PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Change Control Management	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1. PURPOSE:

1.1 To lay down the procedure for request, documentation, justification, appropriate evaluation, impact assessment, tracking, implementation of change in procedures, raw material, packaging material, product, manufacturing process, analytical method, specifications, equipment, utilities and operating environment.

2. SCOPE:

2.1 This procedure is applicable to any change made in approved document, process, materials, product or procedures associated with manufacturing and distribution of pharmaceutical drug.

3. RESPONSIBILITY:

3.1 Concerned department personnel shall initiate the Change Control form.

3.2 HOD/Designee of Initiator's department shall evaluate and forward Change Control Proposal to QA.

3.3 QA Head / Designee shall evaluate and forward change control proposal to Change Control committee for evaluation and feedback.

3.4 Change control committee shall evaluate the change control and gives their feedback.

3.5 QA Head / Designee shall approve Change control.

3.6 Concerned department / QA will initiate the action plans.

3.7 Quality Assurance shall review and close the change control for implementation of changes.

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4. ACCOUNTABILITY:

4.1 QA Head / Plant Head shall ensure the implementation of changes and timely closer of the Change control.

5. PROCEDURE:

5.1 DEFINITION(s)

Change Control – A written procedure to describe the actions to be taken if the change is proposed to facilities, materials, equipment, component and process used in the manufacturing ,packing and testing of drug product or any change that may affect product quality or support system operation.

Change Initiator – Person, raising the change control.

Change Control Committee.

Change control committee shall be comprised of HOD/designee from Manufacturing (Production), Engineering, Purchase, Warehouse, Quality Control, Quality Assurance department as member.

5.2 Classification

5.2.1 Changes are classified as Temporary changes and Permanent changes

5.2.1.1 **Temporary change:** A change that is proposed (but not limited to) to Facility, Product, systems, Utilities, Testing methods, specifications, documents, Raw / packing material components, Manufacturing / Packing process, Manufacturing / Packing Equipment for a pre-defined period of time or for pre-defined number of batches /lots, are termed as Temporary change. A temporary change, which has been executed, will be hull and void after the pre-defined period of time has lapsed or after the pre-defined number of batches /lots has been completed.

5.2.1.2 **Permanent change:** A change that is proposed (but not limited to) to Facility, Product, systems, Utilities, Testing methods, specifications, documents, Raw / packing material components, Manufacturing / Packing process, Manufacturing / Packing Equipments, that cannot be reversed after being executed is termed as a Permanent Change.

5.3 Any change to be made shall be classified by the Head – QA, into following three categories depending upon their criticality.

5.3.1 **Critical** – A change that has a significant impact on quality and/or safety of the final product.

Major – A change that is likely to have an impact on quality of the product, but does not make any significant change in the final quality of the product.

Minor – A change that does not have any impact on the quality of the product and operating system.

All critical, major and minor changes shall be routed through Change Control procedure.

Typical changes that shall be considered for need to follow the Change Control Procedure are as **:**

1. Addition of any New Product/ New Equipment in the existing facility.
2. Change in finalized Manufacturing process / process control parameters.
3. Change in Master manufacturing records / protocols.
4. Change in Source of raw materials / packing materials (vendor)
5. Change in Manufacturing equipments / Utilities.
6. Change in Manufacturing site / location.
7. Change in Utilities
8. Change in primary packaging materials, packing configuration/ style/text
9. Matter and artwork for printed packing material.
10. Change in warehouse / distribution procedure (for raw material / packaging material / finished goods requiring special conditions for storage and handling.

5.3.2 11. Change in warehouse / distribution procedure (for raw material / packaging material / finished goods requiring special conditions for storage and handling.

12. Modifications in water system.

13. Relevant checklists shall be attached as annexure to track the implementation of all relevant action plans/ activities regarding the changes as in site, artworks, addition of new product/ equipment etc.

5.4 **Initiation of Change Control.**

5.4.1 The concerned department shall raise proposal for the change. The proposal shall be initiated by filling the Change Control Form (CCF), **Annexure-II**.

5.4.2 Initiator shall thoroughly describe and justify the proposed changes in the CCF.A specific information shall be filled (as applicable) in the CCF for the following;

- Change related to
- Change required in
- Proposed change
- Scientific rationale
- Data of experimental studies
- Activities to be performed for implementation of change
- Change affecting related documents
- Training
- Enclosure

5.4.3 QA officer shall allot a report number to the form. A unique change control number consists of fourteen alphanumeric character as mentioned below,

CC/AA/Z/XX/YYY

Where, CC stands for change control

AA – stands for Department code as below,

PD – Production(General)

TB – Production Tablet

LQ – Production Liquid

IN – Production Injection

QA - Quality Assurance Department

QC- Quality Control Department

EG - Engineering Department

WH - Warehouse Department

PA- Personnel and Administration

IT- Information Technology

Z - Type of Change (Permanent -P, Temporary-T)

XX – represent the last two digit of current year.

