BAJAJ HEALTHCARE LTD.

SAVLI

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
23/11/2019	25/11/2019	26/11/2019

MASTER COPY

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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)			

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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
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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

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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:

PREPARED BY / DATE	REVIEWED BY / DATE	APPROVED BY / DATE
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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**

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