CHANGE CONTROL FORM

CC NO. (CCXXX/YY):

SECTION A: CHANGE INFORMATION *(To be filled by Initiator/PIC)*

☐ Internal Changes ☐ Authority Directed Changes

Initiator/ PIC : _____ **Date** : _____

Department : _____ **Responsible Person/PIA** : _____

Changed Related To :

☐ Site Transfer ☐ Product ☐ Equipment
☐ Composition ☐ Facility ☐ Layout
☐ Document ☐ Process ☐ Control Parameter
☐ Batch Size ☐ Holding Time ☐ Raw Material
☐ Artwork/ Labelling ☐ Packaging Material ☐ Vendor
☐ Shelf Life ☐ Regulatory
☐ Re- Test Period

☐ Others : _____

Description of Proposed Change:

Justification:

Proposed Implementation Action:

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Related Deviation to be Attached (if any):

SECTION B: CHANGE EVALUATION

Status : ☐ Acceptable ☐ Not Acceptable

Quality Assurance Classification of Change : ☐ Minor ☐ Major ☐ Critical

Comments : _____

_____

_____

Related Department for Evaluation : ☐ Production ☐ E&M ☐ Regulatory
☐ QA ☐ QC ☐ Store
☐ Others : _____

Evaluated By : _____ **Date:** _____

Section(s) below is to be filled if proposed change is acceptable

REGULATORY

a) The proposed change impact to:

The Regulatory Reporting Category ☐ Yes ☐ No

Regulatory Approval/ Notification required ☐ Yes ☐ No

☐ Others: _____

b)Details:

_____

_____

_____

_____

_____

_____

_____

Evaluated By : _____ **Date:** _____

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QUALITY CONTROL (QC)

a)The proposed change impact to:

- ☐ Analytical Instrument
- ☐ Validation/ Qualification
- ☐ Environmental Monitoring
- ☐ Raw Material Spec
- ☐ Finished Product Spec
- ☐ Packaging Material Spec
- ☐ Calibration
- ☐ Analytical Test Method
- ☐ Sampling Method
- ☐ Vendor
- ☐ Stability Study
- ☐ In- process
- ☐ Others: _____

b)Details:

_____

_____

_____

_____

_____

_____

_____

Evaluated By : _____ **Date:** _____

PRODUCTION

a)The proposed change impact to:

- ☐ Process/ Procedure
- ☐ Validation/ Qualification
- ☐ Control Parameter
- ☐ Others:

_____

b)Details:

_____

_____

_____

_____

_____

_____

_____

Evaluated By : _____ **Date:** _____

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ENGINEERING & MAINTENANCE

a)The proposed change impact to:

☐ Piping/ Duct/ Facility Layout ☐ Equipment ☐ Calibration
☐ Preventive Maintenance ☐ Utility Parameter ☐ Facility
☐ Qualification of Equipment ☐ Qualification of Utility
☐ Others: _____

b)Details:

_____
_____

Evaluated By : _____ **Date:** _____

QUALITY ASSURANCE (QA)

a)The proposed change impact to:

☐ Qualification ☐ Validation ☐ Vendor
☐ Others:

_____

b)Details:

_____
_____
_____

Evaluated By : _____ **Date:** _____

Store

a)The proposed change impact to:

☐ Raw Material ☐ Packaging Material ☐ Label/ Leaflet
☐ Storage Condition ☐ Finish Product
☐ Others:

_____

b)Details:

_____
_____

Evaluated By : _____ **Date:** _____

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Others

a)The proposed change impact to:

_____

_____

b)Details:

_____

_____

Evaluated By : _____ **Date:** _____

SECTION C: CHANGE APPROVAL *(To be filled by QA)*

Change Approval : ☐ Approved ☐ Not Approved

Comments (if any) : _____

_____

_____

_____

Verified By (Pharmacist) : _____ **Date** : _____

SECTION D: CHANGE IMPLEMENTATION (**Attach document copy*)

Class of Document	Required	Assign Responsibility To	Done by & Date
Bill of materials (BOM)	* Yes / No		
Batch Manufacturing Record	* Yes / No		
Approved Vendor List	* Yes / No		

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Class of Document	Required	Assign Responsibility To	Done by & Date
Laboratory Specifications	* Yes / No		
Test Method(s)	* Yes / No		
SOPs Instructions or Records	* Yes / No		
Others (Please Specify)	* Yes / No		

Discontinue of Implementation (If Applicable)

HOD Comments : _____

_____

_____

_____

_____

HOD Signature : _____ **Date** : _____

QA Verification

Status : ☐ Acceptable ☐ Not Acceptable

Verified By : _____ **Date** : _____

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SECTION E: CHANGE CLOSURE *(To be filled by QA)*

All completed activities found : ☐ Satisfactory ☐ Not Satisfactory

Comments (if any) : _____

_____

_____

_____

_____

Closed By (Pharmacist) : _____ **Date** : _____

**** To be filled if completed activities not satisfactory initially***

All completed activities found : ☐ Satisfactory

Closed By (Pharmacist) : _____ **Date** : _____

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