STANDARD OPERATING PROCEDURE	
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1.0 PURPOSE

To lay down a procedure to be followed for administration of corrective and Preventive actions (CAPA) including tracking and reporting of the status of CAPA.

2.0 SCOPE

2.1 This procedure is applicable for all Corrective and Preventive Action that are recommended if any, but not limited to the following documents:

2.1.1 Incident/Deviation – Investigation

2.1.2 Change control

2.1.3 Laboratory deviations

2.1.4 Repeat analysis

2.1.5 OOS/OOT

2.1.6 Planned Modification

2.1.7 Market complaints

2.1.8 Documents review (SOP/BMR/Specification)

2.1.8 Audits (Internal/External)

2.1.9 Regulatory recommendations

2.1.10. Outcome of risk assessment

2.1.11 Self Inspection

2.1.12 Product Recall

2.1.13 Returned Goods

2.1.14 Annual Product Review

2.1.15 Management Action Plan

2.1.16 Any Discrepancies

3.0 REFERENCE(S) & ATTACHMENTS

3.1 References

3.1.1 WHO Guideline: TRS-908: Annexure-4: Good manufacturing for pharmaceutical product: main principles.

3.1.2 PIC's Guideline: Guide to good manufacturing practice for medicinal products (PE009-09) Part-I.

3.2 Attachments

3.2.1 Attachment –I : Corrective and Preventive Action form issuance register

3.2.2 Attachment – II : Corrective and Preventive Action Form

3.2.3 Attachment –III : Flow Chart of CAPA

4.0 DEFINITION & ABBREVIATION(S)

4.1 Definitions

4.1.1 **Corrective and Preventive Action (CAPA):**

CAPA is a reactive tool for system improvement which focuses on the action taken to eliminate the cause of a detected nonconformity or other undesirable situation to prevent their recurrence (for corrective action) or action taken to eliminate the cause of a potential nonconformity or other undesirable potential situation to prevent occurrence(for preventive action).

4.1.2 **Corrective Action:**

Action taken to eliminate the cause of a detected nonconformity or other undesirable situation.

NOTE: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

4.1.3 **Preventive Action:**

Action taken to eliminate the cause of a potential nonconformity or other undesirable potential situation.

NOTE: Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence

4.2 Abbreviations

4.2.1 OOS: Out of Specification

4.2.2 CAPA: Corrective and Preventive Action

4.2.3 QA: Quality assurance

4.2.4 QC: Quality control

4.2.5 CQA: Corporate Quality Assurance

4.2.6 BMR: Batch manufacturing record

4.2.7 SOP: Standard operating procedure

4.2.8 OOT: Out of trend

5.0 RESPONSIBILITY:

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5.1 Concerned Department Person:

5.1.1 To implement the Corrective and Preventive Action.

5.2 Quality Assurance:

5.2.1 To assign the Corrective and Preventive Action those are suggested by the approving authorities through Corrective and Preventive Action form.

5.2.2 To assign a number to the Corrective and Preventive Action (CAPA) form.

5.2.3 To issue the CAPA form.

5.2.4 To follow up and close of the Corrective and Preventive Action after review.

5.2.5 To evaluate and close the CAPA on completion

5.3 Concerned Department Head:

5.3.1 To implement the Corrective and Preventive Action

5.3.2 To complete the CAPA as per defined schedule.

5.4 Quality Assurance (QA) Head:

5.4.1 To ensure tracking, follow - up and closure of Corrective and Preventive Action.

5.4.2 To provide extension approval of the target date.

5.4.3 To ensure implementation of defined procedure.

5.5 Plant Head:

5.5.1 To ensure tracking, follow - up and closure of Corrective and Preventive Action.

5.5.2 To ensure implementation of defined procedure.

6.0 Distribution:

I. Quality Assurance
II. Quality Control
III. Production
IV. Ware house
V. Engineering
VI. Human resource and Administration
VII. Environment, Health and safety

7.0 PROCEDURE:

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7.1 QA shall review the approved documents (i.e. incidence/Deviations report investigation report, change controls, Laboratory variations reports, repeat analysis reports, OOS/OOT reports, Planned modification, Market complaints, External audits, Internal audits, Outcome of Risk Assessment, Annual product review, management action plan, any discrepancies where ever Corrective and Preventive Action are suggested and shall list out CAPA in order of the decreasing effectiveness as mentioned below:

- Elimination
- Replacement
- Facilitation
- Detection
- Mitigation

Elimination: Eliminate the possibility of error. This can be accomplished by eliminating the task.

For example, eliminate mixing errors by purchasing pre-mixed materials.

Eliminate recording errors by linking the measurement device to a printer.

Elimination can be also be accomplished by an error proof device.

Replacement: Change the current process by replacing it with more reliable process.

For example: Design a more robust screen for milling machines so they do not break so often.