YYY – represent the sequential serial number.

5.5 **Approval of Change proposal by HOD/Designee of initiating department**

5.5.1 The Change Control Form shall be forwarded to Concerned HOD/Designee with necessary details and justification of change required. HOD/Designee evaluates the change requested, if proposed change is feasible, HOD/Designee shall put their opinion and approve to forward to QA.

5.5.2 If, any additional information/justification is required, change proposal shall be returned to initiator for further actions.

5.5.3 If, proposed change is not feasible, then change proposal shall be rejected.

5.5.4 A CCF shall be thoroughly filled, reviewed and signed by initiator and Head of the Department (HOD) shall be sent for evaluation to the Head –QA. (Note: In absence of Head Quality, his designee shall approve the CCF after seeking a Telephonic approval.)

5.6 **Review by QA**

5.6.1 QA head shall classify CCF into 'Critical / Major / Minor' category.

5.6.2 QA Head/Designee shall determine the potential impact of the proposed change. Potentially impacted areas have been illustrated in **Annexure- III**.

5.6.3 Depending on the criticality of the change and its possible impact on product quality, risk Assessment shall be performed prior to implementation of the change as per current procedure of, "Quality Risk Management".

5.6.4 After determining the potential impact of change, an implementation plan shall be recommended which may include validation requirements stability studies and / or appropriate action plan.

5.6.5 Interlinked activities and commitments from different departments, a detailed action plan indicating each of the commitments with the respective tentative timelines shall be addressed in the Change Control. This action plan shall be tracked through **Annexure VII, "Notification/Tracking Implementation of Action Plan".**

5.6.6 The implementation plan shall also include, at what stage during implementation of change each recommended action shall be completed (e.g. items to be completed before plant trial and items to be completed after a plant trial) and time frame for closure of change.

5.6.7 If change proposal is found appropriate, QA shall forward change proposal to the members of change control committee, getting impacted by the proposed changes.

5.6.8 QA may forward the change proposal to any individual(s) other than change control committee members/customer for their evaluation/approval (if necessary).

5.7 **Evaluation of Change Control by Change Control Committee**.

5.7.1 On receipt of the change proposal to review the feasibility of change proposal and access its

impact on cGMP, practicality and effect on respective process.

5.7.2 The member of change control committee shall indicate any additional document or activities effected or to be changed.

5.7.3 Member shall enter the details in Approval comments and approve to forward change proposal to QA.

5.7.4 Evaluation by each department shall be considered as an option listed below, but not limited to :

5.7.4.1 **Evaluation by Manufacturing Team (Production / Packing)**

Member shall review, evaluate the impact of propose Changes on Training, documentation, Process, equipment, Validation requirement (Process / cleaning / equipments) and update the Change control Form.

5.7.4.2 **Evaluation by Supply Chain Management (Purchase) Team**

Member shall review, evaluate the impact of proposed change on Supply chain management and update the change proposal.

5.7.4.3 **Evaluation by Quality Control Team**

Member shall review, evaluate the impact of proposed change on analytical method, additional method development (If any), method validation, quality control analysis, stability studies, inventory related to reagent solution and related documentation and update the change proposal.

5.7.4.4 **Evaluation by Warehouse Team**

Member shall review, evaluate the impact of proposed Change Control on stocks, consumptions, write offs, physical segregation & storage requirement etc. and update the change proposal.

5.7.4.5 **Evaluation by Engineering Team**

Member shall review, evaluate the impact of proposed Change on calibration and preventive maintenance schedule, operation condition of the machine, any modification in the building/facility/equipment, Layout, Equipments lists, safety aspects and update the change proposal.

5.8 If the change requires permission from or intimation to customers/ regulatory authorities (e.g.

USFDA, MCC, MHRA, TGA, Local FDA, etc.), then it shall be notified to the customer/ authorities. Approval shall be obtained before implementation wherever required.

5.9 **Approval of Change Control by QA:**

5.9.1 After approval of all change control committee members, QA Head will receive the change proposal for final approval.

5.9.2 QA Head shall review, evaluate the opinion made by change control committee members.

5.9.3 On complete evaluation, QA shall either approve or reject the Change proposal and enter his final comments and corrective actions (if any) comments / indicating summary of actions to be carried out.

