



Procedure

Loading and Unloading of Materials in Production

AUTHOR

Quality Assurance Assistant	Signature.....
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VERIFICATION

Quality Assurance Manager	Signature
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AUTHORIZATION

Quality Assurance Manager	Signature Date 22.04.2013
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Expiry Date 22/04/2015



Re-Approvals Form

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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01		Date Rev. 00 Withdrawn
02		Date Rev. 01 Withdrawn
03		Date Rev. 02 Withdrawn
04		Date Rev. 03 Withdrawn
05		Date Rev. 04 Withdrawn
06		Date Rev. 05 Withdrawn
07		Date Rev. 06 Withdrawn
08		Date Rev. 07 Withdrawn
09		Date Rev. 08 Withdrawn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 general rules to be observed in order to ensure that there is no possibility of contamination during the loading and unloading of products in the production plant.

2. Responsibility

Responsibility lies with production personnel

3. Procedure

The steps outlined in this procedure form constitute a requirement to avoid any possibility of product contamination. It is very important that there is no contact between different products or any human or environmental contamination. For this purpose it is necessary to respect these general rules that are to be strictly followed by production operators when they are engaged in a process of loading or unloading a product in the production area:

- Always keep the doors of the department closed.
- Check that the area above the place for loading or unloading does not contain any objects that can drop into the reactor or material that may cause contamination. This area will be subject to constant cleaning and maintenance.
- Before any operation, it is important to make sure that the surrounding area has been thoroughly cleaned in accordance with the rules laid down in procedure G.SOP.008.
- Use only tools and utensils which are either new or thoroughly cleaned if used in previous operations.
- Use the local exhaust system by placing it in the area over the equipment in use. Clean the nozzle with anti-static cloth and replace the vacuum hose before each loading or unloading operation.
- Wear the appropriate Personal Protective Equipment according to the task to be performed. All disposable Personal Protective Equipment should be discarded immediately after completion of the loading or unloading of each product.
- Carry out all the loading and unloading operations in the context of transferring solvents/liquids between two reactors (or between a reactor and a dropping funnel) according to the instructions detailed in the pertinent production procedures.
- Avoid the loading and unloading of different products simultaneously in the same department. For this purpose, Production Manager, when preparing the production program, evaluates the timing of the various synthesis in such a way that loading and unloading of different products simultaneously does not occur. The Production Manager (or Supervisor) then has the task of ensuring that operators comply with this rule during production.
- At the end of each operation, clean the facility in accordance with the instructions provided in the pertinent batch production record.
- Each reactor has a hopper attached on top of it. This hopper is for the sole use of loading raw materials inside the reactor. Production is prohibited from loading Active Pharmaceutical Ingredients or their intermediates through these hoppers.

The transfer of the product from the reactor to the Buckner Filter will take place according to procedure P.SOP.008 and P. SOP.009.

Procedure P.SOP.008 must be followed in order to transfer the product into previously cleaned and weighed drums. If required by the MPR, the wet product shall be loaded in the dryer in accordance with procedure P.SOP.008.



The Production Manager (or Supervisor) is responsible for verifying compliance with these rules.