Replace human inspection with automated 100% inspection at the source install bar-code scanners.

Facilitation: Make the process easier to perform.

For example: Use dedicated storage areas to reduce the possibility of mix-up. Add pictures to procedures.

Detection: Improve detection by adding new or better sensors. Do this at the source if possible.

For example: Add audible alarms or lights if a process is out of tolerance. Better yet, automatically shut down, or add an interlock so the process cannot move to the next step.

Understand that a corrective action that improve detection is inherent weaker than a corrective action that eliminates the problem. Because detection does not prevent defects, it just prevents escapes.

Mitigation: Minimize the effect of the error.

This is typically the weakest form of corrective action.

For example: Install a metal detector with a link of compression machine, when metal is detected, mitigate by rejecting the product before contaminating the bin.

7.2 QA person shall enter such details into CAPA form issuance register (Attachment–I). This CAPA form

issuance register shall have following details.

7.2.1 **Sr. no.:** The sequential number of the CAPA shall be written.

7.2.2 **Date:** The date on which the CAPA is assigned.

7.2.3 **CAPA No.:** CAPA Number shall be entered into this column (numbering procedure described in point No.7.6.

7.2.4 **Reference document no:** The document reference number in the context of which above CAPA is assigned.

7.2.5 **Recommendation:** The recommendations to be implemented.

7.2.6 **Responsible Person:** The person responsible for the Implementation of CAPA.

7.2.7 **Responsible department:** The department responsible for the Implementation of CAPA.

7.2.8 **Target date:** The target date to fulfill the recommendations.

7.2.9 **Extended target date:** If any extended target date to fulfill the recommendations.

7.2.10 **Justification for extension of target date:** Fill the justification for extension of target date to fulfill the recommendations.

7.2.11 **Status:** On the basis of the fulfillment of the 'status' whether 'open' or 'close' shall be determined.

7.2.12 **Remarks:** Remarks shall be written if any.

7.3 Based on the CAPA register entries a CAPA form (Corrective and Preventive Action form; Attachment-II) shall be issued to concerned department. Details of CAPA issuance procedure is described into point # 7.7.

7.4 Concerned department head shall be responsible to complete the CAPA as per requirement and within defined time schedule.

7.5 For proper traceability CAPA No. shall be entered into subjected document from where CAPA is initiated.

7.6 For each document a separate CAPA number shall be assigned for traceability and tracking for example Planned deviation No., Change control No, Audit Report, Market complaint No., Planned modification No., incident Report No., etc.

A typical numbering system shall be:

Note: If CAPA to be taken for Different documents is same then one common CAPA No. can be issued.

7.6.1 First four characters shall be the prefix **CAPA** followed by a slash (/).

7.6.2 Next two characters shall comprise of the manufacturing unit code "PK".

7.6.3 Next three characters shall comprise of the **department code** as per SOP for SOP succeeded by last two digits of the **current year** followed by a slash (/). (Like 20 for year 2020 and so on…).

7.6.4 Last three digits shall be the **serial number** beginning with 001 and shall start with 001 from 1st January of each year.

7.6.5 For example: First CAPA of the Production department of ……for the year 2020 shall be numbered as **CAPA/PK/PRD20/001**.

7.7 For each CAPA the CAPA form shall be issued by QA to concerned department by whom necessary action will be taken to implement the recommendation. The Corrective and Preventive Action Form shall be issued to the concerned department (Department code shall be as per defined in SOP on SOP).

Following details will be filled in Corrective and Preventive Action form (Attachment-II).

7.7.1 **Department:** Name of concerned department to whom CAPA is issued

7.7.2 **Issued by:** Name of the QA representative by whom CAPA form is issued.

7.7.3 **CAPA No.:** The CAPA form is assigned a sequential number as per step #7.5.

7.7.4 **Target date:** QA shall fill the target date in consultation with the concerned department.

Any extension in target date shall be authorized by the QA Head or designee by striking out the previous target date and countersigning and writing the extended date in the next column with justification.

7.7.5 **CAPA recommended as per:** Reference of the document no. against which the CAPA is issued shall be documented.

7.7.6 **Details of recommendation/Action:** The recommendations/action of the respective documents shall be written in the CAPA Form.

7.7.7 **Responsible person:** The name of the responsible person for completion of the recommendations shall be written in consultation with the concerned department head by QA.

7.8 After filling the above details CAPA form shall be forwarded to concerned department for the implementation of the recommendation.

7.9 Upon completion of the recommended activity concerned department shall write down the details of action taken along with supporting data, if any after verification from department head or designee.

7.10 The person performing the assigned CAPA shall sign in the performed by column and the respective person of the concerned department verifying the above action shall sign in the verified by column.

7.11 After completion of above activity the duly filled and signed CAPA form shall be submitted to QA department for evaluation.