5.9.4 If CCF is rejected then the reason for rejection shall be mentioned in the remarks section.

5.10 **Implementation of Change Control and Action Plan:**

5.10.1 All change control form shall be reviewed after every 30 working days and all the identified CAPA (corrective and preventive action) shall be handled as per SOP “Corrective and Preventive Action”.

5.10.2 All the documents undergoing changes due to implementation of change control proposal shall be revised and controlled as per the SOP for Document and Data Control.

5.10.3 Quality Assurance department shall maintain change control logbook as per **Annexure-IV** & **Annexure-V** separate for Permanent and Temporary changes and retain records of all change controls. The change control logbook shall include details like Sr. No, Change Control No., issued by, description of change, Classification, date of approval, status (Open/ Closed), date of closure and remarks if any).

5.10.4 Implementer may extend the target date with proper comments / justification (duly approved by QA) only in case of permanent change control as per SOP “Corrective and Preventive Action”.

5.10.5 On completion of the proposed changes / actions, Implementer shall put their comments in the change control and where required shall scan the proof of implementation and attached to the change control.

5.10.6 Document the reason for closure as 'Change implementation completed' in routine cases. In

case of any additional comments the same is to be documented.

5.11 Refer **Annexure VI,** "Flow Chart for Change Control Procedure".

5.12 Log of Change control shall also be maintained in Excel sheet for easy retrieval and filter the required detail in glance, excel sheet shall be password protected, maintained and updated by concern personnel only.

5.13 Review and trending of Change control:

5.13.1 All change controls forms (Temporary and Permanent), shall be subjected to the reviewed and trending on a frequency of six months.

5.13.2 All the CCF raised as well as closed and those which are under implementation during the period shall be considered for trending and review.

5.13.3 Trending and review of change controls shall be done as per Annexure-VIII "Trending and review of permanent change control" and Annexure-IX" Trending and review of temporary change control"

5.13.4 Trending of Change controls shall be done based on following criteria:

- Trending of Change control based on classification (Minor, Major and Critical)
- Trending of Change Control based on type of change (Product, equipments, Utilities, Documentation, Facility, Component or others if any)

5.13.5 Based on the review of trending summary report shall be prepared for permanent and temporary change controls as per Annexure-VIII & Annexure-IX.

5.13.6 Summary report shall be reviewed by Head QA and Approved by Head Quality.

6.0 REFERENCE:

6.1 EU Guidelines to Good Manufacturing Practice; Volume 4-Medicinal Products for Human and Veterinary Use

6.2 GMP Guide for Active Pharmaceutical ingredients ICH Q7.

6.3 Guidance for Industry Quality Systems Approach to Pharmaceutical cGMP Regulations, U.S Department of Health and Human Services Food and Drug

Administration.

6.4 ICHQ-10: Pharmaceutical Quality System

7.0 CROSS REFERENCES TO SOP:

7.1 Procedure for Document & Data Control

7.2 Corrective and Preventive action

7.3 Procedure for Quality Risk Management

8.0 ANNEXURES:

8.1	Annexure	I	:	List of typical changes and their category
8.2	Annexure	II	:	Change Control Form
8.3	Annexure	III	:	Areas of change and potential areas to evaluate for impact due to change
8.4	Annexure	IV	:	Permanent Change Control Log Book
8.5	Annexure	V	:	Temporary Change Control Log Book
8.6	Annexure	VI	:	Flow chart for Change Control Procedure
8.7	Annexure	VII	:	Checklist for Notification/Tracking implementation of action plan.
8.8	Annexure	VIII	:	Trending and review of permanent change control
8.9	Annexure	IX	:	Trending and review of temporary change control

9.0 ABBREVIATION:

S.No.	Short forms	Expanded forms
1	SOP	Standard Operating Procedure
2	QA	Quality Assurance
3	XX	Latest version Number
4	C.C. No.	Controlled copy Number
5	CAPA	Corrective actions & preventive actions.

10.0 REVISION HISTORY:

Effective Date	Revision No.	Change Control No.	Reason For Review

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ANNEXURE I

LIST OF TYPICAL CHANGES

Type of change	Critical	Major	Minor
Manufacturing process	√		
Manufacturing formula	√		
Manufacturing lot size /Batch size (>10 fold)	√		
Manufacturing lot size /Batch size (<10 fold)		√	
Manufacturing location.	√		
Source of active raw material/Key raw material	√		
Bill of material	√		
Source of Excipients / non critical materials		√	
Storage conditions		√	
Specifications		√	
Primary packaging material	√		
Secondary packaging material			√
Packaging style		√	
Printed text on packaging material		√	
Addition of new equipment	√		
Modification in existing equipment		√	
Change in equipment	√		
Testing methods		√	
Formats			√
Equipment Numbering system			√

* The list is only for indicative purpose. However, depending upon the exact nature /gravity of change, there can be a change in above classification.

