MEHA PHARMA Kundaim-Goa	**Title**	**CHANGE CONTROL FORM**
	Ref. Doc. No.	**SOP/QAD/009**
	Change Control No.	
	Department	

Initiating Department:		
Date of Initiation:	**Initiated by**	

A. TYPE OF CHANGE (To be filled up by the origination dept.)

Process [ ] Equipment[ ] Product[ ] Document[ ] System[ ] Facility[ ] Method[ ]

Specification [ ] Component[ ]

Other[ ]:_____

B. CHANGE INITIATION

REASON & JUSTIFICATION OF PROPOSED CHANGE:
Is the Change due to CAPA: Yes/No. If yes, CAPA #: _____dated_____

DETAILS OF PROPOSED CHANGE: Change Required in (name of document / Procedure / equipment /facility)

COMMENTS BY INITIATION DEPARTMENT HOD

Head of Initiating Department
(Signature / Date)

Reviewer-Sign and Date 17/01/2024 **Approver-Sign and Date** 17/01/2024

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MEHA PHARMA Kundaim-Goa	**Change Control No.**

C. <u>Impact assessment of Proposed Change</u>:

C.1: EVALUATION AND IMPACT ASSESSMENT OF PROPOSED CHANGE: (To be filled up Quality Assurance)

Process	**Tick**	**Responsible Dept**	**Remarks**
Product Quality			
SOP			
Specification			
STP			
SDS			
MOA/AWR			
BMR/MFR			
Equipment			
Measurements			
Material			
Validation			
Stability Studies			
PV			
AMV			
DQ/OQ/IQ/PQ			
Statutory			
FDA License			
WHO License			
Koscher			
ISP 9001:2015			
DMF			
Others			
Others			
Environment			
Machine			
Skills			
Safety			
Vendor			
Training			
Others			

C.2. Impacted Departments. Circulation of Change Control

QAD		QCD		PRD	
ENG		STR		PAD	
SNML		ACC		GM-PLANT	
PUR		RND		CUSTOMER	

Reviewer-Sign and Date 17/01/2024 **Approver-Sign and Date** 17/01/2024

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MEHA PHARMA Kundaim-Goa	**Change Control No.**

C.3. Category: Section B to be filled by QAD

Critical		Major		Minor	

A change that directly or indirectly affects the Safety, Identity, Strength, Quality and Purity of the Product and which will require regulatory agencies notification/ notification to the customer.	Any change that may directly or indirectly affect the Product Quality and Reproducibility of the Process or System and may require regulatory notification.	Any change which does not affect the product quality or reproducibility of the process and may not require notification from regulatory agencies.

REVIEW OF ACTION PLAN & APPROVAL BY QA

Head QA (sign & date)

Reviewer-Sign and Date Cawade **17/01/2024** **Approver-Sign and Date** **17/01/2024**

MEHA PHARMA Kundaim-Goa	**Change Control No.**

D: Impact assessment <u>of Proposed Change</u>: (To be filled up by all the dept.)
D.1. Document to be revised / updated.

Departments	Impact assessment and action plan	Responsibility/TCD	Sign / Date
QCD			
PRD			
ENG			
RND			
PAD			
STR			
QA			
SNML			
PUR			
GM-Plant			
MD			
Customer (Attach List of Customers)			

Reviewer-Sign and Date 17/01/2024 **Approver-Sign and Date** 17/01/2024

D.2. Document to be revised / updated

Department	Name of the Document	Document No.	Existing reference No.	Revised reference No.	TCD	Sign & Date	Remarks

(Attach separate sheet if required)

Reviewer-Sign and Date Sawade **17/01/2024** **Approver-Sign and Date** **17/01/2024**

D.3. Equipment to be revised / updated

Department	Name of the Equipment	Equipment Code	New Equipment Code	TCD	Sign & Date	Remarks

Reviewer-Sign and Date Pawade **17/01/2024** **Approver-Sign and Date** **17/01/2024**

MEHA PHARMA Kundaim-Goa	**Change Control No.**

E. REVIEW OF ACTION PLAN & APPROVAL BY QA

Approved:		Not Approved:	
Action plan assigned to:		Target completion date:	

Head QA (sign & date)

Reviewer-Sign and Date **17/01/2024** **Approver-Sign and Date** **17/01/2024**

F. **Closure Evaluation**

Attachments for closure:

F.1. Document Review

Name of the Document	Document No.	Updated by user Department	Verified by	Remarks

(Attach separate sheet if required)

Reviewer-Sign and Date Sawade **17/01/2024** **Approver-Sign and Date** **17/01/2024**

F.2. Equipment Review

Name of the Equipment	PO No	Updated by user Department	Verified by	Remarks

Reviewer-Sign and Date 17/01/2024 **Approver-Sign and Date** 17/01/2024

F.3. Training Review

Name of the Document/Equipment	Document No.	Training Date	Reviewed by QA	Remarks

Reviewer-Sign and Date 17/01/2024 **Approver-Sign and Date** 17/01/2024

MEHA PHARMA Kundaim-Goa	**Change Control No.**

Process	**Completion date**	**QA Review Dt**	**Remarks**
Product Quality			
SOP			
Specification			
STP			
SDS			
MOA/AWR			
BMR/MFR			
Equipment			
Measurements			
Material			
Validation			
Stability Studies			
PV			
AMV			
DQ/OQ/IQ/PQ			
Statutory			
FDA License			
WHO License			
Koscher			
ISP 9001:2015			
DMF			
Others			
Others			
Environment			
Machine			
Skills			
Safety			
Vendor			
Training			
Others			

Remarks QAD:

Sign/Date

Reviewer-Sign and Date Sawade **17/01/2024** **Approver-Sign and Date** **17/01/2024**

MEHA PHARMA Kundaim-Goa	**Change Control No.**

Comments for Effectiveness Monitoring Required:- Yes/No **Head – QA** **(Sign / Date)**
G. Effective Batch No:
Comments for Verification of Effectiveness: **Head – QA** **(Sign / Date)**
H. Change Control Closure: **Head – QA** **(Sign / Date)**

Reviewer-Sign and Date Gawade **17/01/2024** **Approver-Sign and Date** **17/01/2024**