



## Procedure

# FRACTIONATION

### AUTHOR

|                             |                |
|-----------------------------|----------------|
| Quality Assurance Assistant | Signature..... |
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### VERIFICATION

|                           |                 |
|---------------------------|-----------------|
| Quality Assurance Manager | Signature ..... |
|---------------------------|-----------------|

### AUTHORIZATION

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

**Expiry Date      22/04/2015**



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## Re-Approvals Form

REAPPROVED ON \_\_\_\_\_  
EXPIRES ON \_\_\_\_\_  
QUALITY ASSURANCE \_\_\_\_\_

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| 01       |      | Date Rev. 00 Withdrawn                   |
| 02       |      | Date Rev. 01 Withdrawn                   |
| 03       |      | Date Rev. 02 Withdrawn                   |
| 04       |      | Date Rev. 03 Withdrawn                   |
| 05       |      | Date Rev. 04 Withdrawn                   |
| 06       |      | Date Rev. 05 Withdrawn                   |
| 07       |      | Date Rev. 06 Withdrawn                   |
| 08       |      | Date Rev. 07 Withdrawn                   |
| 09       |      | Date Rev. 08 Withdrawn                   |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

This Operative Instruction aims to regulate the activities of raw materials fractionation.

## 2. Definitions

**Fractionation:** the division of a raw material batch in multiple parts according to the dispensing requests.

## 3. Responsibility

Warehouse

## 4. Procedure

- Wear appropriate Personal Protective Equipment... In particular wear: disposable and acid resistant coveralls; antistatic safety footwear, full face or half face mask with the appropriate filters (based on the concentration of potential contaminants), safety glasses (with half-face masks), latex gloves for handling non-corrosive substances, neoprene gloves for manipulation of acids and bases. In case of any uncertainty about Personal Protective Equipment consult the material safety data sheet of the substance in question. In case of small accidental spills, use the available anti-spreading kits. In case of contact with substances, consult the material safety data sheet and use the emergency showers and eye wash in the Department.
- Wear work gear and use the containers stipulated in the raw material specification in question.
- Check the cleanliness of the premises, equipment and containers from the pertinent cleaning records.
- Label containers of raw materials with appropriate labels described in M.SPC. 001 and corresponding form, bearing the information specified in specification M.SPC. 001.  
The label must be prepared and applied directly on the site used for fractionation by warehouse operators. The label shall be applied directly on the primary packaging and a transparent sticker placed over the label to maintain its integrity.
- In the case of flammable substances, the containers must be earthed by means of cable clamp.
- Only open containers of raw materials under aspiration hoods.
  - Unless instructed otherwise by quality assurance, always use the oldest batch first (FIFO), unless another batch with a nearer expiration date is



available (FEFO). It's up to quality assurance to occasionally verify, compliance with this rule by comparing the batch number printed on the batch production record with the warehouse record sheets.

- If you have multiple containers of the same batch of raw material, first open the container from which an earlier withdrawal had already been carried out.
  - During the opening and subsequent manipulations verify the absence of visible abnormalities in both the container and the raw material; in the event of anomalies, the fractionation operation must be suspended and communicated to quality assurance and quality control. The faults found and the resulting measures should be recorded on the Batch Production Record.
- Reset the balance and make sure it is on a level plane.
  - Perform the weighing directly into the container after you reset the tare with the container. In the case of solid raw materials, these should be placed inside a double polyethylene bag.
  - If a fraction must be set up using portions of two or more different batches of the same raw material, each of these portions should be contained in a different container.
  - Close the container and note the net weight on the warehouse record sheet, on the container label and on the Batch Production Record.
  - Close and put into storage containers of raw materials at the end of their use.
  - Remove or cancel out all labels and/or descriptions from completely emptied containers.
  - All containers used for the operations described are considered "disposable" and should thus be disposed of in accordance with the procedures in force.

Operators are required to wear all necessary disposable Safety Protective Equipment, and change them when working on a different product. It is the responsibility of quality assurance to ensure compliance with these rules.