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ANNEXURE II

CHANGE CONTROL FORM

Classification : ☐ Temporary ☐ Permanent	
CCF No.:	Date:
1.0 Initiation of Proposal	
Initiating Dept.	Change Related To (Check all that apply) : ☐ Product ☐ Equipment ☐ Utilities ☐ Documentation ☐ Facility ☐ Other (specify) _____
1.1	Change required in: *(specify Market wherever applicable)*
1.2	Proposed change (mention change from and change to):

1.3	Scientific rationale / justification (Enclose supporting if required): □ Enclosed / □ Not Required _____ _____ _____ _____ _____ _____ _____ _____
CCF No:	
1.4	Data of Experimental studies (if applicable): _____ _____ _____ _____
1.5	Activities to be performed for implementation of change: _____ _____ _____ _____ _____ _____

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1.6	Change affecting related documents (specify): _____ _____ _____ _____
1.7	Training (if Applicable):
1.8	Enclosures:

Change initiated by:	**Reviewed by Head of the Department**
Sign & Date:	Sign & Date:

CCF No:

2.0 Change Control Evaluation (By Quality Assurance)

2.1	Type of Change : ☐ Critical ☐ Major ☐ Minor
2.2	Risk Assessment required : ☐ Yes ☐ No (Please justify in case if "No" is selected) _____ _____ _____ _____ _____ _____
2.3	Validation requirements (if applicable give brief details of type / extent of validation required): Yes / No (Please justify in case if "No" is selected)

	Qualification : ☐ Yes ☐ No	_____ _____ _____ _____ _____
	Process Validation : ☐ Yes ☐ No	_____ _____ _____ _____ _____
	Cleaning Validation: ☐ Yes ☐ No	_____ _____ _____ _____
CCF No:		
2.4	Stability studies to be performed : YES / NO (Please justify in case if "No" is selected) (If yes, give details like Accelerated / CRT / No. of Batches etc.) _____ _____ _____	
2.5	Tentative time frame for closure: _____ _____	

2.6	Notification to Customer (in case of product under contract manufacturing): _____ _____ _____ _____ Customer Approval: Sign _____ Date: _____
2.7	Notification to Regulatory Authorities (in case of product under contract manufacturing): _____ _____ _____ _____
2.8	Remarks (if any): _____ _____ _____ _____

CCF No:

2.9	Requirements of Comments / Evaluation to be done by respective department (Select the department to be considered for their comments / evaluation)				
	Purchase	☐ Yes ☐ No		Quality Control	☐ Yes ☐ No
	Engineering	☐ Yes ☐ No		Production	☐ Yes ☐ No
	Warehouse	☐ Yes ☐ No		**If any other**_____	☐ Yes ☐ No
2.10	Evaluation done by (QA) : Sign _____ Date: _____				

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3.0	**Evaluation by respective department of plant**		
	Department	Evaluation	Comment
3.1	Purchase:	Change Accepted: ☐ Yes ☐ No Sign/Date: Name: Designation:	_____ _____ _____
3.2	Engineering:	Change Accepted: ☐ Yes ☐ No Sign/Date: Name: Designation:	_____ _____ _____ _____
3.3	Warehouse:	Change Accepted: ☐ Yes ☐ No Sign/Date: Name: Designation:	_____ _____ _____ _____
3.4	Quality Control:	Change Accepted: ☐ Yes ☐ No Sign/Date: Name: Designation:	_____ _____ _____ _____
3.5	Production:	Change Accepted:☐ Yes ☐ No Sign/Date: Name: Designation:	_____ _____ _____ _____
CCF No:			
3.6	If any other:	Change Accepted: ☐ Yes ☐ No Sign/Date: Name: Designation:	_____ _____ _____
4.0 CONCLUSION: Proposal is **APPROVED / REJECTED**			

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Remarks (if any):_____

_____

_____

Head- Quality **Sign & Date**	

5.0 Follow up and close out

Closure review

Attachment :-

Impact assessment: ☐ Yes ☐ No

Implementation Task list :☐ Yes ☐ NA

Effectiveness Check list: ☐ Yes ☐ NA

Timeline Extension Request :☐ Yes ☐ NA

Risk Assessment :☐ Yes ☐ NA

All section of CCF and attachment completed :☐ Yes

Recommended activities in CCF are completed / not completed. Hence the change control Performa is be treated as closed / not closed.

