



Procedure

Maintenance of Filters in Finishing Area

AUTHOR

Quality Assurance Assistant	Signature.....
-----------------------------	----------------

VERIFICATION

Quality Assurance Manager	Signature
---------------------------	-----------------

AUTHORIZATION

Quality Assurance Manager	Signature Date 22.04.2013
---------------------------	------------------------------------

Expiry Date 22/04/2015



Re-Approvals Form

REAPPROVED ON _____
EXPIRES ON _____
QUALITY ASSURANCE _____

REAPPROVED ON _____
EXPIRES ON _____
QUALITY ASSURANCE _____

REAPPROVED ON _____
EXPIRES ON _____
QUALITY ASSURANCE _____

REAPPROVED ON _____
EXPIRES ON _____
QUALITY ASSURANCE _____

REAPPROVED ON _____
EXPIRES ON _____
QUALITY ASSURANCE _____

REAPPROVED ON _____
EXPIRES ON _____
QUALITY ASSURANCE _____



0. 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01		Date Rev. 00 Withdrawn
02		Date Rev. 01 Withdrawn
03		Date Rev. 02 Withdrawn
04		Date Rev. 03 Withdrawn
05		Date Rev. 04 Withdrawn
06		Date Rev. 05 Withdrawn
07		Date Rev. 06 Withdrawn
08		Date Rev. 07 Withdrawn
09		Date Rev. 08 Withdrawn



1. Scope and Application

To define the rules to follow to ensure that the ventilation system filters in the finishing are in perfect working order.

2. Responsibility

Production Operators, Quality Assurance Manager, Production Manager and Process Engineer.

3. Procedure

To ensure working conditions in the finishing area are in full compliance with the requirements of Good Manufacturing Practice, one of the fundamental requirements is to have a perfect ventilation system, for which purpose it is essential that the installed filters are perfectly efficient and that do not present any abnormalities, fractures, saturation or anything that does not allow satisfactory working conditions.

For this purpose, and in order to ensure the conditions of pressure defined by procedure P.SOP.016 with respect to the finishing area, a daily check by means of verification of the lights present in the technical room and a periodic inspection of the same filters in the manner described below is required.

3.1 Daily Checks

For a daily check the operator, at the start of shift, has the task of checking that the red lights in the technical room is not lit to signal filter anomalies relating to:

- Expulsion Units (HEPA filter)
- Air Handling Units (HEPA filter)
- Ventilation Units (HEPA filter)

These lights come on when there is a pressure difference before and after the filter.

In the event that one or more of these indicators is lit, the operator has the duty to inform the Production Manager who will proceed to communicate this to the Process Engineer, who will be responsible for maintenance of these filters.

3.2 Periodic Inspection

Not all filters have a signaling device in case of an inefficiency. Also, it is possible to have an ignition failure of the lamp that would indicate a filter abnormality. For these reasons it is necessary to carry out maintenance of the filters during their cleaning.

In the case that these operations indicate filter abnormality, that filter is immediately replaced.

It is the task of the Process Engineer to ensure that the internal maintenance is carried out as defined in the maintenance plan. It is also the task of the Process Engineer to supervise the execution of these operations.