

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	n dept.)
Process [] Equipment[] Product[] Document	[] System[] Facility[] Method[]
Specification [] Component[]	
Other[]:	
B. CHANGE INITIATION	
REASON & JUSTIFICATION OF PROPOSED CHANG Is the Change due to CAPA: Yes/No. If yes, CAPA:	
I POLL	
DETAILS OF PROPOSED CHANGE: Change Require equipment /facility)	ed in (name of document / Procedure /
COMMENTS BY INITIATION DEPARTMENT HOD	
	Head of Initiating Department
	(Signature / Date)







C. Impact assessment of Proposed Change:

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

Assurance) Process	Tick	Responsible	Remarks
		Dept	
Product Quality			
SOP			
Specification			
STP			
SDS			
MOA/AWR			
BMR/MFR			
Equipment			
Measurements			
Material			
Validation			
Stability Studies			1
PV			
AMV			cO'
DQ/OQ/IQ/PQ			
Statutory			
FDA License			
WHO License			
Koscher		18-	
ISP 9001:2015		7	
DMF		°O,	
Others		70	
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 Courde 17/01/2024



Approver-Sign and Date



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

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Critical		Major		Minor	
A change that direct	tly or indirectly	Any change that	may directly or	Any change which	ch does not
affects the Safe	ety, Identity,	indirectly affect	the Product	affect the produc	ct quality or
Strength, Quality and	d Purity of the	Quality and Repro	oducibility of the	reproducibility of	the process
Product and which	n will require	Process or Sys	tem and may	and may not req	uire notification
regulatory agencies	s notification/	require regulatory	notification.	from regulatory	agencies.
notification to the cus	stomer.				-

REVIEW OF ACTION PLAN & APPROVAL BY QA JINCONTROLLED COPT Head QA (sign & date)







D: Impact assessment of Proposed Change: (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	=ORT		
STR			
QA	NTROL.		
SNML	JACONIROLLER		
PUR			
GM-Plant			
MD			
Customer (Attach List of Customers)			







D.2. Document to be revised / updated

Department	Name of the Document	Document No.	Existing reference No.	Revised reference No.	TCD	Sign & Date	Remarks
				4			
			C	2,			
			(40)				
			201				
		M					
		MC					

(Attach separate sheet if required)

Reviewer-Sign and Date ______17/01/2024

Approver-Sign and Date





D.3. Equipment to be revised / updated

Name of the Equipment	Equipment Code	New Equipment Code	TCD	Sign & Date	Remarks
		Ŕ	1		
		(0)			
	1P	<u>) </u>			
	.00				
	7/2				
	Name of the Equipment	Name of the Equipment Code	Name of the Equipment Code Requipment Code New Equipment Code New Equipment Code	Name of the Equipment Code Equipment Code TCD TCD	Name of the Equipment Code Sign & Date

Reviewer-Sign and Date @aude_17/01/2024

Approver-Sign and Date





E. REVIEW OF ACTION PLAN & AF	PROVAL BY QA	
	1	
	P	
	/.0	
	OH.	
	CONTROLLED	
Approved:	Not Approved:	
Action plan assigned to:	Target completion	n date:
		Head QA (sign & date)

Reviewer-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
		COR		
	20)			
	,20			
	7,			

(Attach separate sheet if required)

Reviewer-Sign and Date @aude_17/01/2024



Approver-Sign and Date





F.2. Equipment Review

Name of the Equipment	PO No	Updated by user Department	Verified by	Remarks
		c OR		
		20		
	R			
	OF			
	JAG			







F.3. Training Review

Name of the Document/Equipment	Document No.	Training Date	Reviewed by QA	Remarks
		1		
		227		
	C			
	ROV			
	041			

Reviewer-Sign and Date ______17/01/2024

Approver-Sign and Date





Completion date	QA Review Dt	Remarks
		4
		R .
	Ö	
	200	
0		
10		
	Completion date	Completion date QA Review Dt

Remarks QAD:

Sign/Date



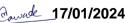
Approver-Sign and Date





Comments for Effectiveness Monitoring Required:- Yes/No	
	Head - QA
	(Sign / Date)
G. Effective Batch No:	
Comments for Verification of Effectiveness:	
1	
R.	
	Head – QA
H. Change Control Closure:	(Sign / Date)
H. Change Control Closure:	
	Head – QA
	(Sign / Date)

Reviewer-Sign and Date @____17/01/2024



Approver-Sign and Date