Remarks (if any) :

Head-QA (Sign & Date)

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ANNEXURE III

Areas of Change and Potential areas to evaluate for impact due to change

S.No.	Area of Change	Potential Areas to Evaluate for Impact due to Change
1	**Facilities, Utilities, and Equipment**	Cleaning
		Containment
		IQ / OQ / PQ / RQ
		Maintenance ➢ Change in Maintenance Schedule ➢ Change in Maintenance Procedure ➢ Lubricants ➢ New equipment added to Maintenance Program ➢ Replacement Parts ➢ Calibration
		Microbial Bio-burden (mandatory for facilities where aseptic areas exist)
		Relocation of Equipment / Process
		Pest Control
		Utilities: HVAC, Water, Coolants, Steam, Compressed Air, Gasses, etc.
		Process and Laboratory Instrumentation Equipment
2	**Computer Systems and Infrastructures**	Computerized Maintenance Management Systems (CMMS)
		Data Historians – Interfaces with other Systems
		Databases
		Hardware / Operating Systems
		Information Systems ➢ Manufacturing Execution Systems ➢ Distribution Management Systems ➢ Analytical Data Management Systems ➢ Document Management Systems ➢ Materials Management Systems ➢ Stability Tracking System ➢ Warehouse / Distribution Warehouse Monitoring Systems
		Laboratory Systems (Equipment)

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S.No.	Area of Change	Potential areas to evaluate for impact
	Computer Systems and Infrastructures	Networks
		Process Control Automation Systems ➢ Distributed Control Systems ➢ Programmable Logic Controls (PLC's) ➢ Supervisory Control and Data Acquisition (SCADA) Systems
		Validation of Systems (CSV)
3	**Regulatory Commitments**	Regulatory Commitment Document
		Country Specific Requirements / Registrations
		Monographs
		Printed Package Materials Text (Labeling)
4	**Impact to the Products, Processes and Delivery Systems Procedure, Analytical Methods, Master Documents**	Specifications and Analytical Test methods
		Standard Operating Procedures (Laboratory, process)
		Analytical Method / Process Validations
		Analytical Method / Process Tech Transfers
		Lab Models (Process Simulations)
		Reference Standards
		Equipment Sequential Logs
		Production Documents ➢ Bill of Materials ➢ Engineering Drawings (e.g. P & Ids) ➢ Process Flow Diagrams / Documents (PFDs) ➢ Master Formulas ➢ Manufacturing Instruction ➢ Master Packaging Orders / Instructions ➢ Process Hazard Review (PHRs) ➢ Waste Stream Information Sheet (WSIS) ➢ Warehouse / Storage Conditions ➢ Distribution / Shipping Conditions
5	**Training**	Course Materials
6	**Stability**	Expiry Period / Expiration Dating

		Stability Protocols
		Stability Regulatory Commitments
		Stability Chambers
		Stability Conditions
		Stability Containers
7	**Components**	Active Pharmaceutical Ingredients (APIs)
		Intermediates
		Raw Materials
		Drug Products
		Animal Health / Veterinary Products
		Devices
		Container Closure System
		Printed Package materials (labeling)
		Expendable Materials ➢ Cleaning Agents ➢ Gowning, Gloves, etc. ➢ Tubing, Product Contact Parts ➢ Filters
8	**Suppliers / Vendors**	Change in Suppliers / Vendors
		Change in the Location within a Supplier / Vendor
		Change in the Supplier's / Vendor's Process
9	**Customers**	Affiliates / Other Sites
		Distributors
		Upstream / Downstream Internal Customers
		Neighbors in the Community
		Third parties

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ANNEXURE IV

PERMANENT CHANGE CONTROL LOG BOOK

S.No.	Change Control No.	Issued on/by (Sign. & date)	Received on/by (Sign. & date)	Description of Change	Classification (Critical/Major/ Minor)	Approved / Rejected on	Status (Open / Closed)	Date of Closure	Remark (If any)

Department……

Year……...

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ANNEXURE V

TEMPORARY CHANGE CONTROL LOG BOOK

Sr. No.	Change Control No.	Issued on/by (Sign. & date)	Received on/by (Sign. & date)	Description of Change	Classification (Critical/Major/ Minor)	Approved / Rejected on	Status (Open / Closed)	Date of Closure	Remark (If any)

Department…….

