STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Control of Non- Conforming Products	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down a procedure for Control of Non-Conforming Products.

2.0 SCOPE:

This SOP is applicable for Control all the Non-Confirming Products at ……...

3.0 RESPONSIBILITY:

Officer/Executive-QA

4.0 ACCOUNTABILITY:

Head – QA

5.0 DEFINATION:

Nonconformity: In quality management, a nonconformity (sometimes referred to as a defect) is a deviation from a specification, a standard, or an expectation. Nonconformities can be classified in seriousness multiple ways, though a typical classification scheme may have three to four levels, including critical, serious, major, and minor.

Sources of nonconformity: the causes of nonconformities aren't unlimited and therefore determinable. Common causes for deficiencies to arise include.

- Poor communication (or miscommunication).
- Poor documentation (or lack of documentation).
- Poor or limited training of personnel.
- Poor motivation of personnel.
- Poor quality materials (or lack of appropriate materials).
- Poor quality tools and equipment (or lack of appropriate tools and equipment).
- Poor or dysfunctional operating environment.

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6.0 PROCEDURE:

6.1 All the received material of a consignment shall be kept in the de-dusting area.

6.2 It shall be De-dusted and checked and ensured that all the supplied pack is having details like: Brand Name, Generic Name, Specification, Batch No., Lot No., Manufacturing Date, Expiry Date, Manufacturer's name etc.

6.3 In case of any non-conformances it shall not entered in the respective material inward register.

6.4 QC and QA shall be intimated about it's non-conformance. QC personnel shall go inside the store and inspect the consignment for it's non conformance and give their observation details to QA.

6.5 QA personnel shall check the report submitted by QC, go inside the store and inspect the consignment and ensure about its non conformance.

6.6 Material's received under consignment declared as non confirming material by QC/QA shall be transferred inside rejected area and purchase department shall be intimated about the same.

6.7 Purchase department shall inform the supplier related with non conformance of the said consignment requesting to return it from factory premises without any delay.

6.8 If Party is not giving response, a reminder shall be sent after 72 hours followed by one reminder every day.

6.9 If party is not giving his consent even after 72 hours from the 3rd reminder, the request for the destruction of the material shall be raised by stores and it shall be sent to Head-QA.

6.10 Head QA shall inform to the director about the same, after director's approval, Destruction Certificate for the same shall be prepared, it shall be authorized by Head QA and material shall be destroyed in presence of Production, QA Personnel, Stores, and Security Personnel as per SOP.

6.11 After Destruction the Certificate shall be signed by all the members present during destruction.

6.12 Original copy of Destruction Certificate shall be stored in QA and Photocopy shall be distributed to following department.

- **a.** HR Department
- **b.** Store Department
- **c.** IPQA Department

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7.0 REFERENCE:

SOP Titled "Destruction of Raw Material, In-Process Material, Finished Product & Packaging Materials".

8.0 ANNEXURES:

Not Applicable

9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department
- Controlled Copy No.1 Head Quality Assurance

10.0 ABBREVIATIONS:

QC : Quality Control

QA : Quality Assurance

No. : Number

HR : Human Resource

Ltd. : Limited

SOP : Standard Operating Procedure

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		