7.12 QA head and Plant head shall finally review and approve the CAPA for final closure.

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7.13 Any supporting data attached with the CAPA form shall be evaluated by QA. On the basis of evaluation CAPA issuance register shall be updated for the status.

7.14 After evaluation the concerned QA person shall sign in evaluated by column.

7.15 CAPA Implementation: Implementation of CAPA shall be done after an accurate understanding of the root cause of a problem is established. Then only the design of corrective action& preventive action shall be determined. These actions shall involve changing documented processes, conducting additional training, or even improving tooling, equipment, materials or facility. The required action also includes changes in management policies. The changes shall be installed into the system in a way that will assure consistent complianceto those changes is critical to avoid reoccurrences of the problem. If exact root cause is not identified, then CAPA shall be taken on the identified probable root causes.

7.16 For the identified root causes, an interim CAPA, such as additional checks, extensive sampling may be put in place so that the process does not result in similar situation of failure by the time formal CAPA is put in place after conclusion of investigation, in case production is continued. For example if the investigation is for any market complaint, situation leading to that complaint shall be arrested by developing additional controls in the batch documents, instantly without waiting for formal revision in documents by using an additional approved document or instruction etc.

The CAPA owner shall perform an impact assessment to assess the impact on the activities that are to be carried out until the implementation of the CAPA and build adequate controls during the interim period of CAPA implementation.

7.17 CAPA Effectiveness: Effectiveness of CAPA shall be determined by follow up of the necessary corrective action & preventive action is taken and whether the outcome of the CAPA is desired one.The most important resources are the people involved in administering and executing the process. They must have the skills, organizational credibility, knowledge and tools to perform the required task so that CAPA will be implemented successfully & its effectiveness shall be known.CAPA owner shall define the effectiveness criteria and tentative time for completion. After implementation of CAPA, CAPA effectiveness shall be measured by reviewing the following data such as deviations, OOS/OOT, market complaints, incidence, product quality parameters, process performance etc.

7.18 **CAPA closure:** If the CAPA implementation is found to be satisfactory based on the set effectiveness criteria, CAPA will be closed.

CAPA shall be closed within 30 working days from the date of logging.

If the CAPA implementation is found to be ineffective, QA shall return the CAPA to the CAPA owner (Responsible person) for further actions with review comments summary. If CAPA is not closed within the target date of completion, then CAPA extension form (Attachment III) shall be issued and reason for extension shall be mentioned by the user department & it shall be approved by the QA head.

7.18.1 If CAPA is not closed within the specified target date then perform additional review at one month interval for total 3 months.

1st Review: 1st review for close out status will be done after 30 working days from the date of logging.

2nd Review: 2nd review for close out status will be done after 30 working days from the date of 1st review.

3rd Review: 3rd review for close out status will be done after 30 working days from the date of 2nd review.

NOTE: If CAPA is not closed after 3rd review also then intimate to CQA head.

7.19 The Status of open CAPA No. shall be circulated to concerned departments on monthly basis.

8.0 REVISION HISTORY

Version No.	00	Effective Date	
Details of revision: New SOP Prepared			

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Attachment-I

CORRECTIVE AND PREVENTIVE ACTION ISSUANCE REGISTER

S. No	Date	CAPA No.	Reference Document No.	Recommendation	Responsible Person	Responsible department	Target Completion Date	Extended target date	Justification for extension of target date	Status	Remarks

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Attachment-II

CORRECTIVE AND PREVENTIVE ACTION FORM

Department :		**Issued By:**	
CAPA No.:		**Target Date:**	

CAPA Recommended as per →

Reference Document No. against which CAPA is raised:	
Responsible Person:	

Proposed (Recommended) CAPA detail:

Detail of Implementation of CAPA:

CAPA effectiveness Evaluation:

Remarks of Responsible Person:

Sign/ Date: _____

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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Supporting Data Attached →	☐ NO	☐ YES

List of Attachment:

1.

2.

3.

Remarks of Evaluator:

Close out Date of CAPA: _____

If not closed within the target date then attach CAPA Extension Form.

Action	Concerned Department		Evaluated By (QA)
	Performed By	Verified By	
Signature			
Date			

Approved By:

QA Head (Sign/Date):	**Plant Head (Sign/Date):**

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Attachment -III

CAPA EXTENSION FORM

CAPA No.:				
	1st Extension	**2nd Extension**	**3rd Extension**	**Final Close out Date**
Extended Target Date				
Reason for extension				
Proposed by User Department				
Checked by Respective Department Head				
Approved by QA Head				

1st Review:

2nd Review:

3rd Review:

Quality Assurance (Sign/Date)	**Quality Assurance Head (Sign/Date)**	***CQA Head (Sign/Date)**

*Applicable if CAPA is not closed after 3rd review.

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Attachment -IV

Flow Chart