Year……

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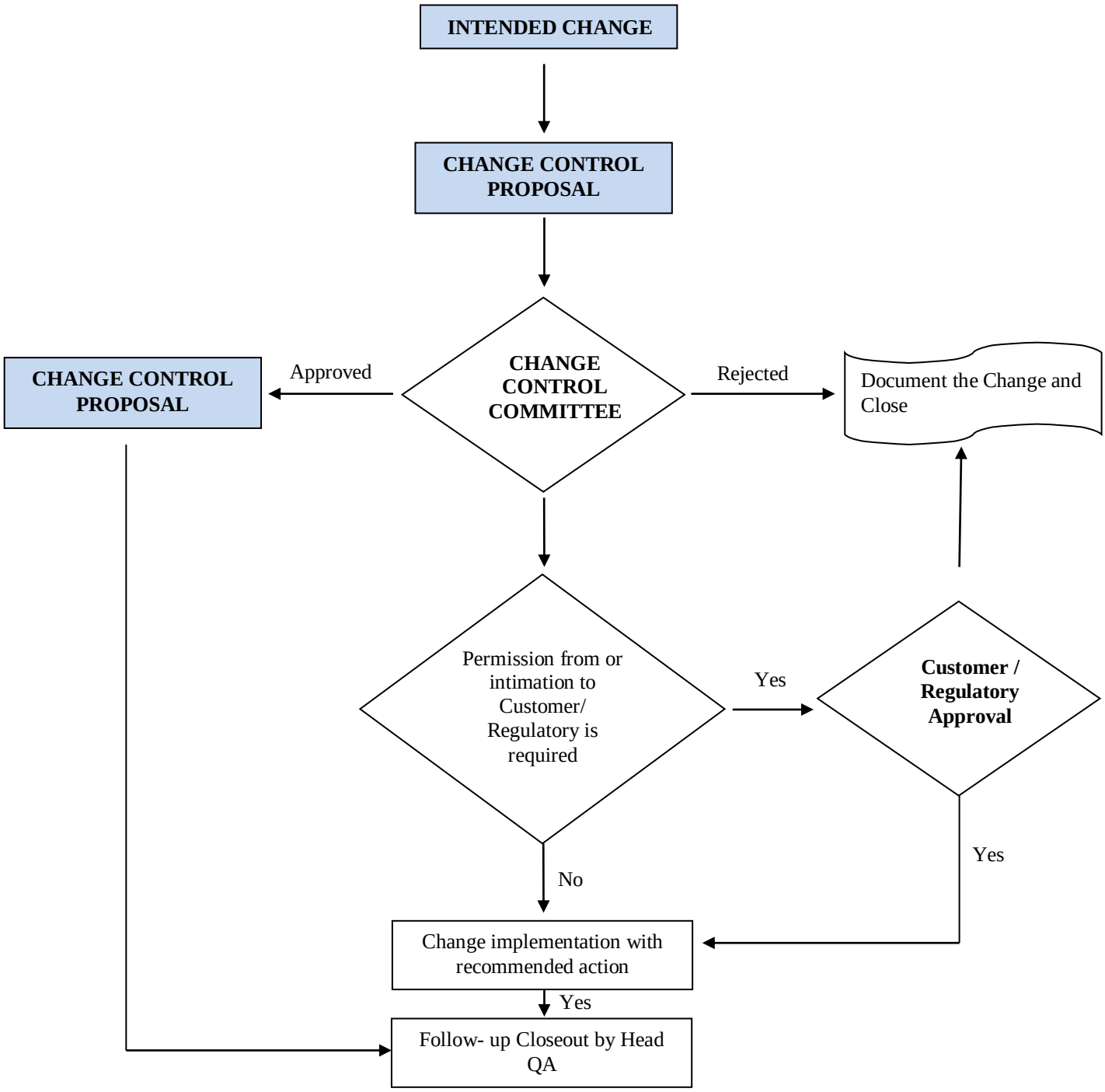
ANNEXURE VI

FLOW CHART FOR CHANGE CONTROL PROCEDURE



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ANNEXURE VII

TRACKING/ IMPLEMENTATION OF ACTION PLAN

S.No.	Activity Planned	Responsibility	Target Completion Date	Activity Done	Verified By

Assigned By (QA): _____

Verified By (QA):_____

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Notification Given To Departments:

Department	Sign/Date
Quality Assurance	
Quality Control	
Production	
P&A	
IT	
Warehouse	
Engineering	
Site Head	
Others (If any)	

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ANNEXURE VIII

TRENDING AND REVIEW OF PERMANENT CHANGE CONTROL FOR THE PERIOD _____TO_____

1.0 Status of Change Control from current and previous review period:

Department	No. of CCF raised in current review Period			Status		No. of Open CCF from previous period	Total No. of Open CCF
	Minor	Major	Critical	Open	Closed		

2.0 Trending of Change Control:

2.1 Trending of Change Control based on classification:

No. of CCF raised in current review Period			Status	
Minor	Major	Critical	Open	Closed
40	20	10	30	40

