

Change Control Report



Change Control No. : CC/P1/QC01/2015/007

PR No : 2158

General Information

Initiator Prajakta Chogale **Date Of Initiation** 29 Dec 2015 01:53 PM
Initiator Group Quality Control - Plant 1 **Initiator Group Code** QC01
Short Description Migration of Finished Product SPC's and STP's into DMS
Due Date 15 Apr 2016
Nature of Change Document Change **If Others** N/App
Supporting Documents 1. Revision of FP SPC STPs Annexure 1.xlsx

Change Details

Current Document No.	Current Version No.	New Document No.	New Version No.
Revision of FP SPC STPs Annexure 1	01	Revision of FP SPC STPs Annexure II	02

Current Practice 12/29/2015 01:53 PM (GMT+5:30) added by Prajakta Chogale (PID-000290):
1) All Plant 1 Finished Product SPC's and STP's have been prepared and finalized in Plant 1 format
2) All STPs having CQC GTP numbers as reference.

Proposed Change 12/29/2015 01:53 PM (GMT+5:30) added by Prajakta Chogale (PID-000290):
1) All Finished Product SPC's and STP's will be migrated into DMS.
2) All STPs will include plant 1 GTP numbers as reference for respective test, which have been initiated in Plant 1 QC

Reason For Change 12/29/2015 01:48 PM (GMT+5:30) added by Prajakta Chogale (PID-000290):
1) To harmonize the Finished Product SPC's and STP's formats of plant 1 and DALC
2) To include the GTP references for the tests which are initiated in plant 1

Supervisor Comments 12/29/2015 03:04 PM (GMT+5:30) added by Ashish Mishra (PID-000153):
The proposed changes may proceed and implemented. The said changes do not have any impact on product quality.

Any Other Comments

Cancellation remarks

Risk Assessment

Risk Assessment

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Identification of Risk	Existing Control	Severity(S)	Occurance(O)	Detection(D)	RPN(S*O*D)

Overall Risk Assessment

Risk Identification	12/29/2015 03:09 PM (GMT+5:30) added by Ashish Mishra (PID-000153): NIL		
Severity	Negligible	Occurence	Rare
Detection	Rare	RPN	8
Risk Evaluation	12/29/2015 03:08 PM (GMT+5:30) added by Ashish Mishra (PID-000153): NIL		
Mitigation Action	12/29/2015 03:08 PM (GMT+5:30) added by Ashish Mishra (PID-000153): All the finished product SPC's & STP's can be migrated on electronic System (Document Management System)		

QA Review

Type Of Change	Minor
QA Review Comments	12/29/2015 05:06 PM (GMT+5:30) added by Kiran Parve (PID-000115): Finished product SPC, STPs can be migrated into electronic Document Management system to harmonize the documentation practice amongst Plant 1 and DALC and to include the GTP references of the tests which have been started in plant 1.
Related Records	N/App
QA Attachments	N/App

Group Assessment

Is Group Review Required?	No
Project Management Comments	
Group Attachments	N/App

QA Evaluation

QA Evaluation Comments	12/29/2015 05:39 PM (GMT+5:30) added by Kiran Parve (PID-000115): Migration of Finished Product SPC, STP's into DMS including revised reference GTP numbers can be proceed
QA Evaluation Attachments	N/App

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QA Approval Comments

QA Approval Comments 12/29/2015 06:12 PM (GMT+5:30) added by Avinash Hasamnis (PID-000307):
Migration of Finished Product SPCs and STPs to electronic document management system to be done by inclusion of revised GTP reference numbers.

Child Records

PR ID	Project	Date Of Initiation	Due Date	PR State	Assigned To
2495	Extension	28 Mar 2016 05:46 PM	28 Mar 2016	Closed - Done	
	Short Description	Migration of Finished Product SPC's and STP's into DMS			
2531	Action Item	07 Apr 2016 01:05 PM	15 Apr 2016	Closed - Done	Prajakta Chogale
	Short Description	Migration of Finished Product SPC's and STP's into DMS			

Change Closure

Affected Documents	Document Name	Document No.	Version No.	Implementation Date	New Document No.	New Version No.
Specification	SPC & STP	As per attached annexure	As per attached annexure	07 Apr 2016	As per attached annexure	As per attached annexure

QA Closure Comments 04/07/2016 05:37 PM (GMT+5:30) added by Kiran Parve (PID-000115):
All Finished Products SPCs and STPs have been migrated & published in DMS and are implemented.

List of Attachments 1. Revision of FP SPC STPs Annexure II.xlsx

Effectiveness Check required? No

Notify To

Electronic Signatures Details

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Submitted By	Prajakta Chogale	Submitted On	29 Dec 2015 01:53 PM
CC Review Completed By	Ashish Mishra	CC Review Completed On	29 Dec 2015 03:10 PM
Change Reviewed By (QA)	Kiran Parve	Change Reviewed On (QA)	29 Dec 2015 05:09 PM
Change Evaluated By	Kiran Parve	Change Evaluated On	29 Dec 2015 05:40 PM
Change Approved By	Avinash Hasamnis	Change Approved On	29 Dec 2015 06:13 PM
Action Items Completed By	Ashish Mishra	Action Items Completed On	07 Apr 2016 05:29 PM
CC Closed By	Kiran Parve	CC Closed On	08 Apr 2016 12:53 PM