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| **STANDARD OPERATING PROCEDURE**  **NON-CONFORMING PRODUCTS (NCR)** |

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| Date | May 8, 2021 |
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## Purpose

To describe a method for identifying, documenting and resolving the non-conforming finished products and establish an effective corrective plan for eliminating undesirable conditions.

## Scope

This procedure is applicable to all non conforming products produced in LMD production area

## Responsibility

## Production Staff

## Quality Control Staff

## Research and Development Staff

3.4 General Manager

## Procedure

* 1. **Identification of non-conforming product**
     1. The person who observes the non-conformance shall inform the concerned department (Quality Control/ R&D Department) immediately
     2. Non-Conformance can occur in quality of finish product, operating procedures or packaging of product
     3. Non-conformance may occur due to planned deviations: Ignorance in weighing, Error in operations, Skipping process parameters, Issuance of faulty or substitute material, Use of secondary packing material, Issuance of erroneous formulations and Negligence in testing procedure
     4. Non-conformance may occur due to un-planned deviations: Change in environmental conditions, Equipment failure during process, Excess wastage
  2. **Initiation of non conformance report NCR form**
     1. Concerned department shall issue a non-conformance report
     2. Concise details of malfunctioning will be mentioned in non-conformance report describing which product and batch is not conforming to specifications and instantaneous remedy (if any) to resolve the malfunction
     3. Initiator sign the document and forward it to production in-charge who then inform the R&D/QC
  3. **Immediate Action Plan**
     1. If non-conforming product can be rectified with immediate action then R&D/QC department will communicate remedy for immediate action
     2. If non-conforming product cannot be rectified then initiator will communicate to production in-charge and evaluation of non-conformance continue till closure with R&D/QC
  4. **Investigation of non-conformance**
     1. Production in-charge will evaluate the non-conformance
     2. Events during manufacturing will be evaluated stepwise for Root cause analysis
     3. Non-conformance will be categorized as mentioned on form. Repetitive non-conformance will be monitored during evaluation process
     4. Describe the problem of the occurrence non-conformance and forward it to R&D department
  5. **Corrective and Preventive Action**
     1. Non conformance report form will be evaluated by GM and R&D person. R&D will inform production for rectification.
     2. If non-conforming product cannot be rectified then plan for work off will be designed
     3. Corrective and preventive actions will be updated on non-conformance report form from R&D department and communicated to all relevant departments (QC and Production)
  6. **Closure of non-conformance**
     1. After all necessary action performed, NCR form will be closed with approval from R&D
     2. All NCR forms must be closed within 15 days of non-conformance occurrence
     3. Repetition of non-conformance occurrence for 3 times will lead to change in formulation, process or packing material
     4. All NCR forms record must be updated and maintained