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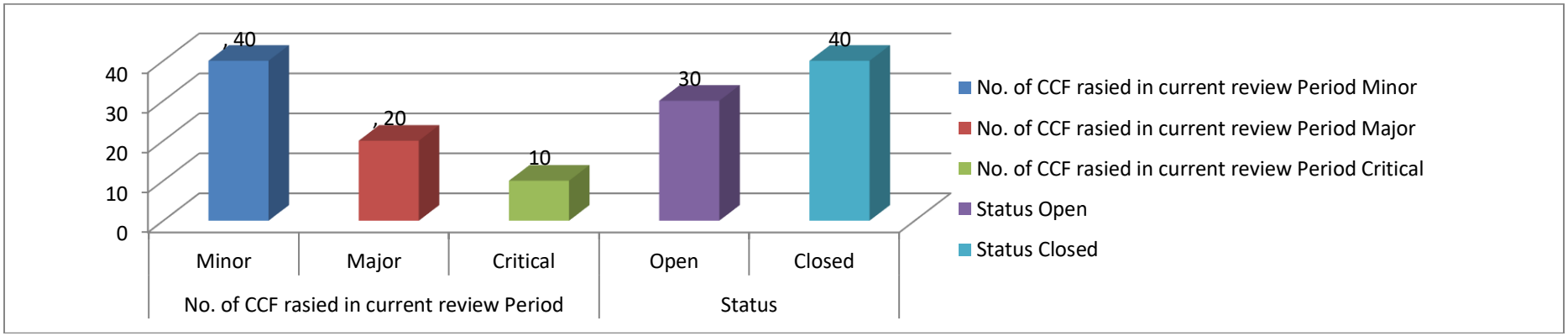

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2.2 Trending of Change Control based on type of Change:

Area of change proposed	No. of CCF raised in current review Period			Status	
	Minor	Major	Critical	Open	Closed
Product	10	05	05	05	15
Documentation	05	10	01	08	08
Instrument/Equipment	08	02	05	08	07
Component	09	05	06	10	10
Facility/Utility	01	08	01	04	06
Other	10	05	10	13	12

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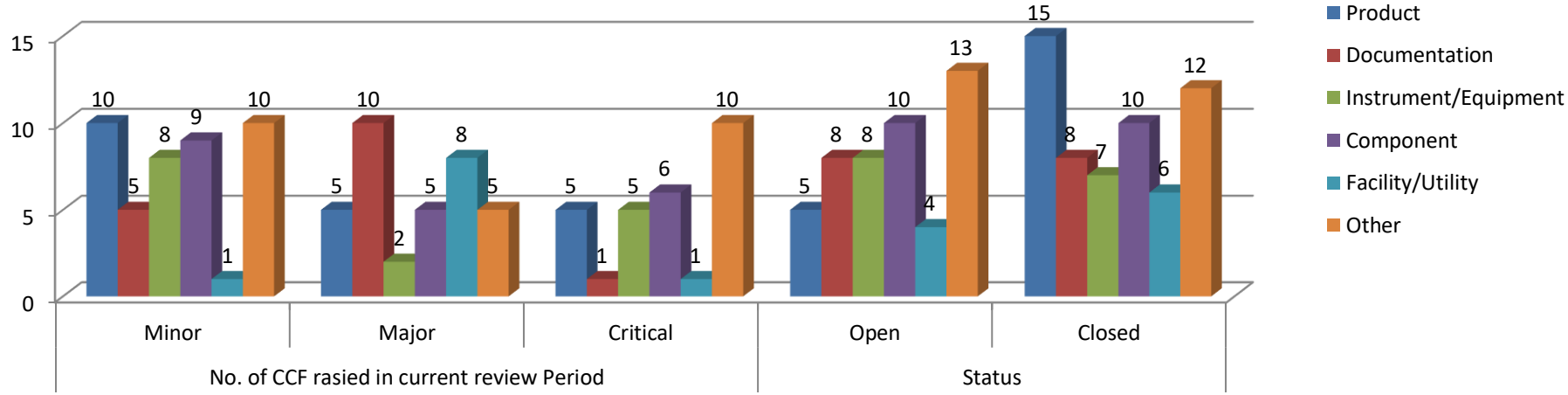

3.0 Summary and Conclusion:

Prepared By (Sign & Date)	**Checked By (Sign & Date)**	**Approved By (Sign & Date)**

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Change Control Management	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE IX

TRENDING AND REVIEW OF TEMPORARYCHANGE CONTROL FOR THE PERIOD _____TO_____

1.0 Status of Change Control from current and previous review period:

Department	No. of CCF raised in current review Period			Status		No. of Open CCF from previous period	Total No. of Open CCF
	Minor	Major	Critical	Open	Closed		

