

<b>STANDARD OPERATING PROCEDURE</b>		
Title <b>Self-Inspection</b>		
SOP No.: <i>XXX</i>	Revision No.: <b>001</b>	Effective Date <i>DD-MMM-YYYY</i>

## 1.0 Purpose

- 1.1 This Standard Operating Procedure (SOP) describes how a self-inspection is to be conducted to assess the GMP compliance.

## 2.0 Scope

- 2.1 This SOP applies to self-inspection to be conducted for *XXX company*.

## 3.0 Responsibility

- 3.1 It is the responsibility of the Management to appoint a team of personnel to perform for self-inspections. To ensure impartiality and comprehensiveness, the appointed self-inspection team should comprise of personnel from different departments. Personnel involved in self-inspection shall have the relevant training and/or experience (e.g. Lead Auditor course and ASEAN GMP Guidelines for *TM or HS*).
- 3.2 It is the responsibility of the appointed team to carry out self-inspection and prepare a self-inspection report. Self-inspection shall be carried out in an independent manner too i.e. no conflict of interest.
- 3.3 It is the responsibility of the Head of the relevant departments and all personnel to implement adequate corrective and prevention actions, and ensure that all findings are addressed and proposed actions are followed-through.

## 4.0 Procedure

- 4.1 A self-inspection is carried out every *monthly, quarterly or yearly*.
- 4.2 The self-inspection is carried out in accordance with the ASEAN GMP Guidelines for *TM or HS* and all areas in the GMP Guidelines will need to be covered.
- 4.3 Before the self-inspection, the appointed team shall review the previous self-inspection to verify that all Non-conformities (NCs)

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have been closed out and all corrective and preventive actions are effectively implemented.

- 4.4 All findings (including observations and recommendations for improvement) shall be documented and reported using the Record of Self Inspection (*FORM-XXX*).
- 4.5 The management shall review the report, classify and assign each NC to respective personnel/department to identify the root cause, follow-up with appropriate and corrective and preventive actions.
- 4.6 Depending on the classification of the NCs, the exact time frame to close out the NCs would be decided by the management. However, all NCs identified in self-inspection shall be closed out in no longer than *6 months* upon appointing the responsible personnel to follow-up.
- 4.7 Assigned personnel shall ensure that all actions are followed-through and closed-out within the agreed time frame, any delay or issues encountered while implementing the relevant corrective and preventive actions shall be reported to the management in a timely manner. All follow-up actions shall be recorded and reviewed by the management.

## 5.0 Reference to other documents

- 5.1 Record of Self-inspection (*FORM-XXX*)

## 6.0 END OF DOCUMENT

### REVISION HISTORY

Rev No:	Document Change Number:	Author	Effective Date	Remarks of Revision
001	<i>XXX</i>	<i>YYY</i>	<i>DD-MMM-YYYY</i>	New Document.

### APPROVAL

Prepared by: \_\_\_\_\_ Signature/Date: \_\_\_\_\_

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Approved by: \_\_\_\_\_

Signature/Date: \_\_\_\_\_