

Next Assessment On : 2 Years	Roha Dyechem Management Systems Manual	Document No : RDC/QPM/QD – 003.5 D
Issue No :01 Issue Date : 4.02.2012		Rev Date : 04.04.2014 Rev No : 04
Page No. :	ISO : 9001: 2008 FSSC: 22000: 2011	Clause No : --/7.5, 7.6 , 7.6.1 to 7.6.5

Control plan for CCP

(1) Critical Control Point/OPRP	(2) Significant hazards	(3) Critical limits for each preventive measure	MONITORING				(8) Corrective action(s)	(9) Records	(10) Verification
			(4)	(5)	(6)	(7)			
			What	How	Frequency	Who			
CCP-1 <u>Coupling</u>	Chemical Unwanted reactions, impurities, unreacted dye intermediates form subsidiary dyes.	Temp 15 to 25°C Tartrazine pH 6 to 6.5 Sunset Yellow and CS and Allura Red : pH 7 to 8 Chocolate B: pH 8 to 9, Ponceu, carmoisine: pH 8 to 9.5	Temperature & pH of Reaction mass	Visually in calibrated temp indicator, pH meter	Every batch at end of reaction	Operator	Addition of acid/ alkali for pH and ice addition for temperature.	Log sheet , RDC/PRD/QR-003	Subsidiary dyes and dye intermediates analyzed for each batch by HPLC- RDC/QAD/QR-008

Prepared By	Approved By
Manager Quality	Head QA

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(1) Critical Control Point/OPR P	(2) Significant hazards	(3) Critical limits for each preventive measure	MONITORING				(8) Corrective action(s)	(9) Records	(10) Verification
			(4) What	(5) How	(6) Frequency	(7) Who			
CCP -2 <u>Passing through 40 mesh Sifter</u>	Physical Contamination with damaged gasket pieces, filter clothes, Iron particles and internal contaminants.	Foreign particles over 0.42 mm should retain over 40 mesh screen and not be present in material.	Damaged sieves and integrity of sieve, SOP: RDC/QPM/QI/PRD -007	Visually ,	Every four hours of operation	Supervisor and Operator	Stop the process, replace the damaged sieves, and repass the product through new sieve.	Log Sheet, RDC/PRD/Q R004.3	Water insoluble matter for every batch, RDC/QAD/QR008

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CCP 3 <u>Metal Detection</u>	Physical Metal pieces	No presence of below metals Fe- 3.5 Non Fe- 4.5mm SS – 4 mm	Pass standard test pieces through the metal detector, SOP RDC/QPM/QI/PRD 024	Buzzer operatio n and stopping of conveyor	Every Hour	IPQA and supervisor	Stop the process, repass the entire lot from the previous deviation, If problem with the metal detector then repair and replace the detector, repass the product through repaired detector.	Metal detector log sheet, RDC/PRD/Q R/004.5	Verification by test pieces

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			(4)	(5)	(6)	(7)			
			What	How	Frequency	Who			
CCP -4 <u>Passing through 40 mesh Sifter Of spray dryer</u>	Physical Contamination with damaged gasket pieces, filter clothes, Iron particles and internal contaminants.	Foreign particles over 0.42 mm should retain over 40 mesh screen and not be present in material.	Damaged sieves and integrity of sieve, SOP: RDC/QPM/QI/PRD 027	Visually ,	Every four hours of operation	Supervisor and Operator	Stop the process, replace the damaged sieves, and repass the product through new sieve.	Sifter/ Magnet Log Sheet	Water insoluble matter for every batch, RDC/QAD/QR008

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