2.0 Trending of Change Control:

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Change Control Management	**Effective Date:**
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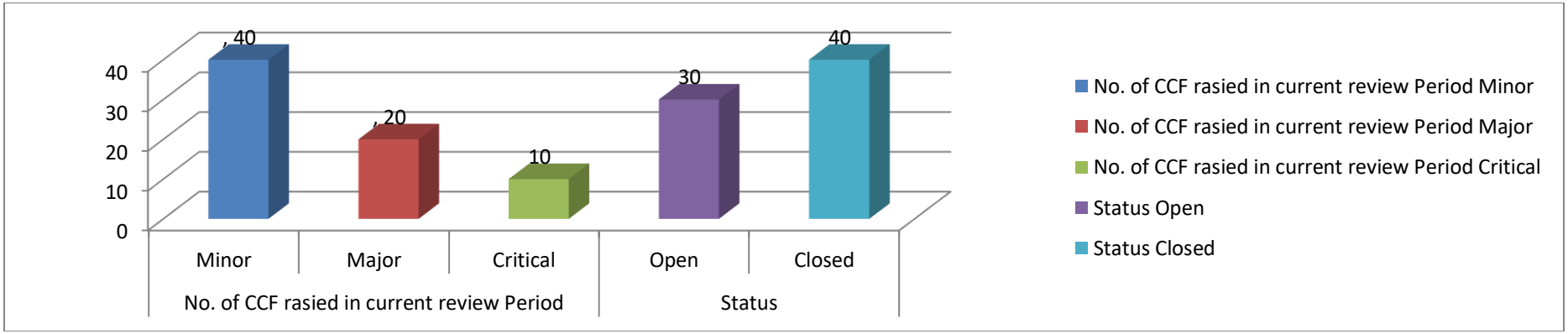
2.1 Trending of Change Control based on classification:

No. of CCF raised in current review Period			Status	
Minor	**Major**	**Critical**	**Open**	**Closed**
40	20	10	30	40

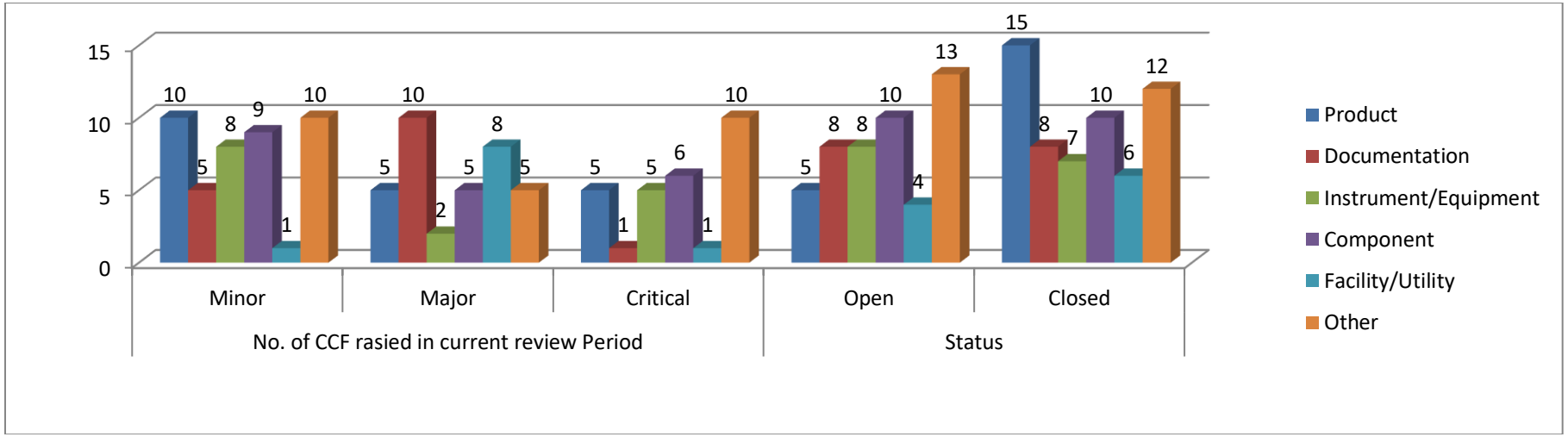


2.2 Trending of Change Control Area wise:

Area of change proposed	No. of CCF raised in current review Period			Status	
	Minor	Major	Critical	Open	Closed
Product	10	05	05	05	15
Documentation	05	10	01	08	08
Instrument/Equipment	08	02	05	08	07
Component	09	05	06	10	10
Facility/Utility	01	08	01	04	06
Other	10	05	10	13	12

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Change Control Management	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**



3.0 Summary and Conclusion:

Prepared By (Sign & Date)	**Checked By (Sign & Date)**	**Approved By (Sign & Date)**