | Initiate and maintain safe and hygienic sampling practices. |
| Quality Manager | Initiate and maintain safe and hygienic sampling practices. |
| Sampling operators | Only trained staff can complete any sampling operation. |

# Procedure

Prior to sampling, materials are to be inspected for identity, integrity, and obvious signs of damage or contamination. Any damage, contamination or spillage is to be reported to the production manager immediately.

## Health, safety and environment

All sampling of chemicals must take place in a suitably ventilated, clean area (for example, a fume hood or fume cupboard).

Hands must be washed before and after sampling raw materials and product.

Protective clothing appropriate for the task must be worn. Any associated Material Safety Data Sheets (MSDSs) for each material should be available and detail the minimum personal protective equipment (PPE) to worn at all times.

Before a sampler carries out any sampling activities, they must read the associated MSDS.

All chemical spillages must be cleaned up and reported to the Production Manager immediately.

## General sampling requirements

Materials requiring sampling are identified by following Procedure QP707: Verification of Purchased Materials and Procedure QP709: Manufacture of Product.

All sampling or dispensing is to be performed in suitably ventilated, clean area (for example, a fume hood or fume cupboard). The sampling area must be clean prior to sampling and any spills must be cleaned up immediately.

Before sampling, verify the identity of the material and ensure that all containers are labelled with quarantine stickers fixed to the individual containers. The quarantine section of the label must be completed.

Each sample is placed in a clean sample bottle or appropriate container and labelled according to Section 4.4.

If one delivery of material is made up of different batches, each batch must be considered as separate for sampling, testing and release.

The quantity sampled should be sufficient to enable a repeat of the required testing of the material or product.

## Sampling difficult materials

For incoming materials that are highly sensitive to moisture or oxygen, sampling should be carried out at the time of use.

For low melting point solids, melt and mix the materials thoroughly prior to sampling to ensure a homogeneous sample is taken.

## Labelling

Status and sample labels are used as per Procedure QP711: Status Labelling.

### Incoming materials

Amend to describe the type of labels the company uses

Attach a quarantine labels to each container of each delivery on receipt, pending testing and release of the material. Quarantine labels record:

* product name
* product code
* control or batch number

Quarantine labels are also used for recording the sampling information.

After sampling, each quarantine label must be updated to include the following information:

* sample x of n, where x is a sequential number and n is the total number of samples to be taken for that sample lot
* initials of the sampler
* sampling date.

For containers that are not sampled, the sampling section of the quarantine label is crossed out and annotated with the words ‘Not Sampled’.

### Laboratory test samples

The sample number (x of n) is recorded on the sample bottle together with storage conditions and all other relevant information as listed in Section 4.4.1.

### Retention samples

Retention samples must be clearly labelled with ‘Retention sample’ and the information for the sample label must be completed according to Section 4.4.1.

## Number of containers to be sampled

Amend to describe the sampling regime used by the company

### Four or fewer containers received

Where four or fewer containers from the same lot number are received from a supplier, each container is sampled for appearance and identity testing and the remaining tests carried out on a composite sample prepared from proportional amounts from each container.

### More than four containers received

Where multiple containers from the same lot number are received from a supplier, each container must be sampled for appearance and identification testing.

For the remaining tests, a composite sample is prepared from proportional amounts taken from randomly chosen containers. The number of containers to be bulked is calculated using the equation: n = √ N + 1

N = number of containers received and

n = rounded up to the nearest whole number

This sampling regime is repeated for each separate delivery or manufacturing lot number supplied.

## Sampling equipment

The following implements are required for sampling. All implements must be clean and dry before use and cleaned or replaced between sampling of different materials. Where appropriate, use single-use, disposable implements.

* Stanley knife - with removable blades
* Scoops of various sizes
* Spatula(s)
* Pipette(s)
* PVC tape and dispenser
* Sample containers of appropriate type and size for the material being sampled

## Sampling techniques for different types of raw materials

Amend to describe the types of bulk containers the company receives

For each separate manufacturing batch number supplied, sample the required number of containers as described below.

### Bags

Bags are to be sampled from the middle section on the side of the bag.

Prior to sampling, the area to be penetrated must be cleaned with a clean, lint-free cloth.

A ‘V’ shaped notch is cut into the bag, so that the bottom of the ‘V’ is pointing downwards.

The material is then sampled using a spatula or sampling thief.

After sampling, the ‘V’ flap is pushed back and the bag cleaned with a clean, lint-free cloth. The flap is then sealed in position with PVC tape by applying tape along each cut of the ‘V’ and then across the ‘V’.

### Cardboard cartons and barrels – powdered materials

The top of the barrel or carton must be cleaned with a clean, lint-free cloth before opening.

The lid of the barrel or the seal of the carton is broken to allow access to the plastic bag enclosed inside and the seal of the plastic bag is then removed.

Using a sampling spatula, form a cylindrical cone with its apex towards the bottom of the container, so that a sample may be removed as near as possible to the centre and middle of the container.

Sample the material from the bottom of the apex, using a spatula.

Reseal the plastic bag and clean up any spillage.

Reseal the carton with PVC tape or close the barrel with its lid.

### Drums – liquid materials

Agitate the drum to mix and then clean the top of the drum with a clean, lint-free cloth.

Remove the external seal and the closure and take a sample using either a pipette or by connecting appropriate taps to the drum for dispensing.

Reseal the drum and clean up any spillage with a lint-free cloth.

### Bottles

Sample bottles in the same manner as drums (Section 4.7.3). Pour the sample out of the bottle rather than pipetting or connecting a tap.

The neck may be cleaned if necessary with a clean, lint-free cloth moistened with alcohol but the bottle need not be washed.

## Incoming packaging materials

Packaging materials should be sampled and inspected on receipt for identification, integrity and absence of damage.

## In-process samples

In-process samples are taken as instructed in the relevant batch processing instruction (BPI). Label requirements for in-process samples are also specified in the BPI.

The actual sample quantity taken, the time and date of sampling and the processing stage are all recorded on the BPI along with any other relevant information.

Quarantine labelling may also be used for in-process product. If this is so for the company, include a paragraph here similar to section 4.4.1.

## Product laboratory test samples

Each batch of finished goods is sampled for release testing and labelled with:

* product code
* batch number
* specific storage conditions (for example, refrigerate, protect from light)
* initials of the person taking the sample
* date the sample was taken.

The samples are then forwarded to the laboratory for final product release testing.

## Retention samples

Retention samples of all manufactured batches and raw materials must be kept.

The quantity sampled for retention should be sufficient to enable the release testing of the material or product to be carried out twice.

Samples are stored under the recommended storage conditions for the product and are retained for:

* the expiry period plus one year, or
* one year after distribution of the product is complete, or
* three years after the date of sampling, whichever comes first.

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 |
| MSDS | Material Safety Data Sheet |
| PPE | Personal Protective Equipment |
|  |  |

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 |
| QP707 | Verification of Purchased Materials |
| QP709 | Manufacture of Product |
| QP711 | Status Labelling |

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.

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