



BAJAJ HEALTHCARE LTD.

SAVLI

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FORMAT FOR CHANGE REQUEST

Format No.: QA004/F/01-03

CHANGE CONTROL FORM FOR TEMPORARY CHANGE

Initiating Department:

CC No.:

Date of Initiation:

A. CHANGE APPLICABLE TO: (Part A : To be completed by change initiator)

Document to be changed / New Documents (Check applicable box as √)

- ☐ Product ☐ Facility ☐ SOP ☐ Document
☐ Batch size ☐ Schedule ☐ Equipment/Instrument ☐ Other

A.1 Title of change:

A.2 Batch no. / Equipment ID/ Instrument ID / Document no./ No. of days:

A.3 Current / Existing Procedure:

A.4 Proposed Change* (s)
(All changes being proposed should be listed here or attached herein)

A.5 Reason / Justification of each Proposed change*(s):
(May be documented and attached herein)

A.6 Affected LMR/BMR version no./ Other document (Specify) (Trial / Regular):

A.7 Attachment with proposed change* (s) e.g. Supporting document:

Attachment No.

Title of Attachment

* Attach separate sheet is required

PREPARED BY / DATE

REVIEWED BY / DATE

APPROVED BY / DATE

[Signature]
23/11/2019

[Signature]
25/11/2019

[Signature]
26/11/2019

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Initiating Department:

CC No.:

B. IMPACT EVALUTION AND ACTION PLAN OF PROPOSED CHANGE:

B.1 Attribute to be evaluated: (one or more of the following)

Sr. No.	Attribute	Yes/ No	Work description	Responsibility for action
01	Process Performance			
02	Product Quality			
03	Product outputs (Yield)			
04	Analytical results			
05	Additional testing			
06	Safety			
07	List of the department and positions required to be informed/trained on the proposed change (attach list if required)			
08	Any Other (Specify)			

PREPARED BY / DATE

REVIEWED BY / DATE

APPROVED BY / DATE

P. S. S.
23/11/2019

M. C. S.
25/11/2019

N. S.
26/11/2019

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CHANGE CONTROL FORM FOR TEMPORARY CHANGE

Initiating Department:

CC No.:

Change Control Initiated by:

Name: _____ Signature: _____ Date: _____

Remarks:

Initiating Department Head:

Name: _____ Signature: _____ Date: _____

PRE-APPROVAL OF CHANGE CONTROL:

Tick the Classification of the proposed change: ☐ MAJOR ☐ MINOR

Proposed Changes are: ☐ APPROVED ☐ REJECTED ☐ CANCELLED

Reason for Rejection / Cancellation:

QA Executive/ Designee:

Name: _____ Signature: _____ Date: _____

QA Comment:

QA Head / Designee:

Name: _____ Signature: _____ Date: _____

Head QA will forward the Change Control to following concerned Departments (Wherever applicable). Put (✓) marks to the applicable department.

Production		Quality Control		Engineering/Project	
Warehouse		EHS		HR	
Regulatory Affairs		R&D		IT	
CQA		Any Other			

PREPARED BY / DATE

REVIEWED BY / DATE

APPROVED BY / DATE

[Signature]
23/11/2019

[Signature]
25/11/2019

[Signature]
22/11/2019

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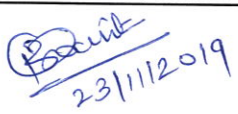
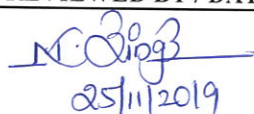
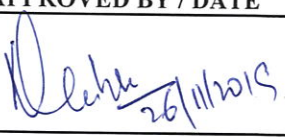
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CHANGE CONTROL FORM FOR TEMPORARY CHANGE

Initiating Department:		CC No.:	
Evaluation by production Department:			
Name:	Signature:	Date:	
Evaluation by Quality Control Department:			
Name:	Signature:	Date:	
Evaluation by Engineering/Project:			
Name:	Signature:	Date:	
Evaluation by Warehouse:			
Name:	Signature:	Date:	
Evaluation by EHS:			
Name:	Signature:	Date:	
Evaluation by HR:			
Name:	Signature:	Date:	
Evaluation by Regulatory Affairs:			
Impact on regulatory filling:			
Name:	Signature:	Date:	
Evaluation by any other department:			
Name:	Signature:	Date:	
Evaluation by IT department:			
Name:	Signature:	Date:	
Evaluation by CQA department:			
Name:	Signature:	Date:	
Evaluation by any other department:			
Name:	Signature:	Date:	

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CHANGE CONTROL FORM FOR TEMPORARY CHANGE

Initiating Department: _____

CC No.: _____

POST-APPROVAL OF CHANGE CONTROL:

QA Head/Designee comment:

Proposed Changes are: ☐ APPROVED ☐ REJECTED

No. of batches / No. of days: _____

Name: _____ Signature: _____ Date: _____

C. Extension (If required):

Sr. No.	No. of days/Batches initially planned	No. of days/Batches required for extension	Justification for Extension

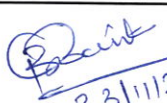

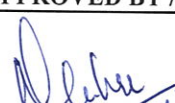
Extension Initiated by:

Name: _____ Signature: _____ Date: _____

Approved by:
(QA Head Sign./Date)

Name: _____ Signature: _____ Date: _____

Additional Impact Evaluation or Action Plan Requirements:

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Initiating Department:

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D.1 EVALUATION OF CHANGE (Post Implementation):

All Change Control Requirements have been met

Comments:

Temporary change to be made permanent:

☐ Yes

☐ No

D.2 CHANGE CONTROL POST RECOMMENDATIONS:

CQA internal and external recommendations:

E. CLOSURE OF CHANGE CONTROL:

Comments by Quality Assurance Head (or Designee):

Name: _____ Signature: _____ Date: _____

F. 1 List of Attachments

Attachment No.	Title of Attachment

* Attach separate sheet is required

PREPARED BY / DATE

REVIEWED BY / DATE

APPROVED BY / DATE

Pratik
23/11/2019

NC Singh
25/11/2019

Aditya
26/11/2019

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