# Procedure

# SAMPLING

AUTHOR

| | |
|---|---|
| Quality Control Assistant | Signature…… |

VERIFICATION

| | |
|---|---|
| Quality Control Manager | Signature ……. |

AUTHORIZATION

| | |
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| Quality Assurance Manager | Signature …….<br>Date 22.04.2013 |

**Expiry Date** **22/04/2015**

# Re-Approvals Form

RE-APPROVED ON _____

EXPIRES ON _____

QUALITY ASSURANCE _____

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## Revision Matrix

| REVISION | DATE | UPDATE CARRIED OUT AND REASON FOR UPDATE |
|---|---|---|
| 01 | | . Date Rev. 00 Withdrawn |
| 02 | | Date Rev. 01 Withdrawn |
| 03 | | Date Rev. 02 Withdrawn |
| 04 | | Date Rev. 03 Withdrawn |
| 05 | | Date Rev. 04 Withdrawn |
| 06 | | Date Rev. 05 Withdrawn |
| 07 | | Date Rev. 06 Withdrawn |
| 08 | | Date Rev. 07 Withdrawn |
| 09 | | Date Rev. 08 Withdrawn |

| REVISION | DATE | UPDATE CARRIED OUT AND REASON FOR UPDATE |
|---|---|---|
| 10 | | Date Rev. 09 Withdrawn |
| 11 | | Date Rev. 10 Withdrawn |
| 12 | | Date Rev. 11 Withdrawn |
| 13 | | Date Rev. 12 Withdrawn |
| 14 | | Date Rev. 13 Withdrawn |
| 15 | | Date Rev. 14 Withdrawn |
| 16 | | Date Rev. 15 Withdrawn |
| 17 | | Date Rev. 16 Withdrawn |
| 18 | | Date Rev. 17 Withdrawn |

## 1. Scope

To define the method of sampling for Products and Materials.

## 2. Application

The procedure applies to any personnel who are carry out sampling.

## 3. Responsibility

**The Head of Quality Control** to define and issue the Sampling Method and to update it.

**The Quality Control Operator, the Production Operator or the Warehouse Operator** for the sampling of:

a) Intermediates
b) Finished products

**The Quality control Operator or the Warehouse Operator** for the sampling of:

a) Raw materials
b) Packaging materials

The samples of the raw materials which require particular storage conditions should be immediately delivered to Quality Control. Quality Control must store these particular samples in the conditions established in their specifications.

## 4. Procedure

The Sampling Method is a document which forms part of the Specifications of the product and is composed of two parts; Sampling Plan and Mode of Sampling.

### 1) Sampling Plan

Defines the **Size of Sample** to be taken and the **Statistical Criteria** of sampling which depend on certain factors:

- Category of product/material
- Nature and use of product/material
- Reliability of supplier
- Precision required

Depending on the case, the following sampling levels can be adopted:

- **If the number of containers of a batch is between 0 and 10**:
  ALL the containers are sampled;

- **If the number of containers of a batch is between 11 and 50:**
  The number of containers sampled is **n/2 + 1**;

- **If the number of containers of a batch is greater than 50:**
  The number of containers sampled is **√n + 1**;

The **Size of the Sample** depends on the destination, for example;
- Routine analysis;
- Retained sample in this case it should be sufficient to perform at least two complete analysis;
- Stability studies
- Other

**2) Mode of Sampling**

Provides all the necessary details for performing the sampling such as:
- Criteria for randomization of samples; what containers are to be used and how packing should be executed;
- Functions responsible for sampling;
- Equipment to be used and how they should be cleaned;
- Description of the container in which the sample is placed;
- Description of the Security Standards and Environmental Protection to be observed and any other protection precaution required to retain the quality of the Sample as well as the Product from which the sample is taken.

The Methods of Sampling should be formulated according to the following specifications:

- Except for dangerous or toxic materials, each batch of each material should be sampled, analysed and approved or rejected.
- The Quality Control Laboratory, according to the needs of production, decide which products should be sampled. Analysis should be performed close to sampling.
- For dangerous or toxic material or those which are impossible to sample on site, it is essential to have the Certificate of Analysis of the supplier which demonstrates that these materials conform to the specifications.
- The dangerous raw materials which should not be sampled on site should be documented.
- The identification of toxic and dangerous goods must be established by checking the container label.
- The products that by their nature cannot be sampled normally because it would compromise the special precautions given by the supplier, must be subject to particular note within the sampling method which should define the exact mode of sampling.

## 5. Documentation

The older editions of the Sampling Methods should be archived and kept for at least 7 years by Quality Control.
Copies of the current editions should always be available to the workers for sampling.

The Sampling operations should be followed according to the operative instructions (QC.SOP.003/SOI.